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DNMS

December 27, 2011

U.S. Nuclear Regulatory Commission,
Region IV
Attn: DNMS/NMSBB Jacqueline D. Cook
612 E. Lamar Blvd., Suite 400
Arlington, TX 76011-4125

Re: License No 25-10994-04
Amendment to add authorize user and food and drinking water in controlled areas

Please find attached for your review and consideration a license amendment to add authorized users to our existing license and documentation to allow drinking water in controlled areas.

- Documentation to add Kevin Duwe as a 1000 user
- Documentation to allow water and food in controlled areas

The physician would like to start these procedures in February of 2012 because no one is providing this treatment within a 200 mile radius. So if you could expedite this amendment that would be greatly appreciated

Thank you for your time and consideration

Sincerely,

Lawrence Slate
Radiation Safety Officer/Medical Physicist
406 522-1626

h 576626

This amendment is based on the guidelines NUREG-1556 Volume 9 "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Material Use Licenses." And 10 CFR part 35.

Item 1 License Application Type

This is an application to amend the facilities present NRC License # 25-10994-04

Item 2 Applicant's Name and Mailing Address

Bozeman Deaconess Hospital
915 Highland Boulevard
Bozeman, Montana 59715

Item 3 Address Where Licensed Material will be Used or Possessed

Bozeman Deaconess Hospital
915 Highland Boulevard
Bozeman, Montana 59715

Item 4 Person to be contacted about the Application

Lawrence J. Slate
Radiation Oncology
Bozeman Deaconess Hospital
915 Highland Boulevard
Bozeman, Montana 59715
406 522-1626

Please find attached for your review and consideration the documentation to add the following individual as an Authorized user on our license for 10 CFR 1000:

Kevin Michael Duwe, MD

Please find for your review and consideration the following commitments that will be adhered to via policies or procedures:

- The written directives 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 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.

- It is our intention to return all unused Y-90 micorspheres to the vendor, but in the case they will not accept unused material we will commit to the following:
  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).

BDH would also like to request to amend our license to allow food and drink for patient use only in controlled areas in lieu of Appendix T NUREG 1556. I spoke to Ms. Cook about this in October and have attached that communication. We would like to request food and drink in these areas necessary for the examination (i.e., toast and eggs for a gastric emptying exam) or for those patients that request water during an exam (i.e., water while waiting for the PET Scan).

Stringent procedures will be followed so that radiation is contained in the controlled area. For example all water would be contained in a sealable container and have the patient name and unique identification number. The water would be surveyed per existing protocols before disposal. The same situation would apply for any remaining food products not ingested by the patient.

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

November 6, 2010

Dr. Kevin Duwe, MD
Interventional Radiology
Banner Desert Medical Center
1400 S. Dobson Road
Mesa, Arizona 85202

Dear Dr. Duwe:

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

This letter certifies that on 10/14/2010, 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 plus three (3) clinical patient ytrrium-90 microsphere administration cases.

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

Yours sincerely,

Neal McMahon

Neal McMahon
Regional Sales Manager

® SIR-Spheres is a Registered Trademark of Sirtex SIR-Spheres Pty Ltd

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eman Deaconess Cancer Center
Highland Blvd., Suite 3130
eman, MT 59715

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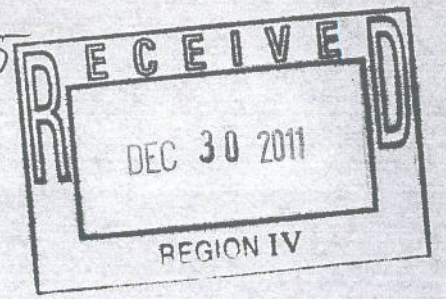
DEC 28 2011
MAILED FROM ZIP CODE 59715

No. 576626

U.S. Nuclear Regulatory Commission
Region IV

ATTN: DNMS/NMSBB Jacqueline D. Cook
612 E Lamar Blvd., Suite 400
Arlington, Texas 76011-4125



NRC FORM 532
(1-2012)

U. S. NUCLEAR REGULATORY COMMISSION

DATE

01/03/2012

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE	LICENSE NUMBER
BOZEMAN DEACONESS FOUNDATION DBA BOZEMAN DEACONESS HOSPITAL ATTN: LAWRENCE SLATE RADIATIONSAFETY OFFICER 915 HIGHLAND BOULEVARD BOZEMAN, MT 59715	25-10994-04
	MAIL CONTROL NUMBER 576626
	LICENSING AND/OR TECHNICAL REVIEWER

This is to acknowledge the receipt of your:

☑ LETTER and/or ☐ APPLICATION DATED: 12/30/2011

The initial processing, which included an administrative review, has been performed.

☑ AMENDMENT ☐ TERMINATION ☐ NEW LICENSE ☐ RENEWAL

☑ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please fill out NRC Form 531, located at the following link:

http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf

Send the completed NRC Form 531, by facsimile, to the following number: (301) 415-5387

A copy of your action has been emailed to our License Fee and Accounts Receivable Branch, in our Headquarters office in Rockville, MD. You will be contacted separately if there is a fee issue involved.

Your application has been assigned the above listed **MAIL CONTROL NUMBER.** When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region IV
U. S. Nuclear Regulatory Commission
DNMS/NMSB - B
1600 E. Lamar Boulevard
Arlington, TX 76011-4511
(817) 200-1103 or (817) 200-1140

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM LTS

Program Code: 02230
Status Code: Pending Amendment
Fee Category 7C
Exp. Date: 01/31/2015
Fee Comments:
Decom Fin Assur Reqd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee:	BOZEMAN DEACONESS FOUNDATION
Received Date:	12/30/2011
Docket Number:	3033305
Mail Control Number:	576626
License Number:	25-10994-04
Action Type:	Amendment

2. FEE ATTACHED

Amount: _____

Check No: _____

3. COMMENTS

Signed: Colleen Brannahan

Date: 1-3-2012

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: _____

NRC FORM 532
(1-2012)

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[✓] AMENDMENT [ ] TERMINATION [ ] NEW LICENSE [ ] RENEWAL

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