



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

October 15, 2003

Docket No. 03003013
CAL No. 1-03-003

License No. 37-01893-01

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

SUBJECT: CONFIRMATORY ACTION LETTER NO. 1-03-003, REVISION 2

Dear Mr. Vanaskie:

On July 28, 2003, NRC issued Confirmatory Action Letter (CAL) No. 1-03-003 which described certain actions you agreed to take following your identification, in June and July 2003, of four medical events that had occurred at your facility in 2001. Revision 1 of the CAL was issued on July 30, 2003, to clarify that an audit of 25% of prostate seed implants performed each year prior to 2001 would be conducted, the audit would be completed within 60 days of the date of the CAL, and a report documenting the audit findings would be submitted to NRC within 15 days of the completion of the audit.

During a telephone conversation between Sandra Gabriel of my staff and Mary Mannix of your staff on October 7, 2003, we were informed that the audit of 25% of prostate seed implants performed each year prior to 2001 was completed; however, Ms. Mannix requested an extension of time for submitting the report so that the audit findings could be first independently reviewed by the physician consultants hired to review the prostate seed implant program.

Pursuant to the telephone conversation between Ms. Mannix and Ms. Gabriel on October 7, 2003, it is our understanding that the findings of the audit of 25% of prostate seed implants performed each year prior to 2001 will be reviewed by your physician consultants and that a report of the audit findings will be submitted to NRC by December 15, 2003.

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 the CAL.

Issuance of the CAL dated July 28, 2003, Revision 1 of the CAL on July 30, 2003, and this second revision of the CAL does not preclude issuance of an Order formalizing the above

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Robert Packer Hospital

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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 CAL 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 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.

Thank you for your cooperation.

Sincerely,

Original signed by Francis M. Costello

George Pangburn, Director
Division of Nuclear Materials Safety

cc:
Ralph D. Zehr, M.D., Radiation Safety Officer
Commonwealth of Pennsylvania

W. Vanaskie
Robert Packer Hospital

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