RADIATION SAFETY DEPARTMENT
West Virginia University • Health Sciences Center • WVU Hospitals
Jefferson Medical Center •Fairmont Regional Cancer Center
G-139 Health Sciences Center • PO Box 9006 • Morgantown, WV 26506-9006 • Phone: 304-293-3413 • Fax: 304-293-4529

APPLICATION TO REQUEST AUTHORIZATION FOR THE DIAGNOSTIC OR THERAPEUTIC USE OF RADIATION IN OR ON HUMANS

For Uses Under 10 CFR 35.1000
Yttrium 90 Microspheres

APPLICATION PROCESS

1. Prospective AUs must submit this completed application and all required attachments to the Radiation Safety Department no later than the end of the month prior to a radiation safety committee meeting month in order for the application to be considered during that meeting. Committee meeting months are January, April, July, and October. The completed application with attachments may be submitted via email to: **radiationsafety@hsc.wvu.edu.**

2. The WVU Radiological Safety Committee has chosen to go above and beyond NRC work experience requirements and, therefore, requires prospective AUs complete additional clinical case experience in each modality in which they are applying. Cases must be completed at WVU, under the direct supervision of an AU for that modality under the WVUH NRC radioactive materials license. If you were an active AU at another institution and have completed at least 10 cases within the last year in each modality in which you are applying, you will only need to complete 3 cases. All other applicants must complete 10 cases in each modality in which they are applying under the supervision of a AU under the WVUH NRC radioactive materials license. *Note: of you are applying for use of both microsphere products, WVURSD will only require 5 of each product rather than 10.*

3. The Radiation Safety Officer (RSO) will review the application. If the RSO approves the application, it will be forwarded to the Human Use Committee (HUC) and the Radiation Safety Committee (RSC) for final review and approval. If the RSO denies the application, the prospective AU will be given an opportunity to amend their application.

4. If approved by the HUC and RSC, a notification of approval letter will be sent to you, your supervisor, department, and others as necessary.

5. AUs wishing to amend their current authorization will follow the same application process as described above, however they will submit a modified application. The AU is required to fulfill all training requirements in 10 CFR Part 35 for the modality in which they are amending their application and will be required to complete 10 supervised cases before the amendment is approved. The application must be approved by the RSO, HUC, and RSC.

DESCRIPTION OF PATHWAYS TO OBTAIN AUTHORIZATION

A prospective Authorized User (AU) may obtain authorization by meeting the requirements in one of the following three training and experience pathways.

- Pathway 1: The prospective AU is currently or had previously been an AU on another institution's NRC or Agreement State radioactive materials license or permit.

- Pathway 2: The prospective AU has a certification in a specialty board recognized by the NRC under 10 CFR Part 35. The applicant must have passed the certifying exam to meet the requirements of this pathway. Being eligible to sit for the certifying exam does not meet the requirements for this pathway. ***Note: Certificates issued by the American Board of Radiology (ABR) after December 31, 2023 are no longer recognized by the NRC. A certificate issued by the ABR after December 31, 2023 does not fulfill the requirements of this pathway to authorization. Therefore, prospective AUs must document training and experience requirements as described in Pathway 3 "alternate route". Individuals who obtained certification prior to December 31, 2023 may continue to use their certification as evidence of their training and experience if "AU Eligible" appears on the certificate.***

- Pathway 3: If the prospective AU does not meet the requirements in pathways 1 or 2, they will need to provide documentation of classroom and laboratory training, supervised work experience, and supervised clinical experience for the use requested. This pathway also requires written attestation, signed by a preceptor physician AU, or the residency program director that the training and experience requirements were satisfactorily completed and that the individual is able to independently fulfill the radiation safety-related duties as an AU for the requested uses.

INSTRUCTIONS TO APPLICANT

1. The following sections will guide the applicant through the different pathways to authorization for use under 35.1000 Yttrium-90 Microspheres. The applicant should follow the directions in the sections closely, as they will indicate what information and attachments that the applicant must provide. If a specific section does not apply to you, you will be instructed to skip it and proceed to another section. Throughout the following application sections will be links (in blue) to various NRC and other reference documents. Applicants should reference these documents as necessary.

2. If training and experience (including Board Certification) has not been obtained within the last 7 years preceding the date of this application, attach recent continuing education and experience required by *10 CFR 35.59*.

3. All new applicants, regardless of pathway to authorization, must submit the following documents with their application. Please check the boxes, indicating that you have attached them.

   ☐ Your CV
   ☐ A copy of your WV medical license
   ☐ Letters of recommendation form at least two individuals who can corroborate your previous training history and experience with radioactive materials.

4. Letters of recommendation provided with application should be addressed to:

   Stephen Root
   Director and Radiation Safety Officer
   PO Box 9006
   Morgantown, WV 26506

PART A: APPLICANT INFORMATION

Name:

☐ MD ☐ DO ☐ PhD

Department:

Title:

Section:

Lab #:

Office Rm #:

PO Box: :

Off Phone:

Dept Chair:

Fax:

Email:

I understand the authorization to use such materials is a privilege granted by the WVUH Human Use of Radiation and Radionuclides Committee and the Radiation Safety Committee, and is regulated by the laws of the US Nuclear Regulatory Commission. I agree to abide by all applicable laws, to follow recognized safe practices in the use of radioactive materials and radiation producing devices. I have received the required training in radiation safety practices and obtained a copy of the applicable regulations and Radiation Safety Manual from Radiation Safety. I am hereby submitting the attached application for approval.

Select One:

☐ **New Application**.

☐ **Modification** to previously approved application and/or authorization.
(Only complete sections that require modification and review.)

Briefly describe modification to previously approved application:

Signed: Date:

PART B: AUTHORIZATION REQUESTED

B.1 Select which type of Y-90 Microsphere you are applying for? (*check all that apply*):

☐ Y-90 SIRSpheres

☐ Y-90 TheraSpheres

PART C: SELECTED PATHWAY TO AUTHORIZATION

C.1 Select the pathway by which the applicant is seeking approval as an Authorized User (AU) (after making your selection, you will be redirected to the Part of this application that you need to complete.

☐ Pathway 1: Previously listed on, or authorized under, an NRC or Agreement State license (**if you select this pathway, complete Part D only**).

☐ Pathway 2: Applicable board certification (**if you select this pathway, complete Part E only**).

☐ Pathway 3: "Alternate route:" Preceptor's written attestation of applicant's completion of specified Training and Experience (**if you select this pathway, complete Part F only**).

PART D: PREVIOUS AUTHORIZED USER (AU) ANOTHER INSTITUTION

D.1 Are you currently or were you previously an AU under 35.1000 for Y-90 Microspheres on another NRC or Agreement State license or permit?

☐ Yes ☐ No

* If you checked Yes, proceed with question D.2. If you checked No, skip to Part E: Board Certification

D.2 Select the type of Y-90 Microspheres that you are currently or were previously an AU for on another NRC or Agreement State license or permit. (Select all that apply)

☐ Y-90 SirSpheres ☐ Y-90 TheraSpheres

D.3 Are you seeking authorization for another type of Y-90 Microsphere for which you were not previously authorized? (For example: previously authorized under 35.1000 for Y-90 SirSpheres and seeking additional authorization for Y-90 TheraSpheres).

☐ Yes ☐ No

*If you selected Yes, you will need to submit device training documentation for the additional type of microsphere use as described in the Y-90 Microsphere licensing guidance.

D.4 Have you completed at least 10 cases within the last year as an AU in each modality in which you were previously an AU for at another NRC or Agreement State license or permit?

☐ Yes ☐ No

*If you checked Yes, you will be required to complete at least 3 cases in each modality in which you are applying at WVU under the supervision of an AU in that modality under the WVUH NRC radioactive materials license. If you checked no, you will be required to complete at least 10 (or 5 if you are applying for both microsphere products) cases in each modality in which you are applying at WVU under the supervision of an AU in that modality under the WVUH NRC radioactive materials license.

D.5 Provide the name of the institution that you are currently or were previously an AU. Provide the name and contact information of the Radiation Safety Officer or another individual who would be able to provide documentation of your AU status (e.g. NRC or Agreement State radioactive materials license, or Radiation Safety Committee approval letter).

Institution:

Contact person:

Phone number:

Email address:

D.6 You will need to provide the following information as attachments to this application.

- ☐ NRC or Agreement State license from institution in which you were previously an AU
- ☐ Radiation Safety Committee approval letter (if NRC or Agreement State license does not specifically list AUs on the license.)
- ☐ Documentation of cases completed within the last year at the institution in which you were previously an AU.
- ☐ Documentation of additional device training required under Y-90 Microsphere licensing guidance, if applicable.
- ☐ Documentation of cases required at WVU under supervision of an AU under the WVUH NRC radioactive materials license.
- ☐ Any other documentation (certifications, additional coursework or training, publications) that may be relevant.

PART E: BOARD CERTIFICATION

E.1 Do you have a Board Certification?

Reference NRC specialty board(s) certification recognized by NRC under 10 CFR Part 35 for each modality at this link: *https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html*

☐ Yes ☐ No

*If you checked Yes, continue in Part E. If you checked No, skip to Part F: Training and Experience

E.2 Provide the name of the Board Certification and date received.

Name of specialty board:

Date received:

E.3 You must complete at least 10 cases at WVU in each modality in which you are applying under the supervision of an AU in that modality. Have you completed this requirement?

☐ Yes ☐ No

E.4 You will need to provide the following information as attachments to this application

☐ A copy of the Board Certification

☐ Documentation of cases in each modality required at WVU under supervision of an AU under the WVUH NRC radioactive materials license.

☐ Documentation of training and expertise as required by *10 CFR 35.390* or *10 CFR 35.490*

☐ A copy of the NRC or Agreement State radioactive materials license where you completed supervised work and clinical experience.

☐ Any other documentation (certifications, additional coursework or training, publications) that may be relevant.

PART F: TRAINING AND EXPERIENCE

F.1 Applicants must provide documentation of classroom and laboratory training, supervised work experience, and supervised clinical experience. Below are links to training and experience requirements for each use as specified in 10 CFR Part 35. Applicants should reference these training and experience requirements to ensure all training and experience documentation is submitted with this application. For Y-90 microspheres, WVU follows the regulatory guidance published under 35.1000, Emerging Medical Technologies. The current version of licensing guidance is "Yttrium-90 Microsphere Brachytherapy Sources and Devices - TheraSphere and SIR-Spheres Licensing Guidance: April 20, 2021, Revision 10.2." Follow the training guidance outlined in Chapter 5.1: Authorized Users.

F.2 Applicants should submit documentation of completed training for delivery system operation, safety procedures, and clinical use of the type of Y-90 microspheres for which authorization is sought. This training can be provided by the vendor or by a physician trained in the same type of Y-90 microspheres. Have you completed this requirement?

☐ Yes ☐ No

F.3 You must complete at least 10 (or 5 of each product type if applying for both) cases at WVU in each modality in which you are applying under the supervision of an AU in that modality. Have you completed this requirement?

☐ Yes ☐ No

F.4 In addition to the required documentation listed in Instruction to Applicants in line number 3, you will need to provide the following additional information as attachments to this application. Check all attachments that you will be submitting with this application. Please submit any other documentation not included on this list (certifications, additional coursework or training, publications) that may be relevant.

- ☐ Documentation of the classroom and laboratory training, supervised work experience, and supervised clinical experience (NRC 313A series form)
- ☐ A written attestation, signed by a preceptor physician AU, or if applicable, the residency program Director (this may be completed on NRC 313A series form).
- ☐ Documentation that the preceptor physician AU is authorized in that modality.
- ☐ Documentation of training in device operation, safety procedures and clinical use as required for each modality in which you are applying.
- ☐ Documentation of cases in each modality required at WVU under supervision of an AU under the WVUH NRC radioactive materials license.
- ☐ A copy of the NRC or Agreement State radioactive materials license where you completed supervised work and clinical experience.
- ☐ Any other documentation (certifications, additional coursework or training, publications) that may be relevant.

Human Use Application Processing Data (For Radiation Safety Department Only)

Application Received_____/_____/_____

Returned for Additional Info _____/ /_____ _____/_____/_____

Application Received_____/ /_____ _____/ /_____

Temp approval: / / Signed:_____

Committee approval:_____/_____/ _____ Denied:_____/_____/ _____

Comments:

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