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SAINT LOUIS
UNIVERSITY

Office of Environmental Safety & Services
Environmental Safety: 314-977-8608
Radiation Safety: 314-977-8609

October 17, 2012

U.S. Nuclear Regulatory Commission
Region III
Nuclear Materials Licensing Branch
2443 Warrenville Road
Lisle, IL 60532

Fax: 630-515-1078

Attention: Ms. Colleen Casey

SUBJECT: Saint Louis University NRC License Amendment Request for Line Item Addition for Yttrium-90 Microspheres; NRC License No. 24-00196-07, Docket No. 030-11789 PLEASE EXPEDITE DUE TO PENDING PATIENTS' MEDICAL NEEDS.

Dear Ms. Casey:

This letter is in follow-up to our telephone conversation earlier this week regarding clarification of our NRC license to remove any potential ambiguity permitting the receipt, possession and use of Therasphere® and SIR-Spheres® Yttrium-90 Microspheres by the Saint Louis University Hospital Nuclear Medicine Department.

Issue: Condition 10.A. of our license broadly permits use of licensed materials at our facilities within the listed street boundaries, which includes Saint Louis University Hospital. Condition 10.C. was later added to specifically list the address for the Saint Louis University Hospital Nuclear Medicine Department (3635 Vista Avenue, 2nd Floor South, Nuclear medicine, St. Louis Missouri) to more easily facilitate radiopharmaceutical shipments by vendors, who preferred to see the specific shipping address listed on the license. While Condition 10.A. does not limit the licensed materials that can be used at our facilities, including Saint Louis University Hospital, the more specific Condition 10.C. limits the licensed materials that can be shipped directly to the Nuclear Medicine Department to those "listed in Subitems 6A. through 6.C. and 6.E."

Amendment Request: For clarity, we are requesting a line item amendment to the license that will permit the receipt, possession and use of Therasphere® and SIR-Spheres® Yttrium-90 Microspheres at Saint Louis University Hospital, to be shipped directly to the Nuclear Medicine Department. The shipping address is 3635 Vista Avenue, 2nd Floor South, Nuclear Medicine Dept., St. Louis, Missouri (consistent with Condition 10.C. of our license). We are requesting a

Yttrium-90 microspheres possession limit of 5 Curies to allow for multiple patient treatments each week over the long-term.

Request for Expedited Review and Approval: We are requesting expedited review of this amendment request due to medical needs of patients. Our Nuclear Medicine Authorized User anticipates beginning treatments in early to mid-November 2012. We would be very grateful if NRC expedited review and approval could be received by Friday, November 2, 2012 to permit adequate time for vendor to receive a copy of our license and make necessary arrangements for shipments.

If you have any questions regarding this license amendment request, please feel free to contact me at 314-977-6885.

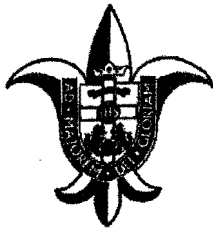
Sincerely,



Mark G. Haenchen, M.S., J.D.
Director, Office of Environmental Health and Safety
and Radiation Safety Officer - NRC

enclosures

Copies to: Philip O. Alderson, M.D., Vice President for Medical Affairs
Raymond C. Tait, Ph.D., Vice President for Research
Paul M. Loewenstein, B.S., Chairman, Radiation Safety Committee
Felicity J. Beckfield, M.S., Radiation Safety Officer (Associate)



SAINT LOUIS UNIVERSITY

Office of Environmental Safety & Services

1402 S. Grand Blvd./ C307
St. Louis, MO 63104-1028
Fax: 314-977-5560

Environmental Safety Office Phone: 314-977-8608
Radiation Safety Office Phone: 314-977-8609

FAX

To: U.S. Nuclear Regulatory Commission - Region III
Nuclear Materials Licensing Branch
ATTENTION: COLLEEN CASEY & KAREN BERNARDINO

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Fax No.: 630-829-9782

Total Number of Pages: 4
(including cover)

Phone No: Karen Bernardino
630-829-9848

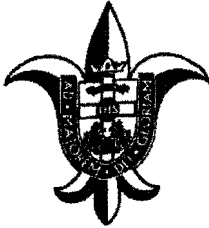
Date: OCTOBER 31, 2012

Subject: License Amendment Request - Please Expedite
(NRC License No. 24-00196-07, Docket No. 030-11789)

From: Mark Haenichen

- Urgent
- Confidential
- Per Your Request
- For Review
- FYI - For Your Information
- Please confirm receipt by telephone

Notes/Comments: Apparently our fax transmission to
630-515-1078 did not go through on Oct. 17, 2012, based
on follow-up phone call to Ms. Casey yesterday evening. I
will call Karen Bernardino to confirm receipt after this fax
transmission today. My apologies, but we still are in
need of expedited review for reasons stated in the original
request (following pages - original request). Thank You!
- Mark Haenichen



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FAX

To: U.S. Nuclear Regulatory Commission - Region III
Nuclear Materials Licensing Branch
ATTENTION: Colleen Casey

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Fax No.: 630-515-1078

Total Number of Pages: 3
(including cover)

Phone No: 630-829-9841 Date: OCTOBER 17, 2012

Subject: License Amendment Request - Please Expedite.
(NRC License No. 24-00196-07, Docket No. 030-11789)

From: Mark Haenchen

- ^{Please Expedite} Urgent
- Confidential
- Per Your Request
- For Review
- FYI - For Your Information
- Please confirm receipt by telephone

Notes/Comments: See letter on following pages.
As always, good talking to you earlier this week.
Thanks for your help!

Sincerely,
Mark Haenchen