



April 15, 2021

Bryan Parker, Licensing Assistance Team
U.S. Nuclear Regulatory Commission
Region III – Division of Nuclear Materials Safety
2443 Warrenville Rd, Suite 210
Lisle, IL 60532-4352

Re: Amendment of Cardinal Health Nuclear Pharmacy Services, License No. 34-29200-01MD

Cardinal Health Nuclear Pharmacy Services (Cardinal Health - CAH) requests an amendment to dispense 10 CFR 35.1000 Y-90 TheraSpheres® or SirSpheres® to authorized recipients.

1. Radionuclides, Form, Possession Limits, and Purpose.

	TheraSphere®	SirSpheres®
Radionuclide	Yttrium-90	Yttrium-90
Chemical/Physical Form	Glass microspheres (current manufacturer as listed in the Sealed Source and device Registry (e.g., Nordion, Inc, Model TheraSphere®))	Resin microsphere (current manufacture as listed in the Sealed Source and Device Registry (e.g., Sirtex Model SIR-Spheres®))
Maximum Possession Limits	3 Ci	3 Ci
Purpose of Use	TheraSphere® for permanent brachytherapy using delivery system as listed in the sealed sour and device registry	SirSpheres® for permanent brachytherapy using delivery system as listed in the sealed sour and device registry

2. Facility Description

Dispensing of the Y-90 will be done in the Radiopharmaceutical Dispensing Zone (Pharmacy).

This main portion of the restricted area is used for preparation and dispensing of radiopharmaceuticals. Drawing stations, such as laminar flow hoods, or optional PET dispensing hood will be located in this area. The drawing stations contain a leaded glass L-block, a dose calibrator, and tongs. Quality control, packing and DOT procedures are also performed in this area.

3. Authorized Users

All Y-90 spheres will be dispensed by Authorized Nuclear Pharmacist (ANP).

4. Procedures for Dispensing.

All dispensing of spheres will be done by an ANP within a sterile hood with absorbent paper, with previously determined Y-90 spheres dose calibrator setting.

- 1) Shake the ⁹⁰Y Spheres vial vigorously and assay it in the dose calibrator.
- 2) Add enough sterile water to the V-vial or D-vial to q.s. the volume to 3 mL.
- 3) Place a 3 or 5mL syringe with a 2" needle in the Lucite syringe shield.
- 4) Place a vent needle in the ⁹⁰Y Spheres manufacturer vial.
- 5) Shake the ⁹⁰Y Spheres and withdraw the calculated volume and then draw air into the syringe before withdrawing the needle from the vial.
- 6) Shake the syringe and then assay in the dose calibrator.
- 7) Inject the ⁹⁰Y Spheres into the V-vial or D-vial opposite of the vent needle at the outer edge of the septum.
- 8) Shake the V-vial or D-vial and assay it in the dose calibrator.
- 9) Swab the V-vial or D-vial one last time and put the top on the vial.
- 10) Fill the dose and print the label.
- 11) Put the syringe tag label on the V-vial or D-vial so as not to block the 3 mL mark
- 12) Remove the vent needle from the manufacturer's vial, swab the septum and store the vial for decay.
- 13) Measure the V-vial or D-vial in the Lucite shield with the ion chamber.
- 14) Label residual ⁹⁰Y waste and store appropriately.

5. Inventory

CAH commits to the requirements for brachytherapy source accountability, receipt, labeling, storage, and disposal to ensure accountability of Y-90 in the form of microspheres.

6. Labeling

CAH commits 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 (i.e., SIR-spheres[®], TheraSphere[®]); and
- b. Label syringes and syringe radiation shields with the radioactive device.

7. Surveys

As the Y-90 microspheres are too small to be seen, CAH will survey, with an appropriate radiation detection survey instrument, all areas that the Y-90 microspheres are prepared for use or dispensed. The survey should be conducted immediately following each preparation/dispensing in restricted areas.

8. Waste

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 CAH may use one or more of the following means to dispose of waste associated with the Y-90 microspheres:

- a. return the Y-90 microspheres to the manufacturer, if the manufacturer is authorized to receive Y-90 microspheres; or
- b. transfer the Y-90 microspheres to an authorized recipient pursuant to requirements in 10 CFR Part 20 and Part 30.

Please let me (glenn.sullivan@cardinalhealth.com, 614-757-9586) if you have any questions.

Sincerely,



Glenn Sullivan, PhD.
Corporate Radiation Safety Officer
Director, Health Physics
Nuclear & Precision Health Solutions

cc: Consolidated NRC License File (3)
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From: Denman, Morgan <morgan.denman@cardinalhealth.com>
Sent: Friday, April 16, 2021 2:19 PM
To: Parker, Bryan
Cc: Sullivan, Glenn; Nothem, Erin
Subject: [External_Sender] Amendment of Cardinal Health Nuclear Pharmacy Services, License No. 34-29200-01MD
Attachments: 210415 Amendment for Y90 Spheres.pdf

Hi Bryan,

Cardinal Health Nuclear Pharmacy Services (Cardinal Health - CAH) requests an amendment to dispense 10 CFR 35.1000 Y-90 TheraSpheres® or SirSpheres® to authorized recipients. Please let us know if you have any questions.

Thank you,
Morgan



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I am *Essential to care*

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