Roldan, Lizette

From: Roldan, Lizette
Sent: Monday, June 25, 2012 2:58 PM
To: 'Matthews, Robert J.'
Subject: REQUEST FOR ADDITIONAL INFORMATION REGARDING RENEWAL CONTROL 576628
Attachments: 08 Microspheres Guidance 14 1 Oct 2011.pdf

License No.: 11-27307-01
Docket No.: 030-32264
Control No.: 576628

Dear Dr. Matthews:

This is in reference to application dated December 30, 2011 regarding the renewal of Nuclear Regulatory Commission License No. 11-27307-01. In order to continue our review, we need the following additional information:

1. You have requested Yttrium-90 (Y-90) Sir-Spheres to be included in your NRC license renewal. Please confirm you will follow the most recent guidance dated October 2011 on Microsphere Brachytherapy Sources and Devices (attached) and you will read this document in its entirety.

2. Please note, the license will be written in accordance with the most recent sealed and source and device registry for the Y-90 Sir-Spheres manufactured by Sirtex Medical and a limit of 189 mCi per source. The maximum possession limit will remain as requested at 250 millicuries total.

3. You are currently licensed for Strontium-90; however you did not request the isotope in your license renewal. Please confirm whether you wish to keep Strontium-90 on your license. If you would like to remove the isotope, please state so, and provide documentation showing the disposal of the material. Otherwise, the material will remain on the license until you can provide proof of the disposal.

4. You have requested "Any byproduct material permitted by 10 CFR 35.300" and "Iodine-131", please note, procedures pertaining to oral administration of I-131 are included in the 35.300 modality. Currently you are authorized for the former request with a 500 millicuries limit. You can increase the 35.300 modality to 1 curie to include the Iodine-131 request, if you see it necessary to go that high. Please confirm the modality you wish to have written on the license and the maximum possession limit.

5. Please have Dr. Davenport confirm that Dr. Arne Michalson has been trained in the operation of the delivery system, safety procedures, and clinical use for each type of Y-90 mircrospheres for which authorization is sought. Otherwise, we will not add the Y-90 authorization but you can provide the letter at a later time in the form of a new amendment request.

Please reply to my attention and refer to Mail Control No. 576628. If you reply via email, please attach a signed letter in PDF format or you may fax your response to (817) 200-1263. . Please reply by **Tuesday, June 26, 2012**.

If you have any technical questions regarding this deficiency letter, please call me at (817) 200-1596.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Industrial, and Academic Uses of Nuclear Material;** then **Regulations, Guidance, and Communications.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

Sincerely,

Lizette Roldán-Otero, Ph.D.
Health Physicist
U.S. Nuclear Regulatory Commission
1600 E. Lamar Blvd.
Arlington, TX 76011-4511
Office: 817-200-1596
Fax: 817-200-1188

Kootenai Cancer Center

A Heart for Excellence

700 Ironwood Drive, Suite 103
Coeur d'Alene, Idaho 83814
208.666.3800 tel
208.666.3833 fax
www.kootenaihealth.org

June 25, 2012

Lizette Roldan-Otero, Ph.D.
Health Physicist
U.S. Regulatory Commission
1600 E. Lamar Blvd.
Arlington, TX 76011-4511

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Dear Dr. Rodan-Otero:

In response to your request for additional information in reference to our application for renewal dated December 30,2011.

1. I have perused the most recent guidance dated October 2011 on Microsphere Brachytherapy Sources and Devices in its entirety and shall direct that it be incorporated in our policies and procedures. All individuals involved in Yittrium-90 microsphere therapies shall be afforded the opportunity to read this guidance document.

2. I understand the stipulation that the license will be written in accordance with the most recent sealed source and device registry for the Y-90 Sir Spheres manufactured by Sirtex Medical and a limit of 189 mCi per source. The maximum possession limit will remain as requested at 250 millicuries total.

3. Strontium-90 use is not in institutional memory as ever having been used and there are no records that a device, such as a beta eye applicator, has ever been in possession of Kootenai Medical Center. There are no plans in the foreseeable future to purchase and use such a device. I can only re-assert that Strontium-90 should be removed from the license.

4. I wish to confirm that our license should indicate "Any by-product material permitted by 10 CFR 35.300". I also request that the possession limit be raised from the 500 mCi originally requested to a 1 Ci possession limit. In the past, perhaps more than sixteen years ago, Strontium-89 as Metastron has been used to treat bone pain from metastatic cancer under this license condition. More recently, Samarium-153 as Quadramet has been used for this purpose. We administer I-131 orally for thyroid uptake and ablation procedures as well as intravenously as Bexxar for monoclonal therapy of lymphoma.

Thank you for your guidance and patience throughout our renewal process. If further information is required please contact me at rmatthews@kmc.org or 208-666-2529 in Coeur d'Alene or 208-619-4149 in Post Falls.

Sincerely,

Robert J. Matthews, Ph.D., DABR
Medical Physicist
Kootenai Medical Center