

**Illinois Emergency Management Agency  
Instructions for Applicants Requesting Use of  
MDS Nordion Yttrium-90 (Y-90) TheraSphere  
or SIRTEX Wilmington, LLC Yttrium-90 (Y-90) SIR-Spheres (Rev. 5)**

Note: These instructions are for use in the preparation of amendments to medical licenses seeking approval to use MDS Nordion Y-90 TheraSpheres or SIRTEX Wilmington, LLC Y-90 SIR-Spheres. Both products herein referenced to as Y-90 microspheres. If this is a new application, Instructional Set 52.2 and these instructions must be used in the preparation/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.)

1. The licensee must commit to all procedures specified in the MDS Nordion Y-90 TheraSphere and the SIRTEX Wilmington, LLC Y-90 SIR-Spheres Instruction Manuals and FDA approved package inserts.
2. For Y-90 microspheres, "prescribed dose" means the total dose documented in the written directive. The written directive should include: (1) prior to implantation: the treatment site, the radionuclide (including the chemical/physical form of (Y-90 microspheres)), and dose; and (2) after implantation but prior to completion of the procedure: the radionuclide (including the chemical/physical form of (Y-90 microspheres), treatment site and the total dose. The written directive should specify the maximum dose that would be acceptable for a specified site (or sites) outside the primary treatment site to which the Y-90 microspheres could be shunted (such as the lung and gastrointestinal tract). 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.
3. The quarterly physical inventory of Y-90 microspheres should include the individual aggregates of the microspheres identifying the radionuclide, the container the aggregate is in, the total activity of the aggregate, and the location of the container.
4. Procedures should describe measures taken to ensure that the bremsstrahlung emissions from each patient or human research subject permits her/his release in accordance with 32 Ill. Adm. Code 335.2110.
5. The SSDR safety evaluations for 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 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).

6. The SDDR 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. Only the manufacturer's approved TheraSphere Administration Set or SIRTEX SIR-Spheres device shall be used for administration of these products.
7. The treatment team shall consist of the radiation oncologist (or approved authorized user) and either the medical physicist or Radiation Safety Officer. The treatment team must be physically present during all administration/retrieval procedures. The authorized user must be trained in accordance with 32 Ill. Adm. Code **335.9050** or 335.9100 and must submit copies of the agenda and evidence of completion for product specific training provided by MDS Nordion or SIRTEX Wilmington, LLC. 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. Records of classroom and practical (i.e., mock administrations and manufacturer's supervised cases) training must be submitted to the Agency upon completion of the 3 initial cases as performed under the manufacturer's supervision. Device specific training can also be completed under by an experience authorized user for the same type of microspheres that the user is currently authorized to use. If the licensee requests to use a different manufactured microsphere, the manufacturer's training is required.
8. Since the device/source does not meet the classic definition of "sealed source" in 32 Ill. Adm. Code 310.20, the requirements in 32 Ill. Adm. Code 335 Subpart H and 32 Ill. Adm. Code 340.410 will not apply and no leak testing in the classical sense is required. However, the licensee must commit to the following requirements for this treatment:
  - a. 32 Ill. Adm. Code 335.1080 – Reports and Notifications of a Medical Event.
  - b. 32 Ill. Adm. Code 335.30(a) – Materials Authorized for Medical Use.
  - c. 32 Ill. Adm. Code 335.2010 – Possession, Use, Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material.
  - d. 32 Ill. Adm. Code 340.540 – Calibration of Survey Instruments.
  - e. 32 Ill. Adm. Code 335.2030 - Assay of Radiopharmaceutical Dosages.
  - f. 32 Ill. Adm. Code 335.2060 - Labeling and Use of Vials and Syringes.
  - g. 32 Ill. Adm. Code 335.2080 and 340.510 - Monitoring for Contamination and Ambient Radiation Dose Rate/Surveys and Monitoring - General.  
(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).
  - h. 32 Ill. Adm. Code 335.2110 – Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material

- i. 32 Ill. Adm. Code 335.5020 - Safety Instruction  
(Note: This must include instruction for attending staff to pay particular attention to dressings and linen around the catheter for leakage during treatment.)
  - j. 32 Ill. Adm. Code 335.5030 - Safety Precautions  
(Note: Bioassays are not required for administration of Y-90 Microspheres.)
9. The licensee must monitor all clothing, food services/utensils, bandages and linens used in the patient's room. These items must be treated as contaminated until monitoring indicates otherwise.
10. 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.
11. A. The MDS Nordion Y-90 TheraSphere microspheres are currently approved by the U.S. Food and Drug Administration (FDA) under the provisions of a "Humanitarian Device Exemption" (HDE No H9800006), which includes unique restrictions on the medical use of the devices. Nothing in the Agency's license relieves the licensee from complying with those FDA requirements.
- B. The SIRTEX Wilmington, LLC Y-90 SIR-Spheres have been approved by the U.S. FDA under a premarket approval application #P990065/S004.
12. An Institutional Review Board is required to approve and monitor the use of the MDS Nordion Y-90 TheraSphere. If this Board determines that the particular use of the Y-90 TheraSphere is for research purposes, the licensee must meet the requirements for research involving human subjects (Note: One of the conditions of approval for an HDE is that there be an Institutional Review Board initial review and approval before a humanitarian use device is used at a facility as well as continuing review of its use).