IEMA-OHS
Illinois Emergency Management Agency
and Office of Homeland Security

JB Pritzker
Governor

Alicia Tate-Nadeau
Director

**Instructions for Applicants Requesting Use of**
**BWXT Medical Ltd. (formerly MDS Nordion) Yttrium-90 (Y-90) TheraSphere**
**or SIRTEX Wilmington, LLC Yttrium-90 (Y-90) SIR-Spheres**

**(Rev. 7.3, June 2023)**

## Background

On April 20, 2021, the U.S. Nuclear Regulatory Commission (NRC) published updated licensing guidance for BWXT Medical Ltd. (formerly MDS Nordion) Y-90 TheraSpheres and SIRTEX Wilmington, LLC Y-90 SIR-Spheres under revision 10.2. Both products are herein referenced to as Y-90 microspheres. IEMA-OHS maintains and publishes licensing guidance as well to address Illinois-specific regulatory requirements under 32 Ill. Adm. Code Part 335. This guidance reflects updates published in the NRC guidance, State and Tribal Communications (STC) letters, as well as regulatory updates to Part 335.

## 32 Ill. Adm. Code 335.2140 Use

In Illinois, the use of Y-90 microspheres is considered an emerging technology under 32 Ill. Adm. Code 335.2140. These instructions are meant to address the relevant requirements in that Part and facilitate the preparation of amendments to medical licenses seeking approval to use Y-90 microspheres. 32 Ill. Adm. Code 335.40 requires existing Illinois licensees wishing to add microsphere authorization to their license, to apply for and receive a license amendment prior to use. New applicants must utilize Instructional Set 52.2 (Rev. 4, January 2022) and these instructions in the preparation and submittal of a complete application.

(Note: If applicants/licensees wish to perform procedures in addition to or in substitution of those noted below, those procedures must be submitted for review by the Agency.)

## Licensing Guidance

This guidance provides applicants with an acceptable means of satisfying the requirements for a license for the use of TheraSphere® and SIR-Spheres® and is not intended to be the only means of satisfying the requirements for a license. The applicant must submit the information required to meet 32 Ill. Adm. Code 330.250 and 32 Ill. Adm. Code 335.40, as described below. The applicant should submit additional information and commitments requested below or may, unless the information is specifically required by regulation, submit alternative information and

commitments for review by IEMA-OHS staff to make a licensing determination. The commitments incorporated into the license, by license condition, will be reviewed during routine inspections. If an applicant commits to the guidance provided below, the applicant is committing to follow commitments described with the use of the word "should."

**Radionuclides, Form, Possession Limits and Purpose of Use**

Pursuant to 32 Ill. Adm. Code 335.2140(b)(3), the applicant shall identify the radionuclide, form and activity. IEMA-OHS will require the applicant to specify the maximum requested possession limit, and purpose of use. This information may be submitted under a signed, dated letter or in the IEMA-OHS "*Application Form for a Medical Radioactive Materials License*." The purpose of use may be sourced from the manufacturer. Unless otherwise specified, IEMA-OHS will utilize*, "for permanent implantation using the delivery system and any required accessory kit, as approved in the Sealed Source and Device Registry, for the treatment of hepatic tumors"*. The following table provides the format for an acceptable request.

| | Radionuclide<br><br>(IEMA Application Form, Item 7A) | Chemical and/or Physical Form | Maximum Activity Per Source | Maximum Possession Limit [1] |
|---|---|---|---|---|
| TheraSphere® | Yttrium-90 | Glass microsphere (current manufacturer as listed in the Sealed Source and Device Registry [e.g., BWXT Medical Ltd. Model TheraSphere®]) | 540 mCi/vial [2] | |
| SIR-Spheres® | Yttrium-90 | Resin microsphere (current manufacturer as listed in the Sealed Source and Device Registry [e.g., Sirtex Model SIR-Spheres®]) | 296 mCi/vial [2] | |

[1] Based on the maximum amount the applicant anticipates having at one time (i.e., 3 Ci)

[2] Based on historically provided manufacturer's data. Verify and update as appropriate.

**Facility Address and Description**

Provide an address of use and description of the location where the Y-90 microspheres will be used and stored. 32 Ill. Adm. Code 335.2140(b)(2)(A) requires a diagram of the use area to be submitted with the application. If this is a new use location, provide either a statement that the

licensee owns the facility or a letter from the facility owner may be required in accordance with 32 Ill. Adm. Code 330.240(a)(9).

**Leak Tests**

Leak tests are not required for Y-90 microspheres. The small size and large number of Y-90 microspheres make leak testing, as required by 32 IAC 340.410(a), impractical. Further, leak testing is not required as the activity of each Y-90 microsphere is below the threshold in 32 IAC 340.410(b)(3).

**Authorized Users**

IEMA-OHS has determined that individuals meeting one of the pathways for Authorized User (AU) training and experience (T&E) in Appendix A can be authorized for the use of Y-90 microspheres. Please note that the NRC published STC-21-083 on December 13, 2021, which provided additional information on the manufacturer training pathway for AU's seeking Y-90 microsphere authorization. The content of that guidance is reflected in Appendix A. The document can be found at the NMSS Web site: https://scp.nrc.gov/asletters/. The Agency developed a form which applicants may use to navigate the authorized user requirements and identify required documentation and preceptors. That form is available on the IEMA-OHS website, from the Office of Nuclear Safety page.

**Authorized User (AU) Training and Experience**

The applicant must submit documentation of the training and experience (T&E) for all physicians requesting authorization to use Y-90 microspheres. This documentation shall include the clinical use cases and written attestation and supervising physician T&E, if necessary. For individuals completing the patient cases following the license amendment, this documentation shall include documentation from the manufacturer's representative or supervising physician of the three mock 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 an AU who is authorized for the type of Y-90 microsphere for which the individual is seeking authorization. The documentation should commit to initiating these three cases within six months following the license issuance or amendment that names the individual as an AU for Y-90 microsphere use and complete the three cases within a year. Additionally, for applicants that have individuals completing the patient cases following the license amendment, the applicant's commitment will include submitting documentation from the manufacturer to IEMA-OHS within 60 days of when these three patient cases have been satisfactorily completed.

**Radiation Safety Officer and Association Radiation Safety Officer**

The Radiation Safety Officer (RSO), or an approved Associate RSO (ARSO), must have training as specified in 32 IAC 335.9010, including training in radiation safety, regulatory issues, and emergency procedures for Y-90 microsphere use. An RSO or ARSO already listed on a license that includes one type of Y-90 microsphere device does not require additional approval for another type of Y-90 microsphere device but should be familiar with all radiation safety aspects, including cleaning up spills, associated with all devices used at the facility. **NOTE:** If the RSO / ARSO is also seeking authorization to function as a member of the treatment team, evidence of satisfactory completion of the manufacturer's training will also be required.

**Treatment Team**

Y-90 microsphere treatment is conducted using a multi-disciplinary team approach. The AU should consult with individuals, as necessary, with expertise in:

- cancer management (e.g., radiation or medical oncology);
- catheter placement;
- radiation dosimetry; and
- safe handling of unsealed byproduct material.

One individual may satisfy more than one of the listed areas of expertise provided the guidelines for the treatment team below are met. The applicant shall commit to provide the training described below as well as training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

The applicant should commit to the following regarding the treatment team:

a) The treatment team shall consist of one of the following combinations of personnel:
   1) An approved authorized user + RSO[1];
   2) An approved authorized user + Associate RSO[1];
   3) An approved authorized user + Temporary RSO[2];
   4) An approved authorized user + AMP[1] *(**NOTE:** Not a "therapeutic radiological physicist" as defined in 32 Ill. Adm. Code 360.20 )*;
   5) An approved authorized user + another approved authorized user; or
   6) An approved authorized user + an Radiation Safety Committee-approved visiting authorized user[1]

[1] As defined in 32 Ill. Adm. Code 335.20
[2] As discussed in 32 Ill. Adm. Code 335.1040(c) and (d)

b) The treatment team must be physically present during all administration/retrieval procedures.

c) The approved authorized user must be trained in accordance with 32 Ill. Adm. Code 335.9050 or 335.9100 or the guidelines for interventional radiologists.

d) Training for radiation safety officers, associate radiation safety officers and medical physicists should include manufacturer training and meet 32 Ill. Adm. Code 335.9010(f) or 335.9150(d), respectively. In accordance with 32 Ill. Adm. Code 335.1040(b), a licensee may appoint one or more associate RSOs to support the RSO. The RSO, with written agreement of the licensee's management, may assign their role on a Y-90 microsphere treatment team to an approved and qualified associate RSO. In accordance with 32 Ill. Adm. Code 335.1040(c), a licensee may also permit a qualified individual to be a temporary RSO. Anyone serving as the RSO or ARSO on a Y-90 treatment team must have received the manufacturer's training and qualify to be the RSO for Y-90 microsphere use in accordance with Sections 335.9010, 335.9160 or 335.9180.

e) All users must submit copies of the agenda and evidence of completion of training for the specific product that is requested. Appendix A contains detailed instructions for documenting training acceptable to the Agency.

f) Technologists participating in these treatments must be accredited by the State of Illinois in nuclear medicine technology or radiation therapy and must also complete the manufacturer's training program.

**Procedures for Administration**

In accordance with 32 Ill. Adm. Code 335.1120, for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to ensure high confidence that the patient's or human research subject's identity is verified before each administration and each administration is in accordance with the written directive. The applicant shall commit to developing written procedures for the administration of Y-90 microspheres that address all applicable requirements in 32 Ill. Adm. Code 335.1120, including how the licensee will determine if a reportable medical event under 32 Ill. Adm. Code 335.1080 occurred. Procedures for administration of Y-90 microspheres should address the following:

a) The licensee shall commit to following all procedures in the manufacturer's instruction manuals and FDA-approved package inserts or submit alternative methods for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration; determining shunting to non-treatment sites; and determining if a medical event has occurred (e.g., performing pre- and post-vial dose measurements with appropriate instrumentation, evaluating post-treatment imaging).

b) For the purpose of these instructions and the development of administration procedures, shunting is defined as blood flow through pathway or bypass due to patient vasculature

causing the Y-90 microspheres to flow to an unwanted location. Unexpected dose or activity to an organ or tissue other than the treatment site that is caused by catheter placement during delivery of the Y-90 microspheres is not considered shunting and should be evaluated as a possible medical event.

c) Procedures for administrations requiring a written directive should, for Y-90 microsphere administrations, describe how to quantify the total dose to the treatment site as well as the total dose to other sites upon completion of the administration to confirm that the administration is in accordance with the written directive.

**AGENCY NOTE:** The Agency recommends that the licensee perform a "brems scan" image of the patient post administration, to ensure that the intended target received the administered dose and that no other unintended target was treated.

d) For the purpose of Y-90 microsphere written directives and medical event reporting, "prescribed dose" means the total dose (rad or Gy). Alternatively, prescribed activity (mCi or GBq) may be used in lieu of prescribed dose. If prescribed activity is used in lieu of prescribed dose, the activity shall be used for all documentation and evaluations.

e) For the purpose of these instructions and the development of administration procedures, stasis is defined as a stoppage or slowdown in the flow of blood. The inability to complete administration due to clogging or kinking of the catheter is not considered stasis.

f) The licensee shall determine and record the activity of each dosage before medical use in accordance with 32 IAC 335.2010 and 32 IAC 335.2030.

g) In addition to developing and maintaining procedures to determine if a medical event, as described in 32 Ill. Adm. Code 335.1080 has occurred, the licensee shall report any event, except for an event that results from intervention of a patient or human research subject, in which:

1) Y-90 microspheres are administered to the wrong individual or human research subject; via the wrong route; or by the wrong mode of treatment; or

2) The total dose or activity administered differs from the prescribed dose or activity, as documented in the written directive, by 20 percent or more, except when stasis or emergent patient conditions are documented and resulted in a total dose or activity administered that was less than that prescribed; or

**AGENCY NOTE:** Although 32 Ill. Adm. Code 335.1080 has a dose threshold of 0.5 Sv (50 rem) to an organ, this is generally met due to the specific activity of Y-90 microspheres.

3) The administration of Y-90 microspheres results in dose that exceeds 0.5 Sv (50 rem) to an organ or tissue other than the treatment site, as documented in the written directive, except for shunting when shunting was evaluated prior to the treatment and determined to be in accordance with the manufacturer's procedures, or

4) Equipment failures meeting the reportable criteria in 32 Ill. Adm. Code 340.1220(c)(2) occur.

h) The licensee shall comply with the medical event reporting, as well as the Agency, patient and referring physician notification requirements as described in 32 Illinois Adm. Code 335.1080.

**Written Directives**

Administration of Y-90 microspheres must be performed in accordance with the written directive. The licensee must complete the written directive, which must be dated and signed by an AU, before the administration in accordance with 32 IAC 335.1110(a) and 32 IAC 335.1110(c) unless a delay in order to provide a written directive would jeopardize the patient's health. The licensee shall retain a copy of the written directive for five years in accordance with 32 IAC 335.1110(d). As mentioned in the section above, for the purpose of Y-90 microsphere written directives and medical event reporting, "prescribed dose" means the total dose (rad or Gy). Alternatively, prescribed activity (mCi or GBq) may be used in lieu of prescribed dose. If prescribed activity is used in lieu of prescribed dose, the activity shall be used for all documentation and evaluations. As defined in 32 Ill. Adm. Code 335.20, “treatment site” means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive. For instance, the treatment site may be described as the lobe or segment that is intended to receive the Y-90 microspheres and the tissue that is expected to receive Y-90 microspheres due to shunting.

Due to the unique properties of Y-90 microsphere administrations, the following written directive condition should be used instead of 32 Ill. Adm. Code 335.1110(b):

*Prior to implantation:*

a) The patient or human research subject’s name.

b) The date of administration.

c) The signature of an authorized user for Y-90 microspheres.

d) The treatment site [I.e., liver, left/right lobe, segment (as appropriate)]

e) The radionuclide (including the chemical/physical form of [Y-90 microspheres]).

f) The prescribed dose/activity.

g) The model of Y-90 microspheres (e.g. TheraSphere® or SIR-spheres®) or manufacturer

h) If appropriate for the type of microsphere used, the statement “or dose/activity delivered at stasis.”

i) Either the maximum dose/activity that would be acceptable to the specified site(s) outside the primary treatment site due to shunting (e.g. lung and gastrointestinal tract): or

accompanying documentation indicating assessment of the patient or human research subject's permissible shunting values in accordance with the manufacturer's instructions, and

*After implantation, but within 24 hours of completion/termination of the procedure:*

a) Total dose/activity delivered to the primary treatment site and to other specified site(s).

b) If the administration was terminated because of stasis, then:

1) The total dose/activity to the treatment site is the value of the total dose/activity administered when the stasis occurred, and the administration was terminated.

2) The name of the individual who made the assessment.

3) The date the record is completed.

4) The signature of an authorized user for Y-90 microspheres.

**Termination of Treatment Due to Stasis**

If the administration was terminated because of stasis, then the total dose or activity to the treatment site is the value of the total dose or activity administered when stasis occurred, and the administration was terminated. The record shall be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who determined the administered dose or activity, the signature of an AU for Y-90 microspheres, and the date signed.

For the purpose of these instructions and the development of administration procedures, stasis is defined as a stoppage or slowdown in the flow of blood. The inability to complete administration due to clogging or kinking of the catheter is not considered stasis.

**Emergent Patient Conditions**

If the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g., artery spasm or sudden change in blood pressure), the AU shall document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive shall include the reason for not administering the intended dose or activity, the signature of an AU for Y-90 microspheres, and the date signed.

**Sealed Source and Device Use**

The SSDR safety evaluations for BWXT Medical Ltd. (formerly MDS Nordion)Y-90 TheraSphere and the SIRTEX Wilmington, LLC Y-90 SIR-Sphere do not cover the use of any other microspheres, including the preparation of Y-90 on other microspheres by a commercial

nuclear pharmacy, the medical use licensee's authorized nuclear pharmacist, or a physician authorized user qualified to prepare radioactive drugs. The licensee should commit to use only Y-90 microspheres for therapeutic medical uses as approved in the Sealed Source and Device Registries for TheraSphere® and SIR-spheres®, including maximum activity per vial limits. The medical use of other microspheres will require a new SSD certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use, safety of the new Y-90 microspheres, and compatibility of the new microspheres with microsphere delivery system(s).

The SSDR safety evaluation for a manufacturer's Y-90 microsphere delivery system does not cover the use of any other delivery system with the Y-90 microsphere device. The licensee should commit to use only the manufacturer's approved TheraSphere Administration Set or SIRTEX SIR-Spheres device for administration of these products. Before authorization, the medical use of such a delivery system will require a new SSD certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use, safety of the microsphere delivery system, and compatibility of the new delivery system with the Y-90 microspheres. Changes to an existing SSD certificate or issuance of an updated SSDR safety evaluation (or safety evaluation by a broad scope medical use licensee) requires training to relevant staff on the changes – which includes training offered by the manufacturer on revised delivery systems (such as changing from the Legacy to Siros systems).

**Inventory**

The licensee should commit to performing a physical inventory at intervals not to exceed 6 months to account for each individual aggregate of microspheres. The semiannual physical inventory records must be maintained for five (5) years and should include the following:

a) The radionuclide and physical form (Y-90 microspheres)

b) The unique identification of each vial in which microspheres are contained.

c) The total activity of the aggregate in each vial.

d) The location of each vial.

**Labeling**

The licensee should commit to the following when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:

a) Label vials and vial radiation shields with the radioactive device they are used with (i.e. TheraSphere®, SIR-spheres®,); and

b) Label syringes and syringe radiation shields with the radioactive device.

**Patient Release**

The licensee should commit to develop procedures that describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research subject permits his or her release in accordance with 32 IAC 335.2110. Guidance for release of patients or human research subjects following administration of radioactive materials may be found in NRC Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials.", Rev. 1 dated April 15, 2020.

**Surveys**

Licensees should commit to following the requirements in 32 Ill. Adm. Code 335.2080 and 32 Ill. Adm. Code 340.510. As the Y-90 microspheres are too small to be seen, licensees should survey, with an appropriate radiation detection survey instrument, all areas that the Y-90 microspheres are prepared for use or administered. The survey should be conducted immediately following each preparation and administration in unrestricted areas and by the end of the day for restricted areas. A licensee should retain a record of each survey for five years and the record should include the date of the survey, the results of the survey, the instrument used to perform the survey, and the name of the individual who performed the survey. Licensees do not need to perform surveys in an area(s) where patients or human research subjects are confined when they cannot be released under 32 IAC 335.2110.

Measurement of removable contamination shall only be performed with a survey instrument, in lieu of wipes, if the instrument is sufficiently sensitive to detect the contamination at the limits specified in 32 Ill. Adm. Code 335.2080.

**AGENCY NOTE**: Licensee must also ensure surveys of equipment/surgical instruments used for implantation/retrieval of the catheter are performed. All surveys must be conducted with instrumentation appropriate for measurement/detection of the radiation associated with Y-90.

**Radiation Protection Program Changes**

This guidance may be revised as additional experience is gained regarding the medical use of TheraSphere® and SIR-Spheres® Y-90 microspheres. A licensee currently authorized to use these products that is committed by license condition to following provisions in a previous revision of this guidance may request a license amendment to commit to following this revision of the guidance instead. The licensee must apply for and receive this license amendment in order to make program changes to conform to this revision of the guidance.

**Waste Disposal Issues**

The Y-90 microsphere dose vial and other disposable equipment used for administering the Y-90 microspheres (including the catheter) should be stored for decay or disposed of as

radioactive waste. Any non-disposable items should be stored for decay. Care should be taken to maintain connections and system integrity to avoid potential radioactive contamination. Licensees should re-evaluate their waste disposal program to allow for disposal of the activities/half-life associated with this material.

Y-90 microspheres are known to potentially contain radioactive impurities, some of which are long-lived (i.e., half-lives of greater than 120 days) (Refer to NRC Information Notice (IN) 2007-10, "Yttrium-90 Therasphere® and Sirspheres® Impurities"). Due to different manufacturing processes, the activity and radionuclides of the impurities vary for different Y-90 microsphere products. Impurities that have been recently found in reactor-activated microspheres include small amounts of long-lived radionuclides such as europium-152, europium-154, and cobalt-60.8 Impurities that have been recently found from microspheres with generator-produced Y-90 include trace amounts of strontium-90.

Licensees should be aware that the activity and type of impurities can change and be different from that described above. The NRC and/or Agreement States in which Y-90 microspheres are produced, do not limit manufacturers to specific manufacturing processes, and it is therefore possible for the activity and types of radionuclide impurities to change for both products. Additionally, unused or partially used vials are likely to contain higher activities of impurities.

Although impurities need not be listed on an IEMA-OHS license; licensees are responsible to ensure the microspheres are handled and disposed of in accordance with 32 IAC Part 340 and Part 335 requirements. Specifically, 32 Ill. Adm. Code 340.1045 requires that licensees monitor radioactive material with a physical half-life of less than 120 days at the surface before disposal and determine that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter before disposal. Therefore, regardless of the length of time they have been allowed to decay, licensees are not permitted to dispose of Y-90 microspheres if radioactivity can be distinguished from the background radiation level with an appropriate radiation detection survey meter.

If waste is determined to contain impurities with a physical half-life of greater than 120 days that can be distinguished from the background radiation level with an appropriate radiation detection survey meter, the licensee may need to use one or more of the following means to dispose of waste associated with the Y-90 microspheres:

a) Hold the remaining microspheres longer in decay-in-storage in accordance with 32 Ill. Adm. Code 340.1045; or

b) return the Y-90 microspheres to the manufacturer, if the manufacturer is authorized to receive Y-90 microspheres; or

c) transfer the Y-90 microspheres to an authorized recipient pursuant to requirements in

32 IAC Part 340 and Part 330.

**Autopsy and Cremation**

Y-90 microspheres are permanent implants that are not removed from the body by biological methods. Because Y-90 has a 64-hour half-life, Y-90 will likely have significantly decayed before a patient's death. Patients treated with Y-90 microspheres will not usually represent an external radiation hazard to persons handling the body. However, in the case of autopsy or cremation, the radiation hazard increases due to the need for individuals to handle tissues that may contain radioactive material, especially if the death occurs soon after treatment with Y-90 microspheres. The National Council on Radiation Protection and Measurements (NCRP) Report No. 155, "Management of Radionuclide Therapy Patients," December 2006, may contain helpful information for radiation safety considerations associated with autopsy or cremation of patients with permanent implants. Additionally, the NRC's NUREG-1556, Volume 9 Rev 3, Appendix N, "Model Emergency Procedures," contains additional guidance regarding autopsy and cremation of patients who have received therapeutic amounts of radionuclides.

# Appendix A

Pathways to become an authorized user of MDS Nordion Yttrium-90 (Y-90) TheraSphere or SIRTEX Wilmington, LLC Yttrium-90 (Y-90) SIR-Spheres.

a) The authorized user must be trained in accordance with:
   1) 32 Ill. Adm. Code 335.9050; and
   2) The requirements outlined in subsection (b) of the Guidelines for Interventional Radiologists (below); or

b) 1) 32 Ill. Adm. Code 335.9100; and
   2) The requirements outlined in subsection (b) of the Guidelines for Interventional Radiologists (below); or

c) 32 Ill. Adm. Code 335.9160; or

d) The guidelines for Interventional Radiologists (below).

## Guidelines for Interventional Radiologists

To authorize an Interventional Radiologist as a user of Y-90 microspheres, the licensee shall require the Interventional Radiologist to be a physician who:

a) Holds an American Board of Radiology certification in interventional radiology/diagnostic radiology or diagnostic radiology; or American Osteopathic Board of Radiology certification in diagnostic radiology; or has three years supervised clinical experience in diagnostic radiology and experience in interventional radiology demonstrated by Board subspecialty certification in interventional radiology by the American Osteopathic Board of Radiology or one additional year supervised clinical experience in interventional radiology; and

   1) 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) above in:

      A) Radiation physics and instrumentation;

      B) Radiation protection;

      C) Mathematics pertaining to the use of and measurement of radioactivity;

      D) Radiation biology; and

   2) Has work experience under the supervision of an authorized user for Y-90 microspheres or a Y-90 microsphere manufacturer representative involving:

      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) Evaluation of each patient or human research subject for the dose/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;

      F) 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

G) Follow up and review of each patient's or human research subject's case history for Y-90 microspheres; and

3) The applicant must submit an attestation to training and experience satisfying (a)(1) and (a)(2) from either a representative of the manufacturer of the requested type of microsphere or an authorized user of the requested type of microsphere; and

b) Has successfully completed 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 additional Y-90 microsphere specific training and experience requirements may be satisfied by satisfactory completion of a training program provided by either:

1) An authorized user who is authorized for the type of microsphere for which the individual is seeking authorization, who has already documented completion of the three supervised clinical cases. The clinical use experience should include at least three supervised hands-on cases for each type of Y-90 microsphere for which the individual is seeking authorized user status; or

2) A Y-90 microsphere manufacturer, if casework was initiated prior to October 2021 . The clinical use experience should include at least three supervised hands-on in-vitro simulated cases for each type of Y-90 microsphere for which the individual is seeking authorized user status. In-vitro simulated cases should demonstrate issues that are encountered during Y-90 microsphere administration procedures. Following the license amendment that names the individual as an authorized user for Y-90 microsphere use. The first three patient cases completed by the individual should be hands-on and supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which the individual is authorized; and

**AGENCY NOTE**: The NRC advised in the, *Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance April 20, 2021, Revision 10.2*, that they would allow clinical casework to be conducted in the physical presence of a manufacturer representative in place of an AU only until **November 8, 2021**. This manufacturer representative can provide a written attestation that the individual has satisfactorily completed training requirements. After this date, the casework and written attestation should be completed in the physical presence of an AU. IEMA will allow supervision of casework by the manufacturer representative that was initiated prior to the publication date of Revision 7 of this guidance document, corresponding to September 2021. Clinical use experience initiated after the publication date of this guidance should be completed in the physical presence of an AU.

3) The applicant must submit documentation for training and experience for:

A) Individuals obtaining clinical use experience under the above pathway (b)(1) to include:

1. Attestation to training operation of the requested manufacturer's delivery system
2. Attestation to training in safety procedures for the use of that type of microsphere
3. The clinical use cases.

B) Individuals obtaining clinical use experience under the above pathway (b)(2) to include:

1. Completion of the manufacturer's training program, including the in-vitro simulated cases.
2. 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 for each type of Y-90 microsphere for which authorization is sought.
3. The licensee's commitment will also include documentation from the manufacturer to the Agency within 30 days of when these three cases have been satisfactorily completed.

**AGENCY NOTE:** Specialty boards whose certification processes have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on NRC's website: http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.