

Microsphere Brachytherapy Sources and Devices

Licensing Guidance - TheraSphere and SIRSpheres Yttrium-90 Microspheres

Y-90 microspheres are manual brachytherapy sources used for permanent brachytherapy implantation therapy.

Authorized users must meet the training and experience requirements of either 10 CFR 35.490 or, until October 25, 2005, 10 CFR 35.940 as well as the specific vendor training in the use of the microspheres and the microsphere delivery system.

Leak tests are not required because the activity per microsphere (the sealed source) meets the criteria in 10 CFR 35.67(f) for relieving the licensee from the requirements to perform such tests.

The licensee shall follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use except where the following license conditions provide regulatory relief:

For Y-90 microspheres, "prescribed dose" means the total dose documented in the written directive.

The written directive should include (1) before implantation: the treatment site, the radionuclide (including the chemical/physical form [Y-90 microspheres]), and dose; and (2) after implantation but before completion of the procedure: the radionuclide (including the chemical/physical form [Y-90 microspheres]), treatment site, and the total dose.

When the authorized user uses the medical end point of stasis to determine when to terminate implantation of the microspheres then this should be included in the written directive before implantation. In this case, the written directive should include (1) before implantation: the treatment site, the radionuclide (including the chemical/physical form [Y-90 microspheres]), and a dose of either XXX rad/Gray (or rem/Sieverts) or the dose delivered at stasis; and (2) after implantation but before completion of the procedure: the radionuclide (including the chemical/physical form [Y-90 microspheres]), treatment site, and the total dose. If the implantation was terminated because of stasis, then the total dose is the value of the total dose delivered when stasis occurred and the implantation was terminated.

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 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.

The quarterly physical inventory of sealed sources and brachytherapy sources should include the individual aggregates of the microspheres identifying the radioisotope, the container the aggregate is in, the total activity of the aggregate, and the location of the container.

Procedures should describe measures taken to ensure that the bremsstrahlung emissions from each patient or human research subject permits his/her release in accordance with 10 CFR 35.75.

The following additional guidance applies when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:

Label vials and vial radiation shields with radioisotope and form (i.e., Y-90 microspheres).

Label syringes and syringe radiation shields with the radioisotope, form, and therapeutic procedure (i.e., Y-90 microspheres, brachytherapy).

Notes to Licensees

Change in physical conditions of use.

If the physical conditions of use exceed those reported in the SSD certificate, the limited specific medical use licensee should request an amendment for the new conditions, and broad scope licensee should perform its own engineering and radiation safety evaluation addressing those differences.

Use of other Y-90 microspheres.

The SSDR safety evaluation for a specific manufacturer's Y-90 microspheres does not cover the use of any other Y-90 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 such a source 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 brachytherapy device. 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.

TheraSphere use outside Humanitarian Device Exemption (HDE) restrictions.

The MDS Nordion TheraSphere[®] Y-90 microspheres are 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 NRC license relieves the licensee from complying with those FDA requirements.

If the Institutional Review Board that is required to approve and monitor the use of the MDS Nordion TheraSphere[®] determines that the particular use of the TheraSphere[®] is for research purposes, the licensee must meet the requirements in 10 CFR 35.6, "Provisions 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.)

Revision of Y-90 Microsphere Radiation Safety programs to conform to changes in this licensing guidance.

The above licensing guidance may be revised as additional experience is gained regarding the medical use of TheraSphere and SIRSpheres yttrium-90 microspheres. A licensee already authorized to use these products that is committed by license condition to following provisions

in this guidance existing at the time of commitment must apply for and receive an amendment to its license in order to make changes to conform with the revised provisions.

An applicant initially applying for authorization for the medical use of TheraSphere and SIRSpheeres yttrium-90 microspheres, or a licensee applying for an amendment to conform with revisions in this guidance, may request authorization to allow future changes to its radiation safety program, provided the following conditions are met:

- (1) the revision is in compliance with the regulations;
- (2) the revision is based upon NRC's current guidance for TheraSphere and SIRSpheeres yttrium-90 microspheres 35.1000 use posted on the NRC Web site;
- (3) the revision has been reviewed and approved by the licensee's radiation safety officer and licensee's management;
- (4) the affected individuals are instructed on the revised program before the change is implemented;
- (5) the licensee will retain a record of each change for five years; and
- (6) the record will include a copy of the appropriate Web site guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

If this authorization is approved, these conditions will be incorporated as license conditions in the licensee's license.