February 24, 1998

Docket No. 070-03092

License No. SNM-2003

Joseph Saunders
Vice President, Support Services
Crozer-Chester Medical Center
One Medical Center Boulevard
Upland, PA 19013-3995

SUBJECT: INSPECTION NO. 070-03092/97-001

Dear Mr. Saunders:

On November 19, 1997, Louis Manning of this office conducted a safety inspection at the above location of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. Additional information provided in your facsimile dated January 6, 1998 was also examined as part of the inspection. The findings of the inspection were discussed with Ms. Diana Stockdale, Radiation Safety Officer and Mr. Frank Kline, Administrative Director of Radiology of your organization at the conclusion of the inspection.

Based upon information obtained during the inspection, the inspector learned that you received a letter from Bio-Control Technology, Inc. in July 1996. This letter requested information concerning a patient who received a nuclear pacemaker at your facility. It is our understanding that you were not aware that this patient existed prior to receiving the letter from Bio-Control Technology, Inc. As a result, you initiated a search to verify whether or not the patient actually received a nuclear pacemaker at your facility. Once the patient was identified, you also confirmed that no additional patients were implanted with nuclear pacemakers, and applied for a new license in January 1997. This license replaced the special nuclear materials license, which you had previously terminated in October 1981 based on your understanding, at that time, that no patients received a nuclear pacemaker implant at your facility. The patient in question, was originally admitted to Hahneman Hospital in Philadelphia, PA., and later transferred, along with the pacemaker, to Crozer-Chester Medical Center. The pacemaker was received and implanted under Crozer-Chester Medical Center's license in February 1977. We also understand, that because this patient was transferred to Crozer-Chester Medical Center, that the patient would not be admitted through normal channels. As a result, your records did not indicate that any patient received a nuclear pacemaker. You learned, from the patient, that she was transferred from Hahneman Hospital to Crozer-Chester Medical Center, because there were no available beds in Hahneman's Cardiology Unit. You are presently following this patient as required. If our understanding differs from yours, please notify this office in writing.

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Condition 14 of NRC License No. SNM-2003 states, in part, that the licensee shall continue patient follow-up procedures for the nuclear pacemaker during the life of the patient. Failure to continue patient follow-up procedures for the nuclear pacemaker, is a violation of Condition 14 of NRC License No. SNM-2003. However, because the violation was self identified, and corrected, the violation will not be cited in accordance with Section VII.B.1. of NRC Enforcement Policy (NUREG 1600). This policy was implemented to encourage licensees to identify and correct problems in their program. You are reminded to continue to follow the patient at intervals not to exceed six months. You must also ensure the proper disposal of the nuclear pacemaker once it is removed from the patient. Please notify this office in writing, once the pacemaker has been explanted and returned to the manufacturer. No response to this letter is required.

In accordance with Section 2.790 of the NRC's "Rules and Practices," Part 2, Title 10, Code of Federal Regulations, a copy of this letter will be placed in the Public Document Room. No reply to this letter is required.

Your cooperation with us is appreciated.

Sincerely,

Original signed by Mohamed M. Shanbaky

Mohamed M. Shanbaky, Chief Nuclear Materials Safety Branch 1

CC

Diana Stockdale, M.S., Radiation Safety Officer Commonwealth of Pennsylvania

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