UNIVERSITY of VIRGINIA
ENVIRONMENTAL HEALTH and SAFETY
Special Materials Handling Facility

April 11, 2005

Ms. Pam Henderson
US Nuclear Regulatory Commission
Division of Nuclear Materials Safety
Region I
475 Allendale Road
King of Prussia, PA 19406

Re: Amendment to USNRC License #: 45-00034-26 (Broadscope)
Docket No. 3003296

Dear Ms. Henderson:

The University of Virginia is requesting to amend its above referenced license as follows:

The University of Virginia plans to use the SIRSpheres Yttrium-90 Microspheres for treatment of patients with liver cancer. We are currently licensed to possess and use the Nordion Model Therasphere microspheres. We would like to add SIRTeX Medical Model SIRSpheres to Item A27 of our license to allow us to use both types of microspheres. The current possession limit of 2.5 Curies should be adequate to cover both therapies. We are currently committed to the following use requirements:

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.

We will 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

515 Edgemont Road • P.O. Box 400322 • Charlottesville, VA 22904-4322
Phone: 434-982-4911 • http://keats.admin.virginia.edu

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).

Please contact me or Debby Steva at (434) 982-4911 if you have any questions.

Very truly yours,

Ralph Allen

Ralph O. Allen
Radiation Safety Officer

This is to acknowledge the receipt of your letter/application dated

4/11/2005, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 45-00034-26

[X] There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

[ ] Please provide to this office within 30 days of your receipt of this card

---

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** 136881.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02110
Status Code: 0
Fee Category: 7B EX 1D 2C 3E
Exp. Date: 20050531
Fee Comments: 170.11(A)(4)
Decom Fin Assur Reqd: Y

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
   Applicant/Licensee: VIRGINIA, UNIVERSITY OF
   Received Date: 20050415
   Docket No: 3003296
   Control No.: 136881
   License No.: 45-00034-26
   Action Type: Amendment

2. FEE ATTACHED
   Amount: /
   Check No.: /

3. COMMENTS

Signed Rebecca Jones
Date 4/22/2005

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 _____