Holy Name Hospital

Member
NewYork-Presbyterian Healthcare System
Affiliate: Columbia University College of Physicians & Surgeons

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July 14, 2006

K-8

Licensing Assistance Section
Nuclear Materials Safety Branch
U. S. Nuclear Regulatory Commission, Region 1
475 Allendale Avenue
King of Prussia, PA 19406-1415

Dear License Reviewer:

03002472

With regard to our Radioactive Materials License No. 29-03382-01, we are requesting the following amendments to our current license:

(1) We request the removal of Glenn Mieszkalski, MD from our license.

(2) We request an update in our Gliasite license to reflect a vendor procedure change in monitoring for unexpected leakage of radioactive material from the Gliasite catheter, as stated in our original amendment (the change is in strikethrough and bold):

Upon completing the Iotrex afterloading and during brachytherapy, radiation exposure rate measurements will be used to monitor for unexpected leakage of radioactive material from the Gliasite catheter. Radiation measurements will be performed at the injection site surface, 20 to 30 centimeters from the injection site, 1 meter from the injection site, and over the patient's bladder. These measurements will be repeated ~~daily~~ **periodically** until the radioactive material is retrieved. Any significant changes from the initial readings (e.g., large decrease in cranial exposure rates concomitant with large increases in bladder exposure rates) will be documented and evaluated for further action as appropriate.

(3) We request an update to our HDR license to change from monthly calibration to quarterly calibration, as per 10CFR35.633.

(4) We request the addition of Y-90 microspheres to our current license.

As per your guidance document posted on your website, we agree to the following:

(a) All authorized users will meet the training and experience requirements of either 10 CFR 35.490, as well as the specific vendor training in the use of the microspheres and the microsphere delivery system.

(b) 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.

(c) 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:

(i) For Y-90 microspheres, "prescribed dose" will mean the total dose documented in the written directive.

(ii) The written directive will include: before implantation: the treatment site, the radionuclide (including the chemical/physical form [Y-90 microspheres]), and dose; and after implantation but

before completion of the procedure: the radionuclide (including the chemical/physical form [Y-90 microspheres]), treatment site, and the total dose.

(iii) 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 will 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 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.

(iv) The written directive will 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).

(v) The 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.

(d) The quarterly physical inventory of sealed sources and brachytherapy sources will be conducted and will 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.

(e) There will be procedures to 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.

(f) We will label vials and vial radiation shields with radioisotope and form (i.e., Y-90 microspheres).

(g) We will label syringes and syringe radiation shields with the radioisotope, form, and therapeutic procedure (i.e., Y-90 microspheres, brachytherapy).

If you have any questions regarding this application, please contact Allan Caggiano, Chief Medical Physicist at 201-541-6369 or e-mail at caggiano@mail.holyname.org.

Sincerely,

Jacqueline C. Brunetti, MD
Radiation Safety Officer

Michael Maron
President & CEO

JCB/MM:md

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

7/14/2006, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 29-03382-01

☒ 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

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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** 139178.
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