IEMA-OHS OFFICE OF NUCLEAR SAFETY
1035 OUTER PARK DRIVE
SPRINGFIELD, ILLINOIS 62704

AUTHORIZED USER TRAINING AND EXPERIENCE FORM

Use this form to provide documentation of training and experience for authorized users requesting use of **Yttrium-90 (Y-90) Microspheres** in accordance with the following parts:

- 32 Ill. Adm. Code 335.9050, **Training for the Use of Unsealed Radioactive Material for Which a Written Directive is Required**
- 32 Ill. Adm. Code 335.9100, **Training for Use of Manual Brachytherapy Sources**
- 32 Ill. Adm. Code 335.9160, **Training for Experienced Authorized User**

NOTE: This form requires the applicant to attach copies of licenses, permits and Board certifications as applicable. Failure to properly attach these documents will result in the request being delayed or denied. This form has been simplified to request the minimum amount of information necessary to process a licensee's request. See Section III. Item 5A, Appendix B of the Instructional Set 52.2 (Rev. 4, 2022), and the Agency's Microsphere Guidance for additional information.

Part 1. Licensee Information

Provide Information on the Radioactive Materials License under which the proposed Authorized User will work.

Licensee Name:

Radioactive Materials License Number: IL-

Part 2. Proposed Authorized User (AU) Information

AU Name:	**IDFPR Medical License Number:**

Requested Use (Mark all that apply):

☐ BWXT Medical Ltd. (formerly MDS Nordion) Y-90 TheraSpheres
☐ SIRTEX Wilmington, LLC Y-90 SIR-Spheres
☐ Other microsphere (specify): _____

Part 3. Authorization Pathway

Part 3A. Has the Proposed AU been Listed on a Radioactive Materials License or Permit for the Requested Use?

☐ No, the proposed AU has not been listed on a radioactive material license or broad scope permit for the requested use. Continue to Part 3B.

OR

☐ Yes, a copy of the radioactive materials license or broad scope permit listing the AU for the requested use (or US NRC or Agreement State equivalent) is attached; **and**

☐ If the license or permit authorization exceeds seven years from the date of this application, submit documentation (dates, description and duration) of related continuing training and experience (See Section III. Item 5A of Instructional Set 52.2, Rev. 4, 2022); **and**

☐ Skip Parts 3B, 3C, 3D, 4 and 5. Complete Part 6 and submit to IEMA-OHS.

Part 3B. Is the Proposed AU Seeking Authorization under 32 Ill. Adm. Code 335.9050, "Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required"?

☐ No, the proposed AU is not seeking authorization for use of Y-90 microspheres through training and experience under 32 Ill. Adm. Code 335.9050. Continue to Part 3C.

OR

☐ Yes, complete and submit, with all necessary attachments, IEMA's *"Authorized User (Unsealed Therapy)"* Form; **and**

☐ Skip Parts 3C and 3D. Provide documentation on supervised case experience in Part 4; **and**

☐ Complete Parts 5 and 6. Submit completed form and attachments to IEMA-OHS.

Part 3C. Is the Proposed AU Seeking Authorization under 32 Ill. Adm. Code 335.9100, "Training for Use of Manual Brachytherapy Sources"?

☐ No, the proposed AU is not seeking authorization for use of Y-90 microspheres through training and experience under 32 Ill. Adm. Code 335.9100. Continue to Part 3D.

OR

☐ Yes, complete and submit, with necessary attachments, IEMA-OHS *"Authorized User (Brachytherapy)"* Form; **and**

☐ Skip Part 3D. Provide documentation on supervised case experience in Part 4; **and**

☐ Complete Parts 5 and 6. Submit completed form and attachments to IEMA-OHS.

Part 3D. Interventional Radiologist Structured Training and Experience Pathway

☐ Complete tables 1, 2 and 3 below, detailing training and experience; **and**

☐ If the dates indicated in the table below exceed seven years from the date of this application, submit documentation (dates, description and duration) of related continuing training and experience (See Section III. Item 5A of Instructional Set 52.2, Rev. 4, 2022); **and**

☐ Complete Parts 4, 5 and 6. Submit completed form and attachments to IEMA-OHS.

Part 3D (continued). Table 1 – Training and Experience in Diagnostic and Interventional Radiology
Select and attach Board Certifications as applicable.

☐ Board certification in interventional radiology/diagnostic radiology by the American Board of Radiology; **or**

☐ Board certification in diagnostic radiology by the American Board of Radiology; **or**

☐ Board certification in diagnostic radiology by the American Osteopathic Board of Radiology; **or**

☐ Three years supervised clinical experience in diagnostic radiology **and** experience in interventional radiology demonstrated by either Board subspecialty certification in interventional radiology by the American Osteopathic Board of Radiology or one additional year supervised clinical experience in interventional radiology

Part 3D (continued). Table 2 – Classroom and Laboratory Training
Board Certified physicians need not complete this table.

Required Training	Location of Training	Dates of Training
80 hours of training for byproduct material, including Y-90 microspheres, to include: A) Radiation physics and instrumentation; B) Radiation protection; C) Mathematics pertaining to the use of and measurement of radioactivity; and D) Radiation biology		

Part 3D (continued). Table 3 - Supervised Work Experience

The following supervised work experience shall be conducted under the supervision of an AU for the type of Y-90 microsphere the applicant is requesting. This part must be certified by the authorized user supervising the required work experience.

Required Work Experience	Location of Experience	Dates of Experience
A) Preparing and administering patient dosage. The individual does not have to be the physician who places the micro-catheter or administers patient dosage, but it is necessary that the individual have training in the administration process, including selection of activity of Y-90 microspheres to be administered to each treatment site and catheter positioning to ensure administration of the Y-90 microspheres is in accordance with the written directive; and B) Using administrative controls to prevent a medical event involving the use of byproduct material; and C) Evaluation of patient or research subject's treatments to determine whether the administered dosage was in accordance with the written directive or if a medical event has occurred. D) Follow up and review of each patient's or human research subject's case history for Y-90 microspheres; and		

The following additional supervised work experience may be conducted either under the supervision of an AU for Y-90 microspheres or may be provided by a Y-90 microsphere manufacturer representative:

Required Work Experience	Location of Experience	Dates of Experience
A) Ordering, receiving/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) Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject; D) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures. The procedures should address any special circumstances that may be encountered, such as the electrostatic charge of Y-90 microspheres and the proper survey instrument and survey technique for beta emitters; and		

☐ As the supervising authorized user of the requested type of microsphere, I attest that the proposed authorized user has satisfactorily completed the required training and supervised work experience detailed in Table 2 and Table 3 above.

Printed name of supervising AU:

License or Permit Number identifying the Supervising AU: | Amendment #:

Supervising AU Signature: _____ Date: _____

☐ If applicable, attach documentation of microsphere manufacturer's training

Part 4. Supervised Clinical Case Experience

This part must be certified by the authorized user supervising the training in the operation of the delivery system, safety procedures, and clinical use for each type of Y-90 microspheres for which authorization is sought. The supervising authorized user must be authorized for the type of microsphere for which the individual is seeking authorization and must have already documented completion of the three supervised clinical cases. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

Proposed Authorized User's Required Clinical Casework	Location of Clinical Experience (Include License/Permit Number)	Dates of Training
Clinical Use – Case 1 ☐ Sir-Spheres ☐ TheraSpheres ☐ Other microspheres (specify):		
Clinical Use – Case 2 ☐ Sir-Spheres ☐ TheraSpheres ☐ Other microspheres (specify):		
Clinical Use – Case 3 ☐ Sir-Spheres ☐ TheraSpheres ☐ Other microspheres (specify):		

☐ As the supervising authorized user, I attest that the proposed authorized user has satisfactorily completed the required clinical case experience, including training in the operation of the delivery system and associated safety procedures, detailed above;

OR

☐ As the authorized manufacturer's representative, I attest that the proposed authorized user has satisfactorily completed the required clinical case experience, including training in the operation of the delivery system and associated safety procedures, detailed above**. Note, IEMA-OHS will only allow supervision of clinical case experience by the manufacturer's representative if initiated prior to October 2021.**

Supervising Authorized User's Printed Name:

License or Permit Number identifying the Supervising AU: | Amendment #:

Supervising authorized user is authorized for the following types of microsphere use (*Check all that apply*):

☐ Sir-Spheres ☐ TheraSpheres ☐ Other microspheres (specify): _____

Supervising AU Signature: _____ Date: _____

Part 5. Preceptor Attestation

This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. By checking the boxes below, the preceptor is not attesting to the individual's "general clinical competency."

Preceptor Attestation is being provided by:

☐ A preceptor authorized user who is authorized for the type(s) of Y-90 microspheres the individual is seeking authorization;.

OR

☐ A residency program director representing the consensus of a residency program where at least one faculty member is a physician who is an AU for the type of Y-90 microspheres 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 or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified on this form.

Preceptor Certification:

I attest that the proposed authorized user listed on this form has satisfactorily completed the training and experience indicated on this application and is able to independently fulfill the radiation safety-related duties as an authorized user for the type of Y-90 microspheres requested.

Preceptor Signature: _____ Title: _____

Preceptor Printed Name: _____ Date: _____

Preceptor Telephone: _____ Email: _____

☐ Attached is a copy of the preceptor's Radioactive Materials License or broad scope permit (or identity the IEMA-OHS license).

Part 6. Requesting Licensee's Certification:

As a member of management or as the radiation safety officer, I am authorized to act on behalf of the licensee. I have completed the appropriate section of this form and certify that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge. I hereby request the above changes to our Illinois Radioactive Material License.

Signature: _____ Title: _____

Printed Name: _____ Date: _____

Signed and completed forms may be submitted electronically with required attachments to Ema.speclic@Illinois.gov