

From: Sandra Gabriel
Sent: Thursday, August 14, 2008 10:35 AM
To: radrem@aol.com
Subject: Additional information for NRC amendment address, mail control 142579

Licensee: St. Vincent's Medical Center
License No.: 06-00843-03
Docket No.: 03001245
Mail Control No.: 142579

To: Gerry Randall, RSO

This is in response to the license amendment request to authorize use of yttrium-90 SIR-Spheres. The NRC licenses yttrium-90 microspheres under 10 CFR 35.1000, with licensing guidance posted at <http://www.nrc.gov/materials/miau/med-use-toolkit/microsphere.pdf>. The current guidance [from December 2007] includes significant requirements for authorized user training, which have been difficult for licensees to meet. NRC Headquarters is in the process of approving new microsphere licensing guidance, which may be finalized by the end of this month.

Please provide the information listed below within 30 days, under signature of senior management, or we shall assume that the hospital does not wish to pursue this application. The response may be mailed or faxed to my attention at 610-337-5269, referencing mail control 142579. If a fax is sent, please consider leaving a voicemail or e-mail message to alert me to look for it.

Please send an e-mail to confirm receipt of this message.

1. Identify the proposed authorized user(s) and how each meets the current NRC 35.1000 licensing guidance. At the present time, we can authorize facilities for SIR-Spheres use only if it has at least one AU who has fully completed SIR-Spheres training, including documented completion of 3 hands-on, supervised clinical cases. [The proposed new guidance incorporates a 2nd pathway, requiring an AU to document completion of 3 hands-on, manufacturer-supervised, in vitro simulated cases before we can authorize your facility for SIR-Spheres. We would also require commitments that your first 3 clinical cases will be supervised by a manufacturer representative and that you will notify us within 30 days of completion of the 3rd clinical case.]
2. Confirm that, in addition to AU training, the RSO and all individuals involved in dose preparation, measurement, dosimetry calculations, and microsphere administration will receive manufacturer training in their areas of responsibility before first use of the SIR-Spheres delivery system.
3. The hospital requested authorization for 81 mCi (3 GBq) of SIR-Spheres. Sirtex is authorized to ship in quantities up to 108 mCi per vial. Your possession limit should be large enough to include the maximum quantity you may have on hand at any one time, including waste. Most of our SIR-Spheres licenses have possession limits similar to "108 mCi per vial and 216 mCi total," or some other multiple of 108 mCi. Please consider revising this requested authorization.

4. Identify the location(s) where yttrium-90 microspheres will be prepared (e.g., Nuclear Medicine hot lab) and administered to patients (e.g., in an interventional radiology suite). Unless this has been previously submitted to the NRC, provide a facility diagram identifying the location(s) where yttrium-90 microspheres will be prepared and administered and surrounding areas.

5. Address each of the items in the current NRC 35.1000 licensing guidance, e.g., "We commit to 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...", then list each of the items below this statement on the website licensing guidance, or propose alternatives. In some cases, you may need to change the wording of the website model commitments, such as changing "should" to "will."

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

7. If you would like authorization to make future SIR-Spheres program changes without need for a license amendment, request this and commit to follow the 6 items listed near the end of the website guidance in the section titled "Revision of Y-90 Microsphere Radiation Safety programs to conform to changes in this licensing guidance."

As noted above, the NRC licensing guidance for SIR-Spheres is expected to change within the next few weeks. After the new guidance is published, we will ask you to comply with it rather than with the current guidance. One option is for you to withdraw the current request and resubmit it after the new guidance goes into effect.

Thank you for your help. If you have any questions, you may e-mail me or call at 610-337-5182. Please note that I will be away beginning on August 28 and returning on September 8.

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

E-mail Properties

Mail Envelope Properties ()

Subject: Additional information for NRC amendment address, mail control 142579
Sent Date: 08/13/2008 4:55:53 PM
Received Date: 08/14/2008 10:35:00 AM
From: Sandra Gabriel

Created By: Sandra.Gabriel@nrc.gov

Recipients:

radrem@aol.com (radrem@aol.com)

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MESSAGE	9519	08/13/2008

Options

Expiration Date:

Priority: olImportanceNormal

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Recipients received: