From: Sandra Gabriel
To: ldipaola22@meridianhealth.com
Date: Wed, Dec 8, 2004 7:31 PM
Subject: NRC amendment request, mail control 135945

Lynn:

Please provide the following additional information regarding your amendment request to authorize use of the GliaSite brachytherapy system:

1) In addition to the commitments provided in your amendment request, please confirm that you will follow all of the requirements in 10 CFR Part 35 for brachytherapy and manual brachytherapy sources except where the items a-g listed below provide regulatory relief. Also confirm that you will follow items a-g listed below (you may repeat or paraphrase each of them):

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

b. The written directive will include two sections:

(1) prior to implantation: the treatment site, the radionuclide (including the chemical/physical form [Iotrex]), and dose; and

(2) after implantation but before completion of the procedure: the treatment site, the radionuclide (including the chemical/physical form [Iotrex]), and the total dose.

c. Your procedures will specify how to confirm that the balloon does not leak prior to injection of the Iotrex or while Iotrex is implanted in the patient.

d. Source leakage for Iotrex implanted in the GliaSite RTS means leakage of I-125 that results in a dose that exceeds 50 rem dose equivalent to any organ other than the treatment site (based on the definition of a medical event).

e. You will retain a record of each leak test for 3 years (the period that 10 CFR 35.2067 requires for brachytherapy sources).

f. You will report a leaking source to the NRC within 5 days of the leakage test to the locations specified and provide the information identified in 10 CFR 35.3067.

g. You will provide instructions on how to safely handle contamination of unsealed materials, in addition to the instructions required by 10 CFR 35.410, "Safety instructions."

2) How will you confirm that the prescribed dose was delivered? Will this be done by volumetric determination or some other method?

3) Please confirm that you will follow the manufacturer's procedures or indicate your method for assuring that contrast medium will not inadvertently shield the dose.

4) Item 6 of your amendment request stated that one method you may use to assess GliaSite integrity during brachytherapy is periodic radiation exposure measurements (in the vicinity of the injection site and patient's bladder), but that this method will not be used exclusively. When

using this method to assess catheter leakage, how often will you take radiation exposure measurements? Please specify the method you will use to assess catheter leakage in cases when you do not perform periodic radiation exposure measurements.

5) Item 7 of your amendment request addressed outpatient GliaSite treatment and stated that you will substantially follow the model guidance in NUREG-1556, Vol. 9, Appendix U, but that you will make minor changes necessary to satisfy 10 CFR 35.1000.

a. What minor changes will you make to the guidance in Appendix U?

b. What are your criteria to identify patients who are suitable candidates for outpatient treatment?

c. How long will you require the patient to remain at the hospital following injection of the Iotrex before you release them for outpatient treatment?

d. How will you assure the balloon catheter does not leak while the patient is at home?

e. What surveys will be done to provide reasonable assurance that no member of the general public will receive more than 0.5 rem?

f. What radiation safety instructions will you provide for outpatients receiving GliaSite treatments? Will you require the patient to wear a lead skull cap? Will you instruct the patient to, when feasible, designate a toilet in their home for their sole use during the treatment? Do you intend to place any restrictions on patient mobility during GliaSite treatment (i.e., remain at home and refrain from traveling by automobile except for trips to and from the doctor or hospital)? What emergency care instructions will you provide to the patient?

g. How will you assure that the patient will return to the hospital for removal of the Iotrex?

Please provide your responses to these questions, signed by senior management, within 30 days. You may fax this to my attention at 610-337-5269, referencing mail control 135945.

Please note that I will be on vacation from December 10 through December 24, returning to my office on December 27. I will address any issues or questions upon my return.

Thanks for your help,
Sandy Gabriel
Senior Health Physicist
Medical Branch
NRC Region I
610-337-5182

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