January 23, 2006
Inova Fairfax Hospital
3300 Gallows Road
Falls Church, Virginia 22042-3300

U. S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

03012235

Reference: NRC license # 45-17128-01

Inova Fairfax Hospital requests our Materials License be amended to add:

Y-90 microspheres for manual brachytherapy sources
used for permanent brachytherapy implantation therapy

Inova Fairfax Hospital commits itself to the following license conditions:

(1) A written directive form will be developed that addresses the following conditions:
   (a) Before implantation: the treatment site, the radionuclide (including the chemical/physical form [Y-90 microspheres])
   (b) After implantation but before completion of the procedure: the radionuclide (including the chemical/physical form [Y-90 microspheres], treatment site, and the total dose
   (c) When the authorized user uses the medical end point of stasis to determine when to terminate implantation of the microspheres then this will be included in the written directive before implantation. In this case, the written directive will include (1) before 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 before 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
   (d) 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)
   (e) Procedures for administrations 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

(2) 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
(3) 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
(4) Syringes and syringe radiation shields will be labeled with the radioisotope, form, and therapeutic procedure (i.e., Y-90 microspheres, brachytherapy)

As additional experience in the medical use of TheraSphere and SIRSpheres yttrium-90 microspheres, Inova Fairfax Hospital may request authorization to allow future changes to its radiation safety program, with the following conditions being met:
(1) The revision is in compliance with the regulations
(2) The revision is based upon NRC's current guidance for TheraSphere and SIRSpheres yttrium-90 microspheres 35.1000 use posted on the NRC Web site
(3) The revision has been reviewed and approved by the licensee's radiation safety officer and licensee's management
(4) The affected individuals are instructed on the revised program before the change is implemented
(5) The licensee will retain a record of each change for five years
(6) The record will include a copy of the appropriate Web site guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change

The following Authorized Users meet the training and experience requirements of 10 CFR 35.490 and will be provided the specific vendor training in the use of the microspheres and the microsphere delivery system before first use.

Each of these authorized users is currently listed on our NRC license, and is certified by the American Board of Radiology in the area of Radiation Oncology

Authorized User	Material and Use
Sang Nam Lee, M.D.	Medical use described in 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.600, 10 CFR 35.1000, Ir-192 in a high dose rate treatment unit.
Glenn L. Tonnesen, M.D.	Medical use described in 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.600, 10 CFR 35.1000, Ir-192 in a high dose rate treatment unit.

Susan Boylan, M.D.	Medical use described in 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.600, 10 CFR 35.1000, Ir-192 in a high dose rate treatment unit.
Susan M. Pierce, M.D.	Medical use described in 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.600, 10 CFR 35.1000, Ir-192 in a high dose rate treatment unit.
Stella Hetelekidis, M.D. (Medical Director, Radiation Oncology)	Medical use described in 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.600, 10 CFR 35.1000, Ir-192 in a high dose rate treatment unit.
Samir Kanani, M.D.	Medical use described in 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.600, 10 CFR 35.1000, Ir-192 in a high dose rate treatment unit.

The licensee shall follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use except where license conditions place further restrictions or conditions.

All requirements of 10 CFR (specifically Parts 19, 20, and 35) and conditions of our NRC license will be maintained.

If you have any questions concerning this request, please contact Gary F. Talkington, Radiation Safety Officer, at (703) 698-3394 or Gary.Talkington@inova.com.

Thank you for your time and attention in this matter.

Colleen Cohen

Colleen Cohen
Senior Director, Outpatient and Ambulatory Services
Inova Fairfax Hospital/Inova Fairfax Hospital for Women and Children

cc:

Gary F. Talkington
Radiation Safety Officer

Michael Taylor
Director, Medical Physics

Keith Turner
Director, Radiation Oncology Department

Glenn L. Tonnesen, M.D.
Chairman, Radiation Safety Committee

Stella Hetelekidis, M.D.
Medical Director, Radiation Oncology

Brigid Anne Castro, M.D.
Medical Director, Radiology/Nuclear Medicine