

## Cook, Jackie

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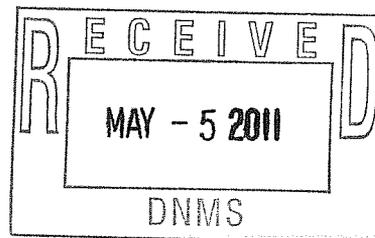
**From:** Richard J. Massoth, Ph.D. [rmassoth@medx-ray.com]  
**Sent:** Thursday, May 05, 2011 1:09 PM  
**To:** Cook, Jackie  
**Cc:** Murnahan, Colleen; 'Mark Sperlich'  
**Subject:** RE: E-MAIL DEFICIENCY LETTER FOR AVERA MCKENNAN HOSPITAL  
**Attachments:** Amendment Request - 5-4-2011.pdf; Dr Casey ABR Certificates\_2.pdf; Dr Casey and Dr Corsini\_Training Certificates.pdf

Dear Ms. Cook,

Attached please find our response to your deficiency letter. We have adapted our amendment request to meet the January 2011 guidance for SIR-Spheres. We withdraw the request for TheraSpheres at this time. We have also improved the documentation of training for the proposed Interventional Authorized User, Dr. Casey. I hope that the large size of the file of Dr. Casey's documentation is below what your email system will accept – if not, then I will need to fax those documents.

Please do not hesitate to contact me by email or cell phone at 605-310-8136 if there are any questions.

Take care,  
Richard  
Richard J. Massoth, Ph.D., DABR  
Radiation Safety Officer  
Avera McKennan Hospital & University Health Center



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**From:** Cook, Jackie [mailto:Jackie.Cook@nrc.gov]  
**Sent:** Saturday, April 16, 2011 9:27 AM  
**To:** Richard Massoth  
**Subject:** ACT: E-MAIL DEFICIENCY LETTER FOR AVERA MCKENNAN HOSPITAL  
**Importance:** High

Dr. Massoth:

Attached you will find an e-mail deficiency letter for Avera McKennan Hospital. Please respond to this e-mail by **Thursday, May 5, 2011**. Please note that I am out of the office **Monday, April 18-Friday, April 22<sup>nd</sup>**, returning to the office on **Monday, April 25<sup>th</sup>**.

Please don't hesitate to contact me at your convenience if you have any questions.

Thanking you in advanced for your response. Please let me know as soon as practical if you need an extension of this due date to respond.

Best Regards,

*Jacqueline "Jackie" D. Cook*  
Senior Health Physicist  
Division of Nuclear Materials Safety  
Nuclear Materials Safety Branch B  
612 E. Lamar Blvd., Suite 400  
Arlington, TX 76011  
817-860-8132 (office)/817-860-8263 (fax)  
e-mail address: [Jackie.Cook@nrc.gov](mailto:Jackie.Cook@nrc.gov)

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May 4, 2011

Via email: Jackie.Cook@nrc.gov

U.S. Nuclear Regulatory Commission, Region IV  
Division of Nuclear Materials Safety  
Nuclear Materials Safety Branch B  
Attn: Jacqueline D. Cook  
612 East Lamar Blvd., Suite #400  
Arlington, TX 76011-4125

Re: License No. 40-16571-01  
Docket No. 030-11252  
Control No. 574318

Dear Ms Cook:

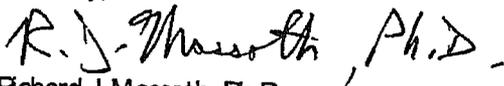
In response to your email deficiency letter dated April 16, 2011, we are hereby correcting and resubmitting our amendment request, originally dated January 5 of 2011, to our NRC Materials License #40-16571-01 to add SIR-Spheres® Yttrium-90 Microspheres use. Attached, please find the revised amendment request for SIR-Spheres. We wish to retract the previously proposed TheraSphere use from our previous amendment request. Any future addition of TheraSpheres to the Avera McKennan license will be via an independent amendment request.

We have restructured our attached amendment request to follow the current NRC guidance of January 2011 for Y-90 uses of the SIR-Spheres system. We have removed all references to the September 2008 Regulatory Guidance for this 10CFR35.1000 use.

We request that our maximum possession limit for Y-90 SIR-Spheres be 800 mCi. We consider this activity to permit sufficient radioactive material to be on hand to permit up to 4 therapeutic applications at any one time with some allowance for Y-90 storage for waste and unused material disposal as decay-in-storage, return to manufacturer or transfer to another licensee (e.g., a licensed radioactive materials waste broker).

Thank you for your attention to this matter. Please do not hesitate to email ([rmassoth@medx-ray.com](mailto:rmassoth@medx-ray.com) or [rmassoth@acm.org](mailto:rmassoth@acm.org) if the medx-ray.com address "bounces") or call me (cell: 605-310-8136) if there are any questions or concerns about this amendment request.

Sincerely,



Richard J. Massoth, Ph.D.  
Radiation Safety Officer  
Avera McKennan Hospital & University Health Center

5 7 5 0 8 5

**Avera McKennan Hospital & University Health Center Proposes to add Y-90 SIR-Spheres as a Therapeutic Use of Radioactive Materials Under 10CFR35.1000.**

***NRC Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Sources No. MA-1229-D-101-S***

- Radonucleide: <sup>90</sup>Yttrium (Y-90)
- Manufacturer's name and model number: Sirtex Medical SIR-Spheres. Sealed Source Model Designation: Sirtex Medical Limited SIR-Spheres@microspheres Y001
- Requested maximum activity (possession limit): 800 mCi
- Device Name: Sirtex Medical Limited SIR-Sphere brachytherapy device
- Manufacturer/Distributor: Sirtex Wilmington/ Sirtex Medical.
- Device type: SIR-Sphere Brachytherapy Afterloader

***Intended Use***

To be used for Intravascular Brachytherapy (IVB) treatments of hepatic carcinoma under 10CFR35.1000.

***Proposed Authorized Users for 35.1000 SIRspheres***

- Michele M. Corsini, M.D. (Dr. Corsini is currently listed as an Authorized User on this RML for 35.400 and 35.600 uses).
- Matthew Casey, M.D. (For Interventional only). Attached are Dr. Casey's ABR certificate in Diagnostic Radiology issued in June 2005, and his ABR certificate in Diagnostic Radiology with Subspecialty Certification in Vascular and Interventional Radiology which was issued November 2007.

Dr. Corsini and Dr. Casey have both successfully completed training in the operation of the delivery system, safety procedures and clinical use of the SIRsphere system of yttrium-90 microspheres to be used for Intravascular Brachytherapy (IVB) treatments of hepatic carcinoma. Training was in accordance with the January 2011 NRC guidance. Training documentation for these users is attached.

Following the license amendment that adds yttrium-90 use and the supervising Authorized Users, we commit that each Authorized User will complete the first three hands on patient cases under the physical supervision of a manufacturer's representative. Documentation will be sent to the NRC within 30 days of completion of the three patient studies.

We commit that the above-named Authorized Users will provide direct supervision (physically present) and have authority for radiation safety and will be the only individuals operating the device during patient treatment.

We request that additional Authorized Users may be trained by the manufacturer's representative or an Authorized User trained by the manufacturer's representative. Such new authorized users will submit their training documents and future amendments will be filed to add or remove Authorized Users for this 10CFR35.1000 use of Y-90.

***Training of Individuals***

Initial training will be provided by the manufacturer to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. In the future, such training may be

## Revised Y-90 SIRspheres Amendment Request – Attachment 1

provided to other individuals by an individual directly trained by a representative of the manufacturer. All training materials will be developed or approved by the manufacturer. Training records will be maintained for inspection in Nuclear Medicine and/or Radiation Physics departments.

The topics covered in annual retraining will be as follows:

- Qualifications
- SIR-Spheres@Yttrium-90 Microspheres product information
- Selective Internal Radiation Therapy (SIRT)
- Dose preparation
- Implant procedure
- Radiation safety

### ***Leak Testing***

Leak testing will not be performed for the Y-90 microspheres per 10 CFR 35.67(f).

### ***Facilities***

Radioactive sources will be received in the Nuclear Medicine Department Hot Lab. The package will be opened using standard procedures. Until use, radioactive material will be stored in the Hot Lab in a manner that will maintain exposures ALARA. Following preparation and assay of the dose, the source will be transported to and from the treatment room by a Certified Nuclear Medicine Technologist. The room will be posted with a "CAUTION: Radioactive Material" sign during the procedure. Only personnel necessary for the procedure will be permitted in the treatment room. All personnel in the treatment room will be monitored for whole body radiation exposure. Authorized Users and Nuclear Medicine Technologists will also be monitored for extremity exposure.

### ***Standard Operating Procedures***

We commit to following the device package insert instructions for use. Records of package receipt and source calibration will be maintained in the Nuclear Medicine Department and will be available for inspection.

### ***Written Directive***

We commit to following the license guidance for Written Directives as defined in the NRC Microsphere Brachytherapy Sources and Device guidance revision January 2011.

### ***Inventory***

We commit to following the license guidance for semi-annual inventory of microspheres aggregates (e.g. vials) as defined in the NRC Microsphere Brachytherapy Sources and Device guidance revision January 2011.

### ***Bremsstrahlung Procedures***

We commit to following procedures to maintain compliance with 10 CFR 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

### ***Usage of vial, syringes or shields that are not labeled by the manufacturer***

Any use of vials, syringes or shields that are not provided by the manufacturer will be labeled as followed:

## Revised Y-90 SRSpheres Amendment Request – Attachment 1

1. Vials and vial radiation shields will be labeled with the radionuclide and form.
2. Syringes and syringe radiation shields will be labeled with the radionuclide, form, and therapeutic procedure.

### ***Emergency Procedures***

We commit to following the license guidance for reporting events as defined in the NRC Microsphere Brachytherapy Sources and Device guidance revision January 2011 as well as medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g). The manufacturer's device package insert instructions will be followed with respect to trouble shooting and preventing adverse events connected with the administration of these sources.

### ***Waste Disposal***

All waste generated during this patient treatment procedure will be surveyed for contamination by a Certified Nuclear Medicine Technologist. Waste found to be contaminated will be stored for decay for at least ten half lives and until indistinguishable from background. Unused sources may be returned to the manufacturer or to a licensed radioactive materials broker, with shipment as allowed under 10CFR71. Records of disposal will be maintained in the Nuclear Medicine Department and will be available for inspection.

### ***QA Tests and Frequencies***

Quality control procedures outlined in the manufacturer's package insert will be followed and results will be documented and maintained in the Nuclear Medicine department for inspection.

A radiation survey of the source container and device will be performed prior to and following the administration to the patient. Results will be maintained in the Nuclear Medicine Department and will be available for inspection.



**SIRTEX MEDICAL, INC.**  
16 Upton Drive, #2-4  
Wilmington, MA 01887  
Tel: 978 642 3000

Ref: 104US03

April 15, 2010  
Michele M. Corsini, M.D.  
Radiation Oncology  
Avera McKennan Hospital  
800 East 21<sup>st</sup> Street  
Sioux Falls, SD 57117

Dear Dr. Corsini:

**Re: SIR-Spheres<sup>®</sup> Microspheres Authorized User Training and Certification**

This letter certifies that on April 15, 2010, 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 September 2008 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.

Following the license amendment that names you as an AU for SIR-Spheres yttrium-90 microspheres use, Sirtex will arrange for the first three (3) *in-vivo* patient cases to be performed in the physical presence of a Sirtex proctor.

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

Yours sincerely,

Alison Yoxall  
Regional Sales Manager

cc: TEC - Sirtex  
Linda Teigland  
David Swanson, RSO



**SIRTEX MEDICAL, INC.**  
16 Upton Drive, #2-4  
Wilmington, MA 01887  
Tel: 978 642 3000

Ref: 104US03

April 15, 2010  
Matthew Casey, M.D.  
Interventional Radiology  
Medical X-Ray Center, PC  
1417 S. Minnesota Ave.  
Sioux Falls, SD 57105

Dear Dr. Casey:

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

This letter certifies that on April 15, 2010, 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 September 2008 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.

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

Yours sincerely,

Alison Yoxall  
Regional Sales Manager

cc: TEC - Sirtex

Linda Teigland

David Swanson, RSO

# The American Board of

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

**Matthew Ray Carey, M.D.**

Has pursued an accepted course of graduate study  
and clinical work, has met or exceeded standards and qualifications and  
has passed the examinations conducted under the authority of  
The American Board of Radiology

On this fifth day of November, 2007

Thereby demonstrating to the satisfaction of the Board  
that he is qualified to practice the specialty of

**Diagnostic Radiology**

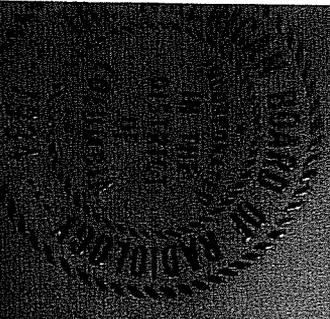
with Subspecialty Certification in:

**Vascular and Interventional Radiology**

By: *Robert M. ...*

*Edith ...*

*...*



# The American Board of Radiology

Organized through the cooperation of the  
American College of Radiology, the American Roentgen Ray Society,  
the American Pediatric Society, the Radiological Society of North America,  
the Section on Radiology of the American Medical Association,  
the American Society for Therapeutic Radiology and Oncology, the Association of  
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Hereby certifies that

**Matthew Ray Carey, M.D.**

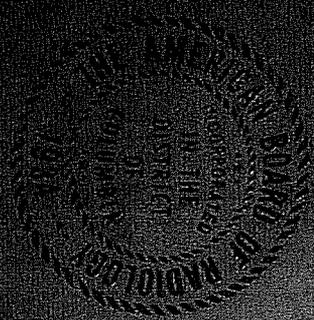
Has pursued an *official* course of graduate study  
and clinical work, has met certain standards and qualifications and  
has passed the examinations conducted under the authority of

The American Board of Radiology

On this eighth day of June, 2005

Thereby demonstrating to the satisfaction of the Board  
that he is qualified to practice the specialty of

**Diagnostic Radiology**



Thomas A. Stahl, M.D.  
President

Howard T. Hoyle, M.D.  
Secretary

FR 1000

5/11/11

DATE

This is to acknowledge the receipt of your letter/application dated 5/5/11, and to inform you that the initial processing, which includes an administrative review, has been performed.

- There were no administrative omissions. Your application will be assigned to a technical reviewer. Please note that the technical review may identify other omissions or require additional information.
- Please provide to this office within 30 days of your receipt of this card:

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The action you requested is normally processed within 90 days.

- A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 575085.  
When calling to inquire about this action, please refer to this mail control number.  
You may call me at (817) 860-8103.

Sincerely,



Licensing Assistant

BETWEEN:

Accounts Receivable/Payable  
and  
Regional Licensing Branches

[ FOR ARPB USE ]  
INFORMATION FROM LTS . . .

Program Code: 02230  
Status Code: Pending Amendment  
Fee Category: 2B 7C  
Exp. Date:  
Fee Comments:  
Decom Fin Assur Reqd: N

**License Fee Worksheet - License Fee Transmittal**

**A. REGION**

1. APPLICATION ATTACHED

Applicant/Licensee: AVERA MCKENNAN HOSPITAL  
Received Date: 05/05/2011  
Docket Number: 3011252  
Mail Control Number: 575085  
License Number: 40-16571-01  
Action Type: Amendment

2. FEE ATTACHED

Amount: \_\_\_\_\_

Check No.: \_\_\_\_\_

3. COMMENTS

Signed: Carol L. Hiee

Date: 5/5/11

**B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / / )**

1. Fee Category and Amount: \_\_\_\_\_

2. Correct Fee Paid. Application may be processed for:

Amendment: \_\_\_\_\_

Renewal: \_\_\_\_\_

License: \_\_\_\_\_

3. OTHER \_\_\_\_\_  
\_\_\_\_\_

Signed: \_\_\_\_\_

Date: \_\_\_\_\_