HENRY FORD HOSPITAL & MEDICAL CENTERS

Radiation Safety Office

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030-02043

September 16, 2004

Materials Licensing Branch
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Rd. Suite 210
Lisle, IL 60532-4352
Voice: (630) 829-9868 FAX: (630) 515-1259

Dear Sir or Madam:

I am requesting an amendment to the Henry Ford Hospital NRC License No. 21-04108-16 to allow for the more efficient use of the MDS Nordion Theraspheres product. I am also updating some other minor items on our license. Presently, our 500 mCi inventory limit (item 6.F) significantly constrains the number of patients that can be treated. Thus, I am requesting to add a separate listing for Y-90 at 2 Ci to accommodate the planned patient volume.

Radioactive material requested (Item 6.F)

Byproduct Material	Chemical/Physical Form	Maximum Amount
Y-90	Glass microspheres - Classified as a sealed source. (MDS Nordion, SSDR# NR-0220-D-113-S)	2 Ci

While not currently planned, we would like the flexibility to use any substantially similar Y-90 microsphere therapy products that are registered in the National Sealed Source and Device Registry (SSDR) such as the SIRSphere product.

As a broad scope licensee, we are responsible for evaluating facilities, operating procedures, training, and experience. Manuel Brown, MD who gained experience in the clinical trails of both these microsphere therapy products as a Professor at the University of Pittsburgh, has been approved as an Authorized

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User for this work by our Radiation Safety Committee. His qualifications are shown in Attachment 1. We will also ensure that other members of the treatment team obtain training and demonstrate competence prior to independently initiating these therapies and obtaining full approval to participate in this work. MDS Nordion has committed to train three of our staff at their training center and to be present at several of the first uses of this product to provide training and evaluate performance. MDS Nordion has also graciously provided model procedures that we will be able to use as a basis to implement these therapies.

We wish to assure you that we are aware of the restrictions resulting from the FDA Humanitarian Device exemption for these products and will require the requisite approval from our Institutional Review Board (Note: the IRB review is currently pending). We are also aware of the need for an appropriate written directive to use these products.

Additional License Updates

Sr-90 Listing

I would also like to modify the existing Sr-90 listing which is essentially exclusively used to cover our Novoste intravascular brachytherapy sources. Since Y-90 is unavoidably produced by Sr-90 decay, the listing for Sr-90 should be changed to Sr/Y-90.

Authorized Medical Physicists

Finally, we ask to delete Jingeng Zhu, Ph.D from our listing of Authorized Medical Physicists in item E. (ii).

Please feel free to contact Alan Jackson, MS, CHP at (313) 916-2739 should you have any questions about this matter.

Sincerely,

Donald Peck, Ph.D., DABR
Radiation Safety Officer

Alan Jackson, MS, CHP
Senior Health Physicist

NRC Theraspheres Amendment.DOC

Attachment 1

Qualifications for Manuel Brown, MD

University of Pittsburgh

Radiation Safety Office

Room G-7 Parran Hall
Pittsburgh, Pennsylvania 15261
412-624-2728, 2729
Fax: 412-624-3562

May 26, 2004

Alan Jackson
Radiation Safety Office
Henry Ford Hospital
2799 West Grand Blvd.
Detroit, MI 48202-2689

Dear Mr. Jackson,

This letter is to inform you that Manuel L. Brown, M.D. was authorized for the medical use of radioactive material permitted by 10 CFR 35.100, 35.200, 35.300 and 35.1000 (for Y-90 TheraSphere) under the University of Pittsburgh's NRC broad scope license (No. 37-00245-02) during his affiliation with the University of Pittsburgh Medical Center. Attached is a copy of the training and support documentation from MDS Nordion, which attests to the qualifications of Dr. Brown in the safe and effective use of Y-90 TheraSphere. Please let me know if you require any additional information.

Sincerely,

Jerry C. Rosen
Radiation Safety Officer

Attachment

MDS Nordion
Science Advancing Health

Memorandum

To: File

From: T.J.Simpson

Date: 27 February 2001

Subject: Qualification of Personnel at UPMC to Administer TheraSphere Using the Mark II Prototype Administration Kit

This memo serves to document that the key personnel at the University of Pittsburgh Medical Centre have been trained in the operation of the TheraSphere Administration Kit. This qualification is based on site visits by T.Simpson and R.Decaire for the purposes of training and for observation of patient infusions. The infusions were performed with the first prototype of the Mark II version of the administration kit. This prototype includes the following features:

1. The original single use administration kit, as described in the current Package Insert.
2. A new, re-usable lucite box (base and cover) for beta shielding and for positioning of the TheraSphere dose vial and the vent line empty vial.
3. A new, re-usable extender arm and valve mounting jig for optimum positioning and orientation of the outlet (blue) stopcock in close proximity above the patient.
4. An additional re-usable lucite box used as a stand underneath the first lucite box to elevate the outlet stop cock above the patient. This provides a flow path that runs downward from the outlet stopcock into the patient.
5. A new, re-usable RADOS personal dosimeter positioned near the dose vial shielding (but shielded from the other fittings on the assembled administration kit). This instrument, positioned as previously described, allows approximation of the percentage of TheraSphere that has been transferred out of the dose vial.
6. A new, single use needle-positioning guide for proper insertion of the inlet and outlet needles.
7. Replacement needles (Becton Dickinson Precision Glide 20G 1.5" Sterile Single Use) to minimize the possibility of septum coring.

The aspects of the TheraSphere Administration which are covered by this qualification are listed below:

1. Assembly of the kit and mounting hardware (as described in 1 to 6 above), maintaining the sterility of the liquid flow path. Operating and positioning the RADOS personal dosimeter.
2. Priming of the system up to the outlet (blue) stopcock, using elevated needle positions and a very slow flow rate.
3. Also included is the step of allowing the fluid in the catheter to flow backwards into the stopcock to totally eliminate the air in the infusion line. Infusion must be initiated immediately after this backflushing step to minimize the possibility of blood coagulation in the infusion line. Such coagulation could cause spheres to remain caught in the infusion lines and catheter.
4. Flushing the TheraSphere dose into the patient using sufficient flow rate and volume, with the needles pushed down. The flow rate should be 1 cc/sec for 3 French catheters and 3 cc/sec for 5 French catheters. The flow volume should be a minimum of 80 cc. Monitoring of the needle positions during infusion is essential, since the needles can move upward out of the septum during the infusion, and they may have to be pushed back down.

5. Using a radiation field measurement instrument to determine bremsstrahlung fields for monitoring of the outlet needle fitting and the outlet (blue) stopcock. These measurements help to determine the relative quantity of TheraSphere that is caught up in these fittings. Also monitoring of the RADOS dosimeter to determine the approximate percentage of TheraSphere transferred from the dose vial.
6. Disassembly of the administration kit into a waste container.
7. Dose calculations as described in the product insert, for both the liver and for lung shunting.

The following personnel are considered qualified:

Personnel	**Procedures**
Michael Sheetz	1,2,3,4*,5,6,7
Laurie Collins	1,2,3
Dr. Manuel Brown	4,7
Dr. Barry McCook	4,7

* Only a qualified physician is allowed to infuse TheraSphere (Step 4), but Michael Sheetz is very familiar with the theoretical basis for the flow velocities and volumes required. Michael Sheetz can train new physicians on these flow requirements.

It is my assessment that Michael Sheetz is sufficiently trained and qualified to train new personnel in all aspects of the TheraSphere Administration with the prototype Mark II kit and hardware. Dr. Brown and Dr. McCook are sufficiently trained and qualified to train new personnel on steps 4 and 7.

Report By

T.J.Simpson T.J. Simpson, P.Eng.

Date: 2001/02/27

The American Board of Nuclear Medicine

Incorporated 1971

A conjoint Board organized with the sponsorship of the American Board of Internal Medicine, American Board of Pathology, American Board of Radiology and the Society of Nuclear Medicine hereby certifies that

Manuel L. Brown, M.D.

has met the requirements of this Board and is certified as qualified to practice as a specialist in all aspects of clinical and laboratory

Nuclear Medicine

including but not limited to Radiobioassay, Nuclear Imaging, in Vivo Measurements & Therapy with unsealed Radionuclides.

F J Bonte MD
CHAIRMAN

S A Goldstein
SECRETARY

NUMBER

DATE