From: Donna Janda
To: thall@solarishs.org
Date: Tue, Dec 5, 2006 3:37 PM
Subject: Additional information needed for NRC amendment request, mail control 139545

Licensee: John F. Kennedy Medical Center
License No. 29-12611-01
Docket No. 03002555
Mail Control No. 139545

Subject: Request to add use of SIR-Spheres to NRC license under 10 CFR 35.1000

Please send an email to confirm receipt of this message.

To: Mr. Trent Hall, Medical Physicist

In order to continue our review of the request to add use of SIR-Spheres yttrium-90 (Y-90) microspheres to your NRC license under 10 CFR 35.1000 authorization, please provide the following additional information:

1. Specify the physician(s) you propose to name as authorized user(s) for use of yttrium-90 (Y-90) microspheres. Please note that authorized users must meet the training and experience requirements of 10 CFR 35.490.

2. Confirm that each authorized user will receive specific vendor training before first use of the Y-90 microsphere delivery system. Also confirm that the Radiation Safety Officer and all individuals involved in dose preparation and treatment administration will also receive vendor training in the use of the microsphere delivery system before first use.

3. Specify the location(s) where Y-90 microspheres will be administered to patients (e.g., in an interventional radiology suite). Unless the location has been previously submitted to the NRC, provide a facility diagram identifying the location(s), and surrounding areas, where Y-90 microspheres will be administered.

4. Confirm that you will follow all of the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy except where the commitments below provide regulatory relief.

5. Confirm that for Y-90 microsphere treatments, “prescribed dose” will mean the total dose documented in the written directive.

6. Confirm that the written directive for use of Y-90 microspheres will include:

A. before implantation: the treatment site, the radionuclide (including the chemical/physical form [Y-90 microspheres]), and dose; and

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

7. If the medical end-point of stasis is used to determine when to terminate implantation of the microspheres, please confirm that this is included in the written directive before implantation. In addition, confirm that the written directive will include:

A. before implantation: the treatment site, the radionuclide (including chemical/physical form [Y-90 microspheres]), and a dose of either XXX rad/Gray (or rem/Sieverts) or the dose delivered at stasis; and

B. after implantation but before completion of the procedure: the radionuclide (including chemical/physical form [Y-90 microspheres]), the treatment site, and the total dose. If the implantation is terminated due to stasis, total dose will be the value of the total dose delivered when stasis occurred and the implant was terminated.

8. Confirm that 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).

9. Confirm that your procedures will describe how to quantify 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.

10. Confirm that your 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.

11. Describe the measures taken to ensure that the bremsstrahlung emissions from each patient permits his/her release in accordance with 10 CFR 35.75.

12. Provide a copy of your procedure for assaying patient dosages and for determining the activity in millicuries that has been delivered to each patient.

13. Confirm that, 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). In addition, confirm that you will label syringe and syringe radiation shields with the radioisotope, form, and therapeutic procedures (i.e., Y-90 microspheres, brachytherapy).

14. An applicant applying for an amendment to authorize medical use of SIR-Spheres Y-90 microspheres may request authorization to allow future changes to its radiation safety program, provided the following conditions are met:

A. the revision is in compliance with the regulations;
B. the revision is based upon NRC's current guidance for SIR-Spheres Y-90 microspheres 35.1000 use posted on the NRC Web site;
C. the revision has been reviewed and approved by the licensee's radiation safety officer and licensee's management;
D. the affected individuals are instructed on the revised program before the change is implemented;
E. the licensee will retain a record of each change for five years; and
F. the record will include a copy of the appropriate Web site guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

If you would like this authorization, please confirm that you will follow items 14.A. through 14.F. above. Please note that, if this authorization is approved, these conditions will be incorporated as license conditions in your license.

Because your response will contain license commitments, please have your response signed and dated by an individual authorized to make binding commitments and sign official documents on behalf of John F. Kennedy Medical Center. Please be sure to include Mail Control No. 139545 in your response. Please note that you may not reply to this email by return email. Your reply must be in writing by letter or facsimile (610-337-5269). If we do not receive a reply from you within 14 calendar days from the date of this email, we will assume that you do not wish to pursue your application.

If you have any questions regarding these items, please call me at 610-337-5371.

Thank you for your attention to this matter.

Sincerely,

Donna Janda
Health Physicist, Medical Branch
Division of Nuclear Materials Safety
U.S. NRC Region I

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Subject: Additional information needed for NRC amendment request, mail control 139545
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From: Donna Janda

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Expiration Date:	None
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