UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

September 18, 2006

Docket No. 03003094 License No. 37-07722-04
Control No. 139247

Brenda DeFeo
Senior Vice President
The Bryn Mawr Hospital
130 South Bryn Mawr Avenue
Bryn Mawr, PA 19010

SUBJECT: THE BRYN MAWR HOSPITAL, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 139247

Dear Ms. DeFeo:

This is in reference to your letter dated July 28, 2006 requesting to amend Nuclear Regulatory Commission License No. 37-07722-04 to add Radioactive Seed Localization (RSL) procedures. In order to continue our review, we need the following additional information:

1. Under purpose of I-125 source use you indicate that "the implant will occur no more than 5 days prior to localization and removal of the seed(s)." Your calculations indicate a dose of 27.3 cGy at 1 cm from 1 seed. Please provide calculations indicating the maximum dose expected to non-removed tissue for implants involving 1.5 millicuries for 5 days. In addition, describe any radiation effects on the breast tissue expected at this dose.

2. Your application includes an exemption request from 10 CFR 71.5 for transport of I-125 sources by the authorized medical physicist (AMP). Please note that 10 CFR 71.9 exempts physicians licensed under 10 CFR Part 35 from following the requirements in 10 CFR 71.5. However, this exemption does not relate to AMPs. Please contact the Department of Transportation for guidance regarding exemptions to their regulations.

3. Please identify the exact location of use in the pathology department.

4. Confirm that the Ludlum 3 with NaI scintillation probe will be used for area surveys following implant, explant, and pathology.

5. Confirm that your emergency response equipment will include gloves and "caution radioactive materials" labels. In addition, confirm that the equipment will be located near each surgery suite and the pathology laboratory when handling sources.

6. Confirm that you will maintain records for seed localization in accordance with the following regulations: 10 CFR 35.2024, 35.2026, 35.2041, 35.2060, 35.2067, 35.2075, 35.2310, 35.2404, 35.2406, and 35.2432.

7. Confirm that you will report a medical event involving seed localization in accordance with 10 CFR 35.3045, 35.3047, 35.3067.

8. Provide the name(s) and training/experience for radiologists you wish to list as authorized users for implanting sources. Applicable training should include:

   a. authorized for 35.200 on an NRC or Agreement State License or meets the qualifications in 10 CFR 35.290; and

   b. work experience under the supervision of a physician authorized for 10 CFR 35.400, that includes at least 3 cases that involved:

      i) preparing, implanting, and removing RSL sources safely, including the use of remote handling tools to manipulate seeds and the proper use of shields;

      ii) ordering, receiving, and unpacking radioactive material safely;

      iii) performing the related radiation surveys using appropriate instrumentation;

      iv) routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a broken or leaking source;

      v) using emergency procedures regarding a broken or leaking source;

      vi) reviewing and understanding the administrative controls in place to prevent a medical event; and

      vii) maintaining running inventories of radioactive material on hand.

9. Confirm that training for general surgeons involved in RSL explants will be provided by an authorized user authorized for RSL or the RSO, as applicable, and will include a description of the implant procedure and a demonstration of routine monitoring to be performed before, during, and after all uses of the seeds to ensure rapid identification and remediation of a broken or leaking source.

10. Confirm that training of pathology personnel will include routine monitoring to be performed before, during, and after all uses of the seeds to ensure rapid identification and remediation of a broken or leaking source.

11. Describe the authorized users active involvement in the implant/explant procedures. For instance, indicate whether a physician authorized on the NRC license for RSL procedures will be present for the RSL implant or explant.

12. Provide detailed written procedures for routine monitoring (i.e., surveys) before, during, and after all uses of the seeds for implant, explant, and pathology to ensure rapid identification and remediation of a broken or leaking source.

13. Your application indicates that seeds will be calibrated by a third party. Please confirm that the activity of the sealed sources will be verified at your institution prior to each patient implant using an instrument calibrated in accordance with nationally recognized standards or the manufacturer's instructions and retain a record that includes: (i) the radioisotope; (ii) the patient's name or identification number; (iii) the measured activity; and (iv) the name of the individual who measured the activity.

14. With regard to your emergency response procedures, please confirm that your procedures for responding to a source rupture or leaking/cut source will include the following: (i) notification of the RSO in addition to the AU; (ii) notification of all persons in the area that an event has occurred; and (iii) controlled entry to the room during decontamination efforts to minimize the risk of inadvertent exposure from seeds. Also, describe your decontamination steps when: (i) the patient is found contaminated; (ii) licensee staff are found contaminated; and (iii) the pathology or surgery area is found contaminated. Additionally, you indicate that thyroid scans of the patient will be done within 24 hours to identify iodine mitigation. Please describe your policy for administration of stable iodine to block the thyroid either prior to after the bioassay.

15. Confirm that you will prepare a written directive for each procedure that will meet the requirements in 10 CFR 35.40(a) and (b)(6).

16. Confirm that patient surveys will be performed in accordance with 10 CFR 35.404, prior to release of a patient.

17. Confirm that patients will be instructed in writing before implantation and agree in writing to return for removal of the radioactive seeds at the appointed date and time. In addition, indicate whether the names/addresses of the patient's relative(s) will be collected to assist in contacting the patient. Also, please confirm that the NRC will be contacted in the event the patient does not return for explant and the dose calculation will be forwarded to the NRC for review.

18. Confirm that staff involved in RSL procedures will be provided training at least annually that covers the topics described in 10 CFR 35.410. Also, confirm that all personnel involved with the RSL procedure, including the Radiation Safety Officer, will be trained on routine monitoring and emergency procedures.

19. Confirm that your will develop, implement, and maintain the appropriate procedures for 10 CFR 35.40 (a), (b)(6), (c), and (d), 35.41, 35.67, 35.75, 35.310, 35.404, 35.406, 35.410, and 35.432.

20. Indicate whether you wish to retain authorization for intravascular brachytherapy, and if so, confirm whether you will use the sources in the Best Medical device. If you no longer wish this authorization, please provide a copy of the last transfer documentation from the manufacturer and confirmation of receipt.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then

**Toolkit Index Page.** Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 139247. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5169.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

***Original signed by Penny Lanzisera***

Penny Lanzisera
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
Marchello J. Barbarisi, M.D., Radiation Safety Officer

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**SUNSI Review Complete:** PLanzisera
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