Fletcher Allen HEALTH CARE

In alliance with
The University of Vermont

March 28, 2011

Nuclear Materials Safety Section
Division of Radiation Safety and Safeguards
United States Nuclear Regulatory Commission Region I
475 Allendale Road
King of Prussia, PA 19406

RE: Fletcher Allen Health Care
License # 44-10187-03
Docket # 03003289
Mail Control: 574255

This is to respond to your requests of February 20, 2011.

1. Please correct the third line of the initial request to read: "Byproduct material: Y-90 SIR spheres microspheres under 10 CFR 35.1000"
2. Attached is a copy of the letter dated December 21, 2010 with Walter Hinton's signature
3. As requested, the following are updated to conform with the licensing guidance of January, 2011.
    a. For the purposes of written directives and medical event reporting for both Theraspheres and SIRspheres, prescribed activity will be used in lieu of prescribed dose.
    b. The written directive for both Theraspheres and SIRspheres will include the patients name, the date, the treatment site, the radionuclide and physical form (Y-90 microspheres), the prescribed activity, manufacturer, and for SIR-spheres the statement "activity delivered at stasis" and the signature of the authorized user.

c. The written directive for both Theraspheres and SIRspheres will further include the maximum activity to sites outside the treatment site due to shunting as evaluated with a MAA study.
d. Following the administration of Y-90 Sirspheres or Theraspheres , a record of administration will be completed within twenty four hours which will include the activity administered to the treatment site and to other specified sites. If terminated due to stasis, the total activity to the treatment site is the value of the activity administered when stasis occurred resulting in the administration being terminated. The record will include the name of the individual who made the assessment for termination, if applicable, the date and the signature of the AU for Y-90 microspheres and the form of Y-90 microspheres.
e. The administration of Y-90 microspheres, both Therasphere and SIR-spheres will be in accordance with the written directive.
f. A semi annual physical inventory will be maintained for both Theraspheres and SIRspheres if materials do not meet criteria for disposal under 35.92.
g. We commit to report any event, except resulting from intervention of the patient, in which the administration of Y-90 microspheres, either Theraspheres or SIR-spheres, results in a dose
    i. that differs from the dose that would have resulted from the prescribed activity, as documented in the written directive, by more that 0.05 Sv effective dose equivalent or 0.5 Sv to an organ or tissue AND the total activity administered differs from the prescribed activity, as documented in the written directive, by 20 percent or more.
    ii. That exceeds 0.05 Sv effective dose equivalent ot 0.5 Sv to an organ or tissue from administration to the the wrong individual or wrong route of administration
h. We commit that we will comply with the medical event reporting and notification requirements as described in 10CFR 35.3045 (b)-(g) for both Theraspheres and SIR-Spheres.

Thank you for your attention to this. If you have questions please contact Marleen M. Moore, M.S., Radiation Safety Officer, at (802) 847-3506. All correspondence should be copied to Marleen Moore, M.S., Shepardson 2.

Sincerely,

Melinda Estes, M.D.
President and Chief Executive Officer
Fletcher Allen Health Care

Marleen M. Moore, M.S.
Radiation Safety Officer
Fletcher Allen Health Care

Attachments (1)

SIRTEX MEDICAL, INC.
16 Upton Drive, #2-4
Wilmington, MA 01887
Tel: 888 474 7839

Ref: 104US03

December 21, 2010

Dr. Janusz Kikut
Nuclear Medicine/Radiology
Fletcher Allen Healthcare
111 Colchester Ave
Burlington VT 05401

Dear Dr. Kikut

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

This letter certifies that on December 21, 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,

Walter Hinton
Regional Sales Manager

cc: Linda Teigland

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