

August 29, 2012

Materials Licensing Branch
Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: NRC License Numbers 24-18655-01

Dear Sir or Madam:

I am requesting amendments to the Radioactive Materials License # 24-18655-01 for Centerpoint Medical Center of Independence, LLC, d/b/a Centerpoint Medical Center.

The amendment requests include the following:

1. Addition to Item 6 - The material to add to item 6 is Yttrium-90 as permitted by 10 CFR 35.1000. The form is in a sealed source as SIR-Spheres. The SIR-Spheres are manufactured by Sirtex Wilmington LLC, Sirtex Medical Limited, SIR-Spheres Microspheres. The authorized use of the SIR-Spheres will be for medical use, as permitted by 10 CFR 35.1000, in a Sirtex Medical delivery system.

3. Addition of 10 CFR 35.1000 to Item 12.B. for authorized uses for Joseph P. Koury, M.D. for the use of SIR-Spheres. Dr. Koury is currently authorized on the license for 10 CFR 35.100 and 35.200. The following documentation for training and experience is attached.
 - Statement of training during a Vascular and Interventional Fellowship from The University of North Carolina;
 - Statement of vendor training provided by Sirtex Medical, Inc.;
 - ABR certificate for Board Certification in Diagnostic Radiology

Dr. Koury is an interventional radiologist who has board certification in diagnostic radiology from the American Board of Radiology. He completed a Vascular and Interventional Fellowship at the University of North Carolina during the 2010-2011 academic year. The 80 hours of classroom and laboratory training for byproduct material, including Y-90 microspheres was concurrent with training received during vascular and interventional fellowship. The attached verification of training documents support the requirements of Item A.3.iii of the Licensing Guidance.

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Imaging Services

The clinical use training and experience requirements for Item B of the licensing guidance are being satisfied by following pathway 2. The statement of vendor training is attached. Dr. Koury will complete at least the first three hands-on patient cases supervised in the physical presence of a manufacturer representative. In addition, within 30 days of each case, documentation will be submitted to the NRC by Centerpoint Medical Center. The documentation will be from the manufacturer verifying the cases were satisfactorily completed.

Additional training will be provided to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed.

The License Commitments included in the Licensing Guidance will be followed for written directives, inventory, patient release, labeling and medical event reporting.

The documentation on-site and available for review include:

- Informational packet from Sirtex Medical, Inc. This packet outlines the training and prerequisites prior to implementation.
- Package insert from Sirtex Medical, Inc. for SIR-Spheres
- User manual for SIR-Spheres
- NRC Microsphere Brachytherapy Sources and Devices Licensing Guidance for Therasphere and SIR-Spheres Yttrium-90 Microspheres, revised June 2012

The use of this medical device will be in compliance with the guidance in these documents.

If you have any questions or require additional information, please contact Linda Dunaway at 816-698-7132.

Thank you for your consideration of this request.

Sincerely,



Aaron M. Lewis, M.D.
Radiation Safety Officer
Centerpoint Medical Center

Enclosures: Centerpoint Medical Center License, Statement of Vendor Training, Memorandum from Sirtex Medical, Inc. regarding SIR-Spheres, Statement of Fellowship Training, Dr. Koury Board Certification, Licensing Guidance Document

Imaging Services

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. Centerpoint Medical Center of Independence, LLC d/b/a Centerpoint Medical Center</p> <p>2. 19600 East 39th Street Independence, MO 64057</p>	<p>In accordance with the letter dated March 14, 2012,</p> <p>3. License number 24-18655-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date January 31, 2021</p> <hr/> <p>5. Docket No. 030-13994 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. As needed (not to exceed one curie of iodine-131)</p>
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9. Authorized use:
- A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
 - B. Any imaging and localization study permitted by 10 CFR 35.200.
 - C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300.

CONDITIONS

- 10. Licensed material shall be used at the licensee's facilities located at 19600 East 39th Street, Independence, Missouri, and at the licensee's facilities located at 19550 East 39th Street, Independence, Missouri.
- 11. The Radiation Safety Officer for this license is Aaron M. Lewis, M.D.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
24-18655-01

Docket or Reference Number
030-13994

Amendment No. 57

12. Licensed material is only authorized for use by, or under the supervision of:

A. Individuals permitted to work as an authorized user, in accordance with 10 CFR 35.13 and 35.14.

B. The following individuals are authorized users for medical use as indicated:

Authorized Users

Material and Use

David E. Hazuka, M.D.

10 CFR 35.100, 35.200, and 35.300 (for iodine-131, limited to the oral administration of sodium iodide iodine-131).

George William Pogson, M.D.

10 CFR 35.200.

Richard L. Cronemeyer, M.D.

10 CFR 35.100, 35.200, and 35.300 (for iodine-131, limited to the oral administration of sodium iodide iodine-131 in quantities less than or equal to 33 millicuries).

Paul Ren Chu, M.D.

10 CFR 35.200.

Stephen A. Bloom, M.D.

10 CFR 35.200.

James P. McGraw, M.D.

10 CFR 35.200.

Thomas L. Rosamond, M.D.

10 CFR 35.200.

Alan Schneider, M.D.

10 CFR 35.200.

Bob Green, M.D.

10 CFR 35.200.

Jeffrey W. Bissing, D.O.

10 CFR 35.200.

Christopher McKinney, M.D.

10 CFR 35.100, 35.200, and 35.300 (for iodine-131, limited to the oral administration of sodium iodide iodine-131 in quantities less than or equal to 33 millicuries).

Robert G. Schwegler, M.D.

10 CFR 35.100, 35.200, and 35.300.

John E. Scott, M.D.

10 CFR 35.100, 35.200, and 35.300.

William M. Chase, M.D.

10 CFR 35.100, 35.200, and 35.300.

Craig M. Bruner, M.D.

10 CFR 35.100, 35.200, and 35.300.

Douglas W. Nemmers, M.D.

10 CFR 35.100, 35.200, and 35.300.

Michael B. Parsa, M.D.

10 CFR 35.100, 35.200, and 35.300.

Jeffrey R. Conaway, M.D.

10 CFR 35.100, 35.200, and 35.300.

John F. Eurich, M.D.

10 CFR 35.100, 35.200, and 35.300.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
24-18655-01

Docket or Reference Number
030-13994

Amendment No. 57

Authorized Users

William Brooks, M.D.

Kelly Hart, M.D.

Rick Moritz, M.D.

Thomas Zinn, M.D.

Sarah L. Sherard, M.D.

Donald J. Stallard, M.D.

Bradley McInay, M.D.

Vandana Halder, M.D.

Leo J. Splitter, M.D.

Craig B. McClure, M.D.

Robert A. Wood, Jr., M.D.

Joseph Philip Koury, M.D.

Jason Eric Himmel, M.D.

Michael J. Brigg, M.D.

Nathaniel R. Jewell, M.D.

Susan Chow, M.D.

Michael B. Robertson, M.D.

Aaron M. Lewis, M.D.

Material and Use

10 CFR 35.100, 35.200, and 35.300.

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10 CFR 35.100, 35.200, and 35.300.

10 CFR 35.100 and 35.200.

10 CFR 35.100, 35.200, and 35.300 (limited to the oral administration of sodium iodide iodine-131 in quantities less than or equal to 33 millicuries).

10 CFR 35.100, 35.200, and 35.300 (limited to the use of sodium iodide iodine-131).

10 CFR 35.100, 35.200, and 35.300 (limited to the use of sodium iodide iodine-131).

10 CFR 35.100, 35.200, and 35.300.

10 CFR 35.100, 35.200, and 35.300 (limited to the use of sodium iodide iodine-131).

10 CFR 35.100, 35.200, and 35.300 (limited to the oral administration of sodium iodide iodine-131).

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
24-18655-01Docket or Reference Number
030-13994

Amendment No. 57

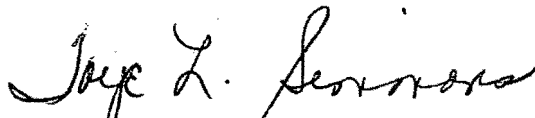
15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated July 28, 2010 (including attachments); and
- B. Letter dated February 18, 2011.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

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By

Toye L. Simmons
Materials Licensing Branch
Region III



SIRTEX MEDICAL INC.
300 Unicorn Park Drive
Woburn, MA 01801
Tel: +1 (781) 721 3800
Fax: +1 (781) 721 3880

Ref: 104US05

August 21st, 2012

Joseph Koury, MD
Interventional Radiologist
Centerpoint Medical Center
19600 East 39th Street
Independence, MO 64057

Dear Dr Koury.

Re: SIR-Spheres[®] Microspheres Authorized User Training and Certification

This letter certifies that on August 21st 2012, you successfully completed training in the operation of the delivery system, safety procedures and clinical use of SIR-Spheres yttrium-90 microspheres that are to be injected via the hepatic artery to treat patients with unresectable liver tumors in accordance with the October 2011 NRC guidance. This training included three (3) supervised hands-on *in-vitro* simulated set-up and delivery procedures that demonstrate possible issues encountered during the yttrium-90 microsphere administration.

Sirtex would like to thank you for your support in this process.

Yours sincerely,

Tom Fromm
Regional Sales Manager

Cc: Linda Teigland



Sirtex Medical Inc.
300 Unicorn Park Drive
Woburn, MA 01801 USA

Telephone: (888) 474-7839
Fax: (978) 229-9585
Web: www.sirtex.com

MEMORANDUM

TO: ALL SIR-Spheres® microspheres Users, RSO's
FROM: Linda Teigland
Date: August 12, 2010
Subject: License Amending Information

In order to use our product, you will need to amend your Radioactive Materials License which will require the following information:

Issuer: The Commonwealth of Massachusetts, Radiation Control Program

License No: MA-1229-D-101-S

Distributor: Sirtex Wilmington LLC
16 Upton Drive, #2-4, Wilmington, MA 01887

Sealed Source Model Designation: Sirtex Medical Limited SIR-Spheres® microspheres

Isotope: Yttrium-90

Minimum Activity: 132 mCi per vial (Maximum activity 189 mCi per vial)



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

Charles T Burke, MD

Division Chief and Associate Professor of Radiology
Director of Fellowship for Interventional Radiology and
UNC Center for Heart and Vascular Care

Re: Joseph Koury, MD

July 18, 2012

To Whom It May Concern:

During his Vascular & Interventional Fellowship at the University of North Carolina during the 2010-2011 academic year Dr. Joseph Koury was involved in multiple therasphere administrations. During that time period he was trained in the following:

- Evaluation of each patient or human research subject for the dose/activity of Y-90 microsphere to be administered to each treatment site.
- Calculating and measuring the activity and safely preparing the Y-90 microsphere to be delivered to the patient or human research subject.
- Using administrative controls to prevent a medical event involving the use of byproduct material.
- Using procedures to control and contain spilled byproduct material including Y-90 microsphere safely and using proper decontamination procedures.
- Follow-up and review of each patient's or human research subject's case history for Y-90 microsphere.

Sincerely,

Charles Burke, M.D.

The American Board of Radiology

*Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Radiation Oncology, the Association of
University Radiologists, and the American Association of Physicists in Medicine*
Hereby certifies that

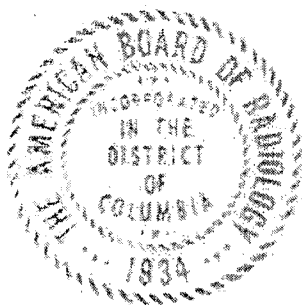
Joseph Philip Koury, MD

*Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications, including
passing the examinations conducted under the authority of
The American Board of Radiology,
demonstrating to the satisfaction of the Board that he is qualified to practice,
and is therefore awarded the Board's certification in the specialty of*

AM Eligible

Diagnostic Radiology

Effective June 30, 2010

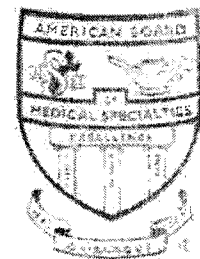


Certificate No. 56860

Eric J. Koury
President

Richard L. Moran
Secretary-Treasurer

Henry S. ...
Executive Director



Valid through 2020

Microsphere Brachytherapy Sources and Devices

REVISED JUNE 2012

Questions should be directed to: Ashley Cockerham (240) 888-7129 or
MedicalQuestions.Resource@nrc.gov

Licensing Guidance – TheraSphere® and SIR-Spheres® Yttrium-90 Microspheres

Yttrium-90 (Y-90) microspheres are manual brachytherapy sources used for permanent implantation therapy. Y-90 microspheres are regulated under 10 CFR 35.1000 "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material." Consistent with the direction in 10 CFR 35.1000, the NRC has evaluated these devices and determined that licensees must use Y-90 microspheres in accordance with the following requirements, which will be incorporated into the license either through license condition or through incorporation by reference to licensee submittals that include commitments consistent with these requirements. Applicants are reminded that licenses issued pursuant to 10 CFR 35.1000 must still meet the general requirements in 10 CFR Part 35, Subparts A, B, C, L, and M.

Training and Experience

NRC has determined that individuals meeting the guidance provided in both A and B below will be considered qualified and can be authorized for the use of Y-90 microspheres. Applicants may also submit alternative training and experience commitments to be reviewed on a case-by-case basis by NRC staff. The alternative information should include an explanation of why the applicant believes the alternative information demonstrates that the individuals are qualified to be authorized individuals.

The authorized user for Y-90 microspheres (AU):

A)

- 1) Is identified as an authorized user for medical uses in 10 CFR 35.400, "Use of sources for manual brachytherapy," or for medical uses in 35.300, "Use of unsealed byproduct material for which a written directive is required," that includes categories 1, 2, and 3 as listed in 10 CFR 35.390(b)(1)(ii)(G) on one of the following licenses or permits that permit the medical use of byproduct material: A Commission or Agreement State license, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State specific licensee of broad scope, or a permit issued by a Commission master material license broad scope permittee; or
- 2) Meets the training and experience requirements of 10 CFR 35.390 or 10 CFR 35.490; or

- 3) Is an interventional radiologist who meets the training and experience guidelines as follows:
- i)
 - a) American Board of Radiology certification in diagnostic radiology and subspecialty certification in interventional radiology; or
 - b) Three years supervised clinical experience in diagnostic radiology and one additional year of supervised clinical experience in interventional radiology; and
 - ii) 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.3.i. in:
 - a) Radiation physics and instrumentation;
 - b) Radiation protection;
 - c) Mathematics pertaining to the use and measurement of radioactivity;
 - d) Radiation biology; and
 - iii) has work experience under the supervision of an AU for Y-90 microspheres or training provided by a Y-90 microsphere manufacturer representative involving:
 - a) Ordering, receiving, and 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 (Appendix S to NUREG-1556, Volume 9 provides additional guidance on this subject);
 - f) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures (Appendix N to NUREG-1556, Volume 9 provides additional guidance on this subject. The procedures should address any special circumstances that may be encountered, such as electrostatic charge of microspheres and 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
- 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:

- pathway 1) an AU who is authorized for the type of microsphere for which the individual is seeking authorization. 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 AU status; or
- pathway 2) a Y-90 microsphere manufacturer. 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 AU 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 AU 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.

The applicant must submit documentation for the above training and experience. For individuals obtaining clinical use experience under pathway 1 above, this documentation includes the clinical use cases. For individuals obtaining clinical use experience under pathway 2 above, this documentation includes the *in-vitro* 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 a manufacturer representative for each type of Y-90 microsphere for which authorization is sought. Additionally for pathway 2, the licensee's commitment will include submitting documentation from the manufacturer to the appropriate NRC Regional Office within 30 days of when these three patient cases have been satisfactorily completed.

In addition, the applicant shall commit to provide 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.

If the NRC staff revises the training and experience criteria, physicians who were authorized for the medical use of a specific type of Y-90 microsphere under these criteria or previous criteria, do not have to meet the revised criteria for that type of microsphere.

Leak Tests

Leak tests are not required for Y-90 microspheres based on the criteria in 10 CFR 35.67(f).

License Commitments - Written Directives, Inventory, Patient Release, Labeling, & Medical Event Reporting

The applicant shall commit to follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use, except where replaced by the following licensing commitments:

- For the purpose of written directives and medical event reporting requirements in the Y-90 microsphere guidance, "prescribed dose" means the total dose (rad or Gy). Alternatively, prescribed activity (mCi or GBq) may be used in lieu of prescribed dose.
- The written directive shall include the patient or human research subject's name; the date; the signature of an AU for Y-90 microspheres; the treatment site; the radionuclide (including the physical form [Y-90 microspheres]); the prescribed dose/activity; the manufacturer; and, if appropriate for the type of microsphere used, the statement "or dose/activity delivered at stasis."
- The written directive should specify the maximum dose(s)/activity(ies) that would be acceptable to the specified site(s) outside the primary treatment site due to shunting (e.g. lung and gastrointestinal tract).
- Administration of Y-90 microspheres must be performed in accordance with the written directive. 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 should document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive should include the reason for not administering the intended dose/activity, the date, and the signature of an AU for Y-90 microspheres.
- The licensee shall record the administered dose/activity delivered to the primary treatment site and to the other specified site(s). If the administration was terminated because of stasis, then the total dose/activity to the treatment site is the value of the total dose/activity administered when stasis occurred and the administration was terminated. The record should be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who made the assessment, the date, and the signature of an AU for Y-90 microspheres, if terminated due to stasis.
- The licensee shall commit to following the manufacturer's procedures for calculating/documenting the dose to the treatment and other sites, preparing the dose for administration, and performing pre/post vial dose measurements; or submit alternative methods.
- The semi-annual physical inventory of microsphere aggregates (e.g. vials) should include:
 - 1) the radionuclide and physical form; and
 - 2) unique identification of each vial in which the microspheres are contained; and
 - 3) the total activity contained in each of the vial(s); and
 - 4) the location(s) of the vial(s).

- The licensee shall retain each semi-annual physical inventory record for three years.
- 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/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:
 - 1) Label vials and vial radiation shields with radionuclide and form (e.g., Y-90 microspheres).
 - 2) Label syringes and syringe radiation shields with the radionuclide, form, and therapeutic procedure (e.g., Y-90 microspheres, brachytherapy).
- The licensee shall commit to report any event, except for an event that results from intervention of a patient or human research subject, in which:
 - 1) the administration of byproduct material results in a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from the use of the wrong radionuclide; or
 - 2) the administration of Y-90 microspheres results in a dose
 - a) that differs from the prescribed dose or the dose that would have resulted from the prescribed activity, as documented in the written directive, by more than 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue, and the total dose/activity administered differs from the prescribed dose/activity, as documented in the written directive, by 20 percent or more; or
 - b) that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from an administration to the wrong individual or human research subject, via the wrong route, or by the wrong mode of treatment; or
 - c) to an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and by 50 percent or more of the prescribed dose/activity expected to that site from the administration of Y-90 microspheres, if carried out as specified in the written directive
- Additionally, the licensee shall comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

Notes to Licensees

Team Approach

Microsphere brachytherapy treatment is usually conducted using a multi-disciplinary team approach. The AU should consult, as necessary, with individuals with expertise in:

- Cancer management (e.g. radiation or medical oncology)
- Catheter placement

- Radiation dosimetry
- Safe handling of unsealed byproduct material

One individual may satisfy more than one of the listed areas of expertise.

Notification for AUs

NRC recognizes that if an AU satisfies the training and experience listed in NRC's licensing guidance for Y-90 microspheres and is currently listed on a Commission or Agreement State medical use license or permit for a specific type of microsphere, the AU should be allowed to work under a different license for the medical use of the same type of microsphere. A limited specific medical use applicant initially applying for authorization for the medical use of Y-90 microspheres or an existing licensee applying for an amendment may request authorization to notify the NRC in the future that it has permitted an AU to work at its facility without the need to request an additional license amendment, provided the following conditions are met:

- 1) the AU satisfies the training and experience listed in NRC's licensing guidance for Y-90 microspheres; and
- 2) the AU is currently listed for the same type of Y-90 microsphere use on a Commission or Agreement State license, a permit issued by a Commission master material license, a permit issued by a Commission or Agreement State licensee of a broad scope, or a permit issued by a Commission master material license broad scope permittee; and
- 3) the licensee provides NRC a copy of the license or permit on which the AU was originally listed for the specific microsphere use; and
- 4) the licensee provides documentation to NRC for each AU of the above listed conditions no later than 30 days after the date that the licensee allows the AU to work as an AU for the specific type of microsphere.

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

Change in Physical Conditions of Use

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

Use of Other Y-90 Microspheres

The SSD 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 SSD safety evaluation for a given manufacturer's Y-90 microsphere delivery system does not cover the use of that manufacturer's Y-90 microspheres with another manufacturer's delivery system or the use of another manufacturer's Y-90 microspheres with the given manufacturer's delivery system. 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® Y-90 microspheres determines that the particular use of TheraSphere® Y-90 microspheres 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 SIR-Spheres® Y-90 microspheres. A licensee currently 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 SIR-Sphere® Y-90 microspheres, or a licensee applying for an amendment to conform with revisions may request to incorporate into its license a change process similar to 10 CFR 35.26. Such a change process can allow some future changes to radiation safety programs provided that the change process requires the following conditions to be met for revisions to the radiation safety program:

- 1) the revision is in compliance with the regulations; and
- 2) the revision is based upon NRC's current guidance for TheraSphere® and SIR-Spheres® Y-90 microspheres 35.1000 use posted on the NRC Web site; and
- 3) the revision has been reviewed and approved by the licensee's Radiation Safety Officer and licensee's management; and
- 4) the affected individuals are instructed on the revised program before the change is implemented; and
- 5) the licensee will retain a record of each change for five years; and
- 6) the record will include a copy of the appropriate website 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 approved, these conditions for use of updated guidance will be incorporated as license conditions in the licensee's license.

Waste Disposal Issues

In March 2007 NRC staff issued an Information Notice (IN 2007-10) to alert all medical licensees of the presence of radioactive contaminants and possible disposal issues with the two variations of commercially available Y-90 labeled microspheres, TheraSphere® and SIR-Spheres®. Depending on the contaminants, licensees may need to:

- hold the remaining microspheres longer in decay-in-storage in accordance with 10 CFR 35.92; or
- return the microspheres to the manufacturer, if the manufacturer is authorized to receive Y-90 microspheres; or
- transfer the microspheres to an authorized recipient.

IN 2007-10, *Yttrium-90 TheraSpheres® and SIR-Spheres® Impurities*, is available on the NRC public website at <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/2007/in200710.pdf>.




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