SAINT PETER'S
UNIVERSITY HOSPITAL

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United States
Nuclear Regulatory Commission
Medical Licensing Assistant
475 Allendale Road
King of Prussia, PA 19406-1415

January 25, 2008

03002502

RE: Amendment of license 29-07566-01

Please amend this license to include the use of Y-90 microspheres as regulated under 10 CFR 35.1000.

The authorized users shall be as follows:

Gopal Desai, M.D.
Alex Haas, M.D.
Robert Knee, M.D.

Each authorized user is currently authorized for 35.400 uses on this license. Additionally, each authorized user will successfully complete at least three supervised cases of each type of Y-90 microspheres available. The microsphere-specific training and experience will be satisfied by receiving training provided by the vendor or by receiving training supervised by an authorized user who is authorized for the type of microsphere for which the individual is seeking authorization. All training will be documented.

We will follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use except where the following licensing commitments provide regulatory relief:

- For Y-90 microspheres, "prescribed dose" means the total dose documented in the written directive.

- The written directive will include:
  - Before implantation: the treatment site, the radionuclide (including the chemical/physical form (Y-90 microspheres), the manufacturer, the dose in rad/Gray, and, if appropriate for the type of microsphere used, the statement "dose delivered at stasis"; and

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- After implantation but before completion of the procedure: the radionuclide (including the chemical/physical form [Y-90 microspheres]), the manufacturer, treatment site, and the total dose to the treatment site. 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.

- 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 (e.g. lung and gastrointestinal tact). The post-implantation written directive should specify the dose that will result to the specified site (or sites) due to shunting.

- The semi-annual physical inventory of microspheres aggregates (e.g. vials) should include:

- The radionuclide and physical form,
- Unique identification for each vial in which the microspheres are contained,
- The total activity of the vial(s), and
- The location of the vials.

- Patients will be released in accordance with 10 CFR 35.75 and guidance stated in NUREG 1556 vol 9, rev 1.

- When the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:

- Label vials and vial radiation shields with radionuclide and form (e.g., Y-90 microspheres).
- Label syringes and syringe radiation shields with the radionuclide, form, and therapeutic procedure (e.g., Y-90 microspheres, brachytherapy).

- The authorized user shall consult, as necessary, with individuals with expertise in:
  - Cancer management (e.g., radiation or medical oncology)
  - Catheter placement
  - Radiation dosimetry
  - Safe handling of unsealed byproduct material

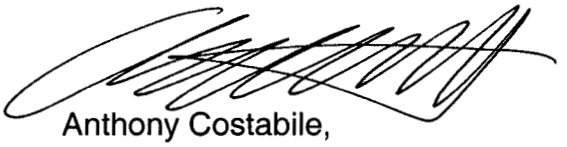
Please direct all questions regarding this application to Robert J. Tokarz, RSO at

732-424-0909,

Robert.tokarz@verizon.net

Thank you for your attention to this matter.

Sincerely,



Anthony Costabile,
Chief Operating Officer
Professional Services

This is to acknowledge the receipt of your letter/application dated 1/25/2008 (RECEIVED 2/11/2008), and to inform you that the initial processing which includes an administrative review has been performed.

☑ AMEND. 29-07566-01 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

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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** 141898.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader