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

July 28, 2003

Docket No. 03003013 License No. 37-01893-01
CAL No. 1-03-003

William Vanaskie
President and CEO
Robert Packer Hospital
Guthrie Healthcare System
One Guthrie Square
Sayre, PA 18840

SUBJECT: CONFIRMATORY ACTION LETTER NO. 1-03-003

Dear Mr. Vanaskie:

On June 16, 2003, your organization reported to the NRC that you identified a medical event that occurred at your facility in May of 2001. You determined that the array of iodine-125 seeds intended for implantation into a patient's prostate was located approximately 3 centimeters from the prostate. Although the patient's CT scan performed shortly after the implant in 2001 indicated that the seeds were not positioned in accordance with the prescription, this was apparently not identified by your staff at that time. A more recent CT scan of the patient also confirmed the erroneous location of the seeds. Dose calculations performed at NRC request indicated that (1) the dose received by the prostate was only a small fraction of the prescribed dose, and (2) the dose to an unintended area was significantly higher than would be expected from the intended treatment. NRC performed an inspection on June 19, 2003, during which it was learned that the Radiation Oncology staff members involved in prostate seed implants in 2001 left your employ in late 2001 or early 2002. NRC also determined that you did not perform the required Quality Management Program review for implants performed in 2001 and you did not follow the requirements of your Quality Management Program to perform dose calculations based on the actual distribution of radioactive sources visible on imaging studies conducted shortly after the implants. Following the inspection, your staff began an audit of other prostate implant cases performed in 2001.

On July 18, 2003, your organization reported to the NRC that your audit identified a second medical event involving a prostate seed implant performed in July of 2001. Again, you determined that the array of iodine-125 seeds was located approximately 3 centimeters from the prostate, the dose received by the prostate was a small fraction of the prescribed dose, and the dose to an unintended area was significantly higher than would be expected from the intended treatment.

On July 25, 2003, your organization reported to the NRC that your audit identified two additional medical events involving prostate seed implants performed in 2001, bringing the total medical events to four. Again, you determined that for these two additional events, the iodine-125 seeds were placed 2 to 3 centimeters from the prostate, and that the dose received by the prostate was a small fraction of the prescribed dose.

Pursuant to a telephone conversation between you and Pamela Henderson, Chief, Nuclear Materials Safety Branch 1, on July 25, 2003, it is our understanding that you have taken or will take the following actions which will be completed by the dates specified:

1) Perform an audit of all prostate seed implants performed at your facility from 2001 to present, and all other prostate seed implants performed at your institution prior to 2001 by the Radiation Oncology staff members who were involved in the four events described above. This audit will include:

   a) a review of written directives;

   b) an assessment of whether post-implant imaging studies and dose calculations were performed, as required by your Quality Management Program;

   c) a review of any available post-implant imaging studies to assess the geometric accuracy of seed placement;

   d) a review of any available post-implant dose calculations to assess the accuracy of dose delivery; and

   e) Identification of the root causes of each medical event, including consideration of information provided by former Radiation Oncology staff members who performed prostate seed implants in 2001, if possible.

   This audit must be completed within 45 days of the date of this letter and a written report addressing each of the items (a) through (e) for each implant case reviewed for the audit (not limited to medical events) must be submitted to the NRC Region I Office within 15 days of the completion of the audit.

2) Perform an audit, in accordance with (a) through (e) of section (1), of 25% of each year's prostate seed implants performed at your facility prior to 2001, by individuals other than those who were involved in the four events describe above, or provide justification as to why this audit is not needed. The 25% is in addition to any implants reviewed that were performed by the Radiation Oncology staff members who were involved in the four events. This audit must be completed within 60 days of the date of this letter and a written report addressing each of the items (a) through (d) for each implant case reviewed for the audit (not limited to medical events) must be submitted to the NRC Region I Office within 15 days of the completion of the audit.

3) Pursuant to 10 CFR 35.3045(c), notify by telephone the NRC Operations Center [(301)951-0550] no later than the next calendar day after the discovery of each additional medical event.

4) Pursuant to 10 CFR 35.3045(d), submit to the NRC a 15 day written report for each medical event which includes all the information required by 35.3045(d)(1) and (2).

5) Pursuant to 10 CFR 35.3045(e), provide notification of each medical event to the applicable referring physician and notify the individuals who are the subject of the medical events as stated in the regulations.

7) Arrange for an independent medical physicist to perform a review to confirm the adequacy of your current prostate seed implant program. The review must include a review of accuracy of treatment delivery and must be completed within 30 days of the date of this letter. A written report detailing what was reviewed and the results of the review must be submitted to the NRC within 15 days following the completion of the program review.

Pursuant to Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, you are required to:

1) Notify me immediately if your understanding differs from that set forth above;

2) Notify me if for any reason you cannot complete the actions within the specified schedule and advise me in writing of your modified schedule in advance of the change; and

3) Notify me in writing when you have completed the actions addressed in this Confirmatory Action Letter.

Issuance of this Confirmatory Action Letter does not preclude issuance of an order formalizing the above commitments or requiring other actions on the part of the licensee, nor does it preclude the NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of this letter. In addition, failure to take the actions addressed in this Confirmatory Action Letter may result in enforcement action.

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room (PDR) and will be accessible from the NRC Web site at http://www.nrc.gov/reading-rm.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information).

If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Sincerely,

Original signed by George Pangburn

George Pangburn, Director
Division of Nuclear Materials Safety

cc:
Joon Park, Radiation Safety Officer
Commonwealth of Pennsylvania

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