License: 40-00238-04
Docket: 030-03231
Control: 600362

Cook, Jackie

From: McKee, James <JMckee1@regionalhealth.org>
Sent: Wednesday, September 13, 2017 12:39 PM
To: Cook, Jackie
Cc: Husman, Lowell; Carver, Charles
Subject: [External_Sender] Fw: Attached Image
Attachments: 1245_001.pdf

Ms. Cook,

Attached is the revised amendment.

Please let me know if anything else is needed.

Thank you,

Jim Mckee
Medical Physicist
Radiation Safety Officer
John T. Vucurevich Regional Cancer Care Institute
353 Fairmont Blvd
Rapid City, SD 57701
(605) 755-2339
jmckee1@regionalhealth.com

From: srv_printsmtp, Service Account
Sent: Wednesday, September 13, 2017 11:11 AM
To: McKee, James
Subject: Attached Image

PUBLIC
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☑ Normal Release

NON-PUBLIC
☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other:

Reviewer: JPC Date: 9/13/17

JOHN T. VUCUREVICH
REGIONAL
CANCER CARE INSTITUTE

353 Fairmont Boulevard Rapid City, SD 57701 (605) 719-2300 FAX (605) 719-2310

9/12/2017

United States Nuclear Regulatory Commission Region IV
License Division
611 Ryan Plaza Dr.
Arlington, TX 76011

This letter is in response to your letter received 9/11/2017 Dockett #030-03231, Control #600362.

The requested changes have been made.

This letter is to request change to our license#40-00238-04

Subject: We would like to change the name of Regional Heart Doctors to Regional Heart and Vascular Institute.

We would also like to request authorization for possession and use of SIR-Spheres Yttrium 90 resin microspheres, to be used and administered at:

Rapid City Regional Hospital
353 Fairmont Blvd
Rapid City, SD 57701

The radioactive material will be received and stored in the nuclear medicine department. The radioactive material will be transported to interventional radiology and administered to patient. While outside of the nuclear medicine department radioactive materials will be in the possession of a nuclear medicine technologist, authorized user, or authorized medical physicist.

Yttrium-90	Sealed Sources (Sirtex Medical Limited SIR-Spheres Microspheres)	189mCi/Vial 1 Ci total	SIR-Spheres for permanent brachytherapy using delivery system as listed in Sealed Source and Device Registry MA-1229-D-101-S

We also request the addition of Dr. Charles Voigt, M.D. as an AU under 35.1000 for the medical use of SIR-Spheres Yttrium 90 resin microspheres. Dr. Voigt has completed the necessary training in accordance with the NRC's February 2016 Microsphere Brachytherapy Sources and Devices Licensing Guidance

Dr Voigt will participate in 3 preceptored cases with an AU from the vendor. We will notify the NRC in writing, within 30 days of the last preceptored case.

We commit to adopting the training and experience criteria in the NRC's February 2016 Microsphere Brachytherapy Sources and Devices Licensing Guidance for Authorized Users and understand that physicians who are currently authorized for SIR-Spheres® under previous criteria do not have to meet the revised criteria.

We commit to following the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use: (1) training for individuals involved in SIR-Spheres® use; (2) following manufacturer's procedures for administration; (3) information contained in the written directive; (4) reporting medical events; (5) conducting semi-annual physical inventory; (6) labeling for vials, syringes and shields; (7) releasing patients following administration; and (8) making certain radiation protection program changes in the future.

1) We commit to provide training to all individuals involved in Y-90 SIR-Spheres® use, commensurate with the individual's duties to be performed. This training will be provided to all individuals preparing, measuring, performing dosimetry calculations, and administering microspheres.
2) We commit to following the manufacturer's procedures for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration; determining shunting to non-treatment sites; and performing pre- and post-vial dose measurements.
3) We commit to follow Sirtex's procedures for administration, including the Sirtex Training Manual, the Sirtex Package Insert, and the Y-90 SIR-Spheres Preparation and Verification.
4) We commit that the administration of Y-90 microspheres will be performed in accordance with the written directive.
    a. We understand that prescribed activity (mCi or GBq) may be used in lieu of prescribed dose (rad or Gy) for the purposes of Written Directives and medical event reporting.
    b. We commit that the Written Directive will include the patient's name; the date; the signature of the AU for SIR-Spheres®; the treatment site; the radionuclide and physical form [Y-90 microspheres]; the prescribed activity; and the statement, "or activity delivered at stasis."
    c. The written directive will be modified within 24 hours of termination of treatment due to stasis or emergent patient condition.
        i. If the administration was terminated because of stasis, then the total dose or activity to the treatment site is the value of the total dose or activity administered when stasis occurred and the administration was terminated. The record should be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who determined the administered dose or activity, the date, and the signature of an AU for Y-90 microspheres.
        ii. If the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g., artery spasm or sudden change in blood pressure), the AU should document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive should include the reason for not administering the intended dose or activity, the date, and the signature of an AU for Y-90 microspheres.

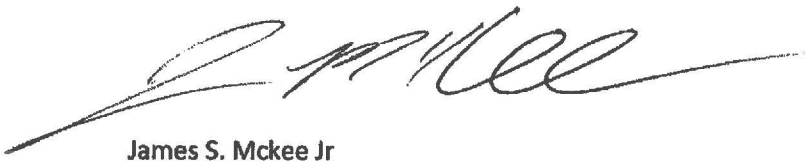
5) We commit to report medical events in accordance with NRC's February 2016 Microsphere Brachytherapy Sources and Devices Licensing Guidance (pgs. 8-9).
6) We commit to perform a semi-annual physical inventory of SIR-Spheres® in accordance with NRC's February 2016 Microsphere Brachytherapy Sources and Devices Licensing Guidance
    a. We commit to label vials and vial shields that are not labeled by the manufacturer with the radionuclide and form (e.g., Y-90 microspheres).
    b. We commit to label syringes and syringe shields that are not labeled by the manufacturer with the radionuclide, form, and therapeutic procedure (e.g., Y-90 microspheres, brachytherapy).
7) In accordance with 10 CFR 35.75(a) and (b) patients will be released with no restrictions. Reference NUREG-1556-vol.9,Rev.2, Program Specific Guidance About Medical Use Licenses, Table U-1. Yttrium-90 activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic and therapeutic purposes.
8) We request authorization to allow future changes to the radiation safety program provided that the conditions in the NRC's February 2016 Microsphere Brachytherapy Sources and Devices Licensing Guidance are met.

We commit to store and dispose of the SIR-Spheres® Y-90 resin microsphere dose vial and other disposable equipment used for administration with other radioactive waste and in accordance with existing radioactive waste procedures.

Although SIR-Spheres® Y-90 resin microspheres are sealed sources, we understand leak tests are not required and will not be performed.

We understand that SIR-Spheres Y-90 resin microspheres are only to be used in accordance with the delivery system described in the Sealed Source and Device Registry certificate.

If there are any further questions concerning this amendment request, Please contact James Mckee at 605-755-2339 or Lowell Husman at 605-755-8427.



James S. Mckee Jr
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