

Medical Health Physics
M.C. 29-00
100 North Academy Avenue
Danville, PA 17822
570 271 7015 Tel
570 214 9248 Fax

Catherine Anderko, M.S., CHP, DABR
Director, Radiation Safety Officer



Heal. Teach. Discover. Serve.

NASB1

US Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pa. 19406-1415

September 28, 2007

Licensee: Geisinger Health System *03002984*
License: #37-01421-01
Subject: Notification to Initiate Microsphere Therapy

This is a notification of our intent to begin ⁹⁰Y - SIRSphere microsphere therapy for unresectable metastatic liver carcinoma from primary colorectal cancer. A summary of the program is attached.

Very Sincerely,

Catherine M. Anderko, M.S., CHP, DABR
Director, Radiation Safety Officer
Geisinger Health System

Robert W. Davies
Vice President - System Services
Geisinger Health System

141132

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Description:

The treatment to initiate is SIRT (Selective Internal Radiation Therapy) with ^{90}Y microspheres (SIRSphere) for the FDA-approved treatment of unresectable metastatic liver carcinoma from primary colorectal cancer. The material will be used within the guidelines of the SSDR certificate, or approved for alternate conditions by the Geisinger Radiation Safety Committee.

Authorized User Training and Experience:

Dr. Pohl is an Interventional Radiologist and Fellowship-trained Nuclear Medicine physician, authorized for 35.100, 35.200, and 35.300 on an existing Geisinger Health System Radiation Source Permit # 050427 (expiration 4/18/2010). Dr. Pohl meets the criteria specified in 10 CFR 35.390. The category 35.1000 for the use of ^{90}Y microspheres for the treatment of metastatic liver carcinoma from primary colorectal cancer was conditionally added to his Permit on 9/27/07 with the consensus approval of the Geisinger Radiation Safety Committee review team. Full authorization will be awarded following completion of three (3) proctored patient cases and the full Radiation Safety Committee approval.

Dr. Pohl completed (or is scheduled to complete) the following training and education specific to SIRSphere:

- Four (4) hrs of training in SIRSphere technology in a didactic training class conducted by Dr. Joseph Saldarini of Sirtex Medical on 4/12/07 and self-study using Sirtex Medical training CD's.
- Participated in two (2) SIRSphere administrations during a site visit to Inova Health System in Fairfax, Virginia on 9/12/07, which included instruction on patient selection, dose calculation, written directive and dose preparation, set up of delivery system, dose administration, spill response, and patient follow-up.
- Delivered a two (2) hr SIRSphere informational and radiation safety training class on 9/18/07 to Geisinger staff who will be involved in the treatment: Health Physicists, Nuclear Medicine technologists, angiography technicians, and Radiology nursing staff.
- On 10/2/07, the SIRSphere representative will visit Geisinger Medical Center and meet with Dr. Pohl, Nuclear Medicine technologists, and Health Physics staff to review the procedures and protocol and conduct dry runs.
- The 1st three (3) patient cases performed at Geisinger by Dr. Pohl will be proctored with a Sirtex Medical physician in attendance. The 1st patient case is planned for late October 2007.

Radiation Safety Program:

1. A written directive (WD) will be generated for each patient with the prescribed dose¹ calculated by the Physician Authorized User, according to the Sirtex protocol. The WD will include:
 - a. Before implantation: the treatment site, the radionuclide, chemical and physical form of the radionuclide, manufacturer, dose in Gy (rad), and the statement "dose delivered at stasis".
 - b. After implantation but before completion of the procedure, the radionuclide, the chemical and physical form of the radionuclide, the manufacturer, the total dose in Gy (rad) to the treatment site, and the treatment site. The WD will specify the maximum dose acceptable for a specific site outside of the primary treatment boundary where microspheres could shunt,

¹ "Prescribed dose" means the total dose documented in the WD in Gray or rad. If the implantation was terminated due to stasis, then the total dose is the total dose delivered when stasis occurred and implantation terminated.

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such as lung or GI tract, and, post-implant, the dose that will result to the specified site(s) due to shunting.

2. SIRSphere packages will be shipped to the Nuclear Medicine department and processed according to normal package receipt protocols. The dose will be drawn as specified in a Written Directive, with syringes and syringe shields labeled with the radionuclide, form, and therapy type. Measurement assay of the drawn dose will be done volumetrically. Measurements will be made outside of a Plexiglas storage box holding the drawn dose for later comparison to identical measurements made of the administration tubing following administration. The dose will remain secure from the time of receipt until the time of administration and waste disposal. When there is leftover stock following dose extraction, the material will be entered into the system inventory and will be subject to the standard inventory requirements of any sealed source. The inventory record will show radionuclide, physical form, ID label on each storage vial, total activity in each vial, and vial storage location. Any storage container used to hold microspheres that is not pre-labeled by the manufacturer will have the radionuclide name and form entered onto the container.
3. Primary staff are those directly participating in the receipt, preparation, administration, and post-administration management of the patient and environment, and include the Physician Authorized User / Interventionalist, Nuclear Medicine Technologists, and Medical Health Physicists. These individuals will wear whole body film and extremity badges, and receive initial radiation safety, operational, and emergency response training as well as vendor mentoring. Ancillary staff such as angiography technicians and radiology nurses will wear whole body badges and have initial radiation safety training.
4. The location of administration will be an IR suite prepared as is standard procedure with the addition of contamination control measures instituted by Health Physics. The room will be posted with warning signs to prevent inadvertent entry. Attending staff will wear protective clothing per Health Physics guidelines, and only exit the room after a full body survey. Radiation surveys of the room will be conducted during the administration and a full room survey conducted at the conclusion of the procedure with decontamination performed as needed.
5. The radiation level in mR/hr will be measured at the surface and at 1 meter from the patient and the patient will be released only when the radiation levels are in compliance with 10 CFR 35.75. Radiation measurements and the details of each administration will be documented on a form for that purpose. Written radiation safety instruction may be provided to patients.
6. Any contaminated items will be collected as radioactive waste and held for decay in storage until radiation levels at the surface of the container with no interposed shielding are indistinguishable from normal background radiation.



Permit for Use of Ionizing Radiation

PERMIT # 050427

Issue Date: April 18, 2005
Revised On: September 28, 2007
Expiration Date: April 18, 2010

NRC License # 37-01421-01
PA DEP License # PA-0006

Christoph Pohl, M.D.
is hereby granted the status "Authorized
User of Radioisotopes" for the procedures
listed below:

| NRC Code Ref. | PA DEP Ref. | Description |
|---------------|-------------|--|
| 35.100 | 224.151 | Uptake, Dilution, & Excretion |
| 35.200 | 224.201 | Imaging & Localization |
| 35.300 | 224.251 | Therapeutic Administrations of Unsealed Byproduct Material |
| 35.1000 | - | 90-Y Microspheres |

This Permit is issued based on information submitted to the Medical Health Physics Office and is subject to the terms and conditions of the application materials and associated documents. The Geisinger Radiation Safety Committee reserves the right to withdraw this permit prior to the stated expiration date.

Cathy Beinlich, PhD.
Chair, Radiation Safety Committee
Geisinger Health System

Catherine M. Anderko, M.S., CHP, DABR
Director, System, Medical Health Physics
Radiation Safety Officer
Geisinger Health System

This is to acknowledge the receipt of your letter/application dated

9/28/2007, and to inform you that the initial processing which includes an administrative review has been performed.

NOTIFICATION 37-CIF-21-01
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 141132.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.