



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4352

DEC 15 2004

Donald Peck, Ph.D.
Radiation Safety Officer
Henry Ford Hospital
2799 West Grand Blvd.
Detroit, MI 48202

Dear Dr. Peck:

Enclosed is Amendment No. 65 to your NRC Material License No. 21-04109-16 in accordance with your request. Please note that the changes made to your license are printed in **bold** font.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers. At this time I updated Condition No.16 to permit the decay-in-storage of materials with a half-life less than or equal to 120 days, instead of 90 days. This reflects a new NRC policy change.

This refers to your letter dated September 16, 2004. Only one of your requests in this letter was incorporated into the license at this time, the deletion of Jingeng Zhu, Ph.D. as an Authorized Medical Physicist.

Your requests to add: the MDS Nordion yttrium-90 theraspheres product as a line item; the flexibility to use any substantially similar yttrium-90 microsphere therapy products that are in the Sealed Source and Device Registry; and change Item 8.F to include yttrium-90 were not included in this amendment and are addressed as follows.

1. Please see the attached enclosure for additional information required to add the MDS Nordion yttrium-90 theraspheres product as a line item. This information was taken from our website guidance for yttrium-90 microspheres under 10 CFR 35.1000. Please address your response to my attention as "additional information to control number 313714" and we will then continue our review.
2. As a broad scope licensee you may already have the flexibility to use byproduct materials that are authorized by the broad scope provisions of your license and in the Sealed Source and Device Registry (SSDR or SSD). However, we cannot add this kind of flexibility as a line item on the license. Each line item request must be reviewed and considered on a "case-by-case basis," as it is outside the broad scope provisions of your license.

As noted on our website guidance for yttrium-90 microspheres under 10 CFR 35.1000:

"The SSDR safety evaluation for a specific manufacturer's Y-90 microspheres does not cover the use of any other Y-90 microspheres, including the preparation of Y-90 on other microspheres by a commercial nuclear pharmacy, the medical use licensee's authorized

nuclear pharmacist, or a physician authorized user qualified to prepare radioactive drugs. The medical use of such a source will require a new SSD certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use, safety of the new Y-90 microspheres, and compatibility of the new microspheres with microsphere delivery system(s).

The SSDDR safety evaluation for a manufacturer's Y-990 microsphere delivery system does not cover the use of any other delivery system with the Y-90 microsphere brachytherapy device. Prior to authorization, the medical use of such a delivery system will require a new SSD certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use, safety of the microsphere delivery system, and compatibility of the new delivery system with the Y-90 microspheres."

3. Item 8.F was not changed to include yttrium-90 because it is not NRC's practice to do so for the strontium-90 materials in question. Such a formatting change is unnecessary to continue the authorization currently on the license.
4. If you have further questions concerning these matters please contact me at either (630) 829-9841 or (800) 522-3025.

Please refer to NUREG 1556, Vol. 9, and 10 CFR Part 35 if you have questions about these matters. 10 CFR 35 and NUREG 1556, Vol. 9 are available on our website at <http://www.nrc.gov>. Then click on the "Nuclear Materials" toolbar key and the "Medical Use Licensing/Part 35" option on the Quick List.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the Public Document Room pending resumption of public access to ADAMS.

D. Peck

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The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

Sincerely,

A handwritten signature in cursive script that reads "Colleen Carol Casey".

Colleen Carol Casey
Materials Licensing Branch

License No. 21-04109-16
Docket No. 030-02043

Enclosures:

1. Amendment No. 65
2. Enclosure for Theraspheres

ENCLOSURE FOR MDS NORDION THERASPHERES

1. **Please confirm** that authorized users will meet the training and experience requirements of either 10 CFR 35.490 or 10 CFR 35.940, as well as the specific vendor training in the use of the microspheres and the microsphere delivery system.
2. **Please confirm** that, for yttrium-90 (Y-90) microspheres, "prescribed dose" means the total dose documented in the written directive.
3. **Please confirm** that the written directive will include: (1) prior to implantation: the treatment site, the radionuclide (including the chemical/physical form (Y-90 microspheres)), and dose; and (2) after implantation but prior to completion of the procedure: the radionuclide (including the chemical/physical form (Y-90 microspheres)), treatment site, and the total dose.
4. **Please confirm** that, when the authorized user uses the medical end point of stasis to determine when to terminate implantation of the microspheres then this should be included in the written directive prior to implantation.

In this case, **please confirm** that the written directive will include: (1) prior to implantation: the treatment site, the radionuclide (including the chemical/physical form (Y-90 microspheres)), and a dose of either XXX rad/Gray (or rem.Sieverts) or the dose delivered at stasis; and (2) after implantation but prior to completion of the procedure: the radionuclide (including the chemical/physical form (Y-90 microspheres)), treatment site, and the total dose. If the implantation was terminated because of stasis, then the total dose is the value of the total dose delivered when stasis occurred and the implantation was terminated.

5. **Please confirm** that the written directive will specify the maximum dose that would be acceptable for a specified site (or sites) outside the primary treatment site to which the microspheres could be shunted (such as the lung and gastrointestinal tract).
6. **Please confirm** that procedures for administration requiring a written directive will, for Y-90 microsphere administrations, describe how to quantify the total dose to the treatment site as well as the total dose to other sites upon completion of the administration to confirm that the administration is in accordance with the written directive.
7. **Please confirm** that the quarterly physical inventory of sealed sources and brachytherapy sources will include the individual aggregates of the microspheres identifying the radioisotope, the container the aggregate is in, the total activity of the aggregate, and the location of the container.
8. **Please confirm** that your procedures will describe measures taken to ensure that the bremsstrahlung emissions from each patient or human research subject permits his/her release in accordance with 10 CFR 35.75.
9. The following guidance applies when the Y-90 microspheres are placed in vials, syringes,

or radiation shields that are not labeled by the manufacturer:

- a. **Please confirm** that you will label vials and vial radiation shields with the radioisotope and form (i.e., Y-90) microspheres).
- b. **Please confirm** that you will label syringes and syringe radiation shields with the radioisotope, form and therapeutic procedures (i.e., Y-90 microspheres, brachytherapy).