



A Duke LifePoint Hospital

July 28, 2014

Dennis O'Dowd
Materials Licensing Branch
U.S. Nuclear Regulatory Commission Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: Materials License No. 21-05432-04 renewal application dated Feb. 5, 2014

This letter is in reference to our telephone conversation last week regarding 35 CFR 1000 use of Y-90 SirSpheres. We confirm that we will follow Regulatory Guidance *Microsphere Brachytherapy Sources and Devices* revised June 2012. The Authorized Users for SirSpheres use continue to be Dr. Chris Mehall, Dr. Michael Ouimette and Dr. Paul Thieme.

The written directive gives the prescribed dose in terms of GBq. Since the dose calibrator uses mCi, the dose is converted to mCi and converted again at the end of the procedure for comparison of injected dose to prescribed dose. The written directive includes the patient name, date, signature of the AU, treatment site, Y-90 SIRSpheres (Sirtex). When appropriate, a post-implant section contains the phrase "Difference due to stasis". The physician may use Sirtex's computerized dose calculation form which becomes part of the WD and is signed and dated by the AU. Any revision to the WD will be completed within 24 hours. The WD also contains analysis of lung shunting. If greater than 10%, acceptable dose is given and dose to the lung is determined in the worksheet. All WDs are audited for completion by the RSO or consultant physicist on a quarterly basis.

We commit to following the manufacturer's procedures for calculating the dose to be given, preparing the dose and performing pre and post procedure vial measurements.

Semi-annual inventory includes the radionuclide and form, date dose received (in event of two doses received on same day, lot number included), activity in mCi remaining in vial when put into storage, location and finally date decayed and disposed. Records of inventory will be maintained for 3 years. Leak testing is not needed.

We confirm that we have procedures for monitoring patient to document release under 10 CFR 35.75.

Once the dose has been drawn and placed into the administration system it never leaves the physical presence of the physicist or technologist who will be assisting with the procedure. If it were to be left unattended (in a secure location such as the locked hot lab), the vial will be labeled as to its intended subject, dose, radionuclide and form. The measurement and waste jug are labeled with date and "Y-90 microspheres".

We commit to report any event resulting in dose deviations as specified in the Guidance and complying with reporting requirements described in 10 CFR 35.3045(b)-(g).

We confirm that we are only using SirSpheres by Sirtex and not any other form of microspheres.

If you have further questions, please contact Shan Marlette at (906) 225-6967, home (906) 273-0249 or fax number (906) 225-7753.

Sincerely,



Shan Marlette, M.S.
Consultant Physicist

MARQUETTE GENERAL HOSPITAL
420 West Magnetic Street, Marquette, MI 49855
Radiology Department

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TO: Dennis O'Dowd, NRC Region III
FAX NUMBER: 630 515-1078
DATE/TIME: ~~7-28-14 1:45 pm~~ 7-28-14 1:45 pm
FROM: Shan Marlette
NUMBER OF PAGES INCLUDING COVER SHEET: 3
RE: ~~Marlette, 2014 letter~~ License Renewal
MESSAGE: ~~This leads to amendment #64.~~

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Radiology Department File Room Phone: 906-225-3835 Fax Number: 906-225-7753