Casey, Colleen

From: linda.Dunaway@hcamidwest.com
Sent: Wednesday, October 10, 2012 2:54 PM
To: Casey, Colleen
Subject: Control Number 577974
Attachments: NRC amendment 102012.pdf

Please see attached information regarding NRC Radioactive Materials License 24-18655-01 and Control number 577974. Please let me know if you need any additional information. Thanks.

Linda Dunaway
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Centerpoint MEDICAL CENTER
HCA Midwest HEALTH SYSTEM®

October 8, 2012

Ms. Colleen Casey
Materials Licensing Branch
Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: Control Number 577974, Radioactive Materials License #24-18655-01

Dear Ms. Casey,

The attached is in addition to the information submitted on August 29, 2012 for the Y-90 SIR-Spheres amendment to our NRC license. If you have any questions or require additional information, please contact Linda Dunaway at 816-698-7132.

Thank you for your consideration of this request.

Sincerely,

Phil Buttell, JD, FACHE
Chief Operating Officer
Centerpoint Medical Center

A. Radiation Safety Precautions and Instructions

All personnel involved will receive instruction appropriate for their roles in the administration of the Y-90 microspheres and care of the patient.

Personnel monitoring devices (personal dosimeters) will be used by all personnel involved with the procedure. Ring badges will be worn by personnel actually handling the microspheres.

Microspheres will be stored in a lead shield and/or behind acrylic shielding between the time of receipt and the time of administration. Vials and vial radiation shields will be labeled with "Y-90 microspheres." Syringes and syringe radiation shields will be labeled with "Y-90 microspheres" and the therapeutic procedure.

Handling of the microspheres and any contaminated materials will be carried out insofar as possible using tongs or forceps.

A spill pack will be maintained in the vicinity of the actual microspheres' administration.

Room clearance is the responsibility of the radiation safety officer or a designated nuclear medicine technologist. All staff will be checked for contamination before leaving the room. All equipment, gowns, drapes, etc., will be checked for contamination and either decontaminated or bagged and sent to the radioactive waste storage room for decay.

The recovery room staff will be briefed on the radiation status of the patient and instructed to hold any dressings or other potentially contaminated material for a radiation survey at the time of patient discharge.

The patient will receive appropriate instruction concerning precautions that should be taken to prevent needless exposure of others in the week following the administration of Y-90 microspheres.

B. Methodology for Measurement of Dosages

Doses will be measured in Nuclear Medicine using a dose calibrator according to the instructions of the manufacturer. The manufacturer's procedures for calculating/documenting the dose to the treatment and other sites, preparing the dose for administration and performing pre/post vial dose measurements will be followed.

C. Calibration, Maintenance and Repair of Instruments and Equipment Necessary for Radiation Safety

Existing dose calibrators and survey instruments will be used. Microspheres with traceable calibrations will be obtained initially and annually thereafter, as well as after any repairs to the instrument, in order to ensure the accuracy of the calibration of the dose calibrator.

Survey instruments are currently calibrated annually and this will continue on the same schedule.

D. Written Directive

Before implantation, the written directive will include the patient's name, the date, the signature of an authorized user (AU) for Y-90 microspheres, the treatment site, the radionuclide including the physical form, the prescribed dose /activity, the manufacturer and the dose/activity delivered at stasis.

After implantation but before the completion of the procedure, the written directive will include the treatment site, radionuclide and physical form, and the total dose actually administered in mCi or GBq.

In each case, the written directive will include the maximum dose/activity that will be acceptable for sites to which the Y-90 microspheres may be shunted such as the lung and GI tract.

Following administration of the Y-90 microspheres, a SPECT scan will be performed to determine the distribution of the microspheres into different compartments in order to quantify the dose to the treatment site and other sites to which the Y-90 microspheres may be shunted such as the lung and GI tract.

Administration of Y-90 microspheres will be performed in accordance with the written directive. If the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive, the AU will document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive will include the reason for not administering the intended dose/activity, the date and the signature of the AU for Y-90 microspheres.

The administered dose/activity delivered to the primary treatment site and to the other specified site(s) will be recorded. If the administration was terminated because of stasis, then the total dose/activity to the treatment site is the value of the total dose/activity administered when stasis occurred and the administration was terminated. The record will be completed within 24 hours after the completion or termination of the administration and will include the name of the individual who made the assessment, the date and the signature of the AU for Y-90 microspheres, if terminated for stasis.

E. Release Criteria

Prior to release of the patient, radiation emissions, which may include bremsstrahlung, will be measured with a suitable instrument by personnel familiar with and experienced with the release criteria of 10 CFR 35.75.

F. Physical Inventory

Following administration, unused microspheres will be returned to the shipping container and the radionuclide, activity and date marked on the container. The tentative disposal date will be two months (approximately 22 half lives later) as described in 10 CFR 35.92.

The decayed activity of unused microspheres will be included in the quarterly inventory of radionuclides and will include:

1. the radionuclide and physical form
2. unique identification of each vial in which the microspheres are contained
3. the total activity contained in each of the vial(s)
4. the location of the vial(s)

G. Records

The semi-annual physical inventory records will be retained for three years.

H. Reportable Events

Medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g) will be followed. In addition, any event, except for an event that results from intervention of a patient or human research subject, will be reported if:

1. the administration of byproduct material results in a dose that exceeds 0.05Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from the use of the wrong radionuclide.

2. the administration of Y-90 microspheres results in a dose

   a. that differs from the prescribed dose or the dose that would have resulted from the prescribed activity, as documented in the written directive, by more than 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sb (50 rem) to an organ or tissue, and the total dose/activity administered differs from the prescribed dose/activity, as documented in the written directive, by 20 percent or more; or

   b. that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from an administration to the wrong individual or human research subject, via the wrong route, or by the wrong mode of treatment; or

   c. to an organ or tissue other than the treatment site that exceeds by 0.5 SV (50 rem) to an organ or tissue and by 50 percent or more of the prescribed dose/activity expected to that site from the administration of Y-90 microspheres, if carried our as specified in the written directive.