From: Sandra Gabriel
To: Randall, Gerry
Date: Fri, Apr 21, 2006 5:40 PM
Subject: Amendment request for St. Vincent's Medical Center, mail control 138433

Reference: St. Vincent's Medical Center
License No.: 06-00843-03
Docket No.: 03001245
Mail Control No.: 138433

To: Gerry Randall, RSO

I received your voicemail and e-mail messages. Based on the documents submitted as part of the current request plus those previously submitted under mail control 137036, we now have sufficient information to name Dr. Tazi as authorized medical physicist for HDR. The current license amendment request did not initially ask to remove your Guidant intravascular brachytherapy authorization, however a previous one did. Based on the new documentation that you provided, we can now remove this authorization.

I have reviewed your request to add SIR-Spheres and have developed an additional list of questions. We would like to try to issue this amendment in a timely fashion, and therefore request that you respond within 15 days. Please provide a written response, signed by senior management, either by fax to 610-337-5269, or as an e-mail attachment. If you send a fax, you may wish to alert me by leaving a voicemail or e-mail message.

1. The current standard SIR-Spheres authorization is for resin microspheres manufactured by ANSTO Radiopharmaceuticals and Industrials in the Sirtex Medical Limited Model SIR-Spheres delivery system (per Sealed Source and Device Registration No. MA-1229-D-101-S). Please confirm that this is your request.

2. Please specify a SIR-Spheres possession limit in millicuries.

3. Please specify the proposed authorized users for SIR-Spheres. Do you wish to propose Drs. Ianuzzi and Fang?

4. Please confirm that you will follow all of the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use except where the following license conditions provide regulatory relief. [these items are from the SIR-Spheres licensing guidance on the NRC public web site]. You may provide your response in the format: "We confirm that...." for each item.

- "Prescribed dose" means the total dose documented in the written directive.

- The written directive will 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 use 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.

- 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).

- Procedures for administrations requiring a written directive will, 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 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.

- Procedures will describe measures taken to ensure that the bremsstrahlung emissions from each patient or human subject permits his/her release in accordance with 10 CFR 35.75.

- When the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer, you will label vials and vial radiation shields with the radioisotope and form (i.e., Y-90 microspheres); and you will label syringes and syringe radiation shields with the radioisotope, form, and therapeutic procedure (i.e., Y-90 microspheres, brachytherapy).

5. Your application stated that authorized users will receive vendor training in use of the microspheres and the microsphere delivery system, and that the nuclear medicine technologist will receive vendor training for drawing the appropriate dose per the written directive without causing contamination. Please confirm that the RSO and all other individuals involved in dose preparation and treatment administration will also receive vendor training in the use of the microspheres and delivery system before first use.

6. Please provide a copy of your procedures for assaying patient dosages and for determining the activity in millicuries that has been delivered to each patient.

Please feel free to contact me by telephone or e-mail with any questions.

Thank you,

Sandy Gabriel
Senior Health Physicist
Medical Branch
NRC Region I
610-337-5182

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