

From: Sandra Gabriel
To: caggiano@mail.holyname.org
Date: Tue, Aug 15, 2006 5:47 PM
Subject: Additional information for NRC amendment request, mail control 139178

Licensee: Holy Name Hospital
License No.: 29-03382-01
Docket No.: 03002472
Control No.: 139178

To: Allan Caggiano, Chief Medical Physicist

This is regarding the amendment request dated July 14, 2006. Please provide the following additional information within 30 days, signed by a representative of senior management. You may mail your response or fax it to 610-337-5269, referencing mail control 139178. If you send a fax, you may wish to leave a voicemail or e-mail message to alert me.

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

1) Item 2 of your request states that there is a vendor procedure change in monitoring for unexpected leakage of radioactive material from the GliaSite catheter, and proposes to change your procedure from "daily" measurements to "periodic" measurements.

- a) Please submit a copy of the updated vendor procedure.
- b) How frequently do you propose to make the "periodic" measurements?

2) Please specify which (one or both) of the following yttrium-90 microsphere delivery systems you are requesting authorization to use:

a) MDS Nordion Model Therasphere glass microspheres (Sealed Source and Device Registration No. NR-0220-D-113S)

b) ANSTO Radiopharmaceuticals and Industrials Model Microspheres resin microspheres used in the Sirtex Medical Limited Model SIR-Spheres delivery system (Sealed Source and Device Registration No. MA-1229-D-101-S)

3) Please specify a possession limit (in millicuries) for each requested yttrium-90 microsphere delivery system.

4) Please specify the physician(s) you propose to name as authorized user(s) for use of yttrium-90 microspheres.

5) Your request stated that authorized users will receive the specific vendor training in the use of the microspheres and the microsphere delivery system. Please confirm that each authorized user will receive the specific vendor training for each microsphere delivery system before first use. Also confirm that the RSO and all individuals involved in dose preparation and treatment administration will also receive vendor training in the use of each delivery system before first use.

6) Please specify the location(s) where yttrium-90 microspheres will be administered to patients, for example, 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 administered and surrounding areas.

7) Please clarify item 4(c)(v) of your request, changing the word "should" to "will", for example: "Our procedures for administrations requiring a written directive will, for Y-90 microsphere administrations, describe how to quantify....."

8) Please provide a copy of your procedure(s) for assaying yttrium-90 microsphere patient dosages and for determining the activity in millicuries that has been delivered to each patient.

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 on an inspection trip from August 21-25.

Sandy Gabriel
Senior Health Physicist
Medical Branch
NRC Region I

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