BAYONNE HOSPITAL

May 12, 1997

Docket No. 030-0254 License No. 29-12253-01

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

SUBJECT: **"Reply to a Notice of Violation"**

Dear Sir:

This letter will serve as Bayonne Hospital's reply to the Notice of Violation received under a cover letter from Mohamed Shabanky, Ph. D., Chief of Nuclear Materials Safety Branch 1 of the Division of Nuclear Materials safety at the NRC region I office in King of Prussia, PA. The Notice of Violation concerns (1) A misadministration involving a High Dose Rate Afterloading device (HDR), and (2) the failure to notify the patient involved in the misadministration in writing within the time period specified in 10 CFR 35.33. The Notice was received in the Radiation Safety Office on April 22, 1997, posted in the Radiation Oncology Department on April 23, 1997 and removed from public viewing on April 30, 1997.

Violation 1:

Reason: Bayonne Hospital began treating patients with its HDR unit in 1993 and had performed 124 treatments without incident , and in a timely manner to minimize patient discomfort during these types of procedures. A vital part of the treatment process involves creating a customized treatment plan for each patient, and transferring the data from the treatment planning computer to the treatment unit via a magnetic program card. On the day of the misadministration Nov. 12, 1996, the program card read/write interface unit malfunctioned which mandated that treatment times be manually entered on the treatment console.

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The medical physicist entered an incorrect time at one of the dwell positions and did not ensure that the treatment times printed from the

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treatment unit were checked for agreement with the treatment plan from the treatment planning computer. The reason for the error was the medical physicist's failure to devote sufficient time to the task of manually programming the source dwell times at the treatment console, and the failure of the medical physicist to enforce the part of the quality management program requiring a second person to check the treatment times before treatment commenced.

Corrective Action: In Bayonne Hospital's Nov. 20, 1996 report of the misadministration, a form entitled "HDR Brachytherapy Dosimetry Check and T_x Record" was submitted for review by the NRC. The second part of the form documents the second check of the treatment times by a person who did **not** perform the original calculations. An inservice was held to train all personnel in the Radiation Oncology Department on the use of the form. The second check involves the medical physicist who reads the treatment times from the treatment plan and the second person who checks the treatment times printed from the treatment console. The number of dwell positions and the total treatment time is also checked. These inservices were held on December 4, 1996 and December 13, 1996. The form was put into use on December 4, 1996, and all HDR treatments have been completed since then without incident. As of December 13, 1996 full compliance with 10 CFR 35.32(a) has been achieved.

Future Action: Personnel will be trained annually on the completion of the second check form as part of the annual radiation safety training requirement.

Violation 2:

The violation concerns the failure to notify the patient in writing of the misadministration that occurred on November 12, 1996 within 15 days of the misadministration.

Reasons: The radiation safety officer upon determining that a misadminstration had occurred, on November 13, 1996 notified the NRC region I office, and the NRC operations center in Rockville, MD via telephone. The patient's referring physician was notified verbally within 24 hours, and attempts to notify the patient verbally via telephone were made within 24 hours and the patient was notified verbally as soon as was practicable. The Nov. 20, 1996 notification to the NRC refers to verbal communications with the patient and patient's referring physician on November 13, 1996, and follow up examinations of the patient by the authorized user on November 15 and 19, 1996. These actions are

documented in the progress notes of the patient's radiation oncology record.

The RSO completed the written documentation of the physical events leading to the misadministration prior to taking vacation. The RSO left a copy of his report with the authorized user with instructions to insert a section describing the effects on the patient. The authorized user completed the letter and the report was sent to the NRC region I office on November 20, 1996. A copy of the report was not sent to the patient at that time which caused the violation of 10 CFR 35.33 (a) (4).

The RSO focused his attention on completing the report of the misadministration, ensuring that the patient was notified verbally, along with the referring physician, and ensuring that the authorized user complete the written report on the effect on the patient prior to the RSO's scheduled vacation. While on vacation, the RSO contacted the department secretary to ensure that the report was sent to the NRC within the proper time limit. The RSO was reminded of the necessity of reporting the misadministration to the NRC by the NRC inspector during the exit interview on November 15, 1996.

Corrective Action: A letter to the patient describing the misadministration was delivered to the patient on February 12, 1997. Full compliance with 10 CFR 35.33 has been achieved.

Future Action: Misadministrations involving the medical use of byproduct material are serious occurrences and hopefully, rare occurrences. When they happen, the need to take swift, corrective action to prevent their recurrence is paramount. To assist the RSO in the reporting process a checklist has been developed for additional management personnel to internally monitor the flow of information to the NRC and the patient. A copy of this checklist is enclosed and will be incorporated into Bayonne Hospital's Quality Management Program.

We believe the corrective actions described above sufficiently address all of the items cited in the Notice of Violation, and we await your response concerning any further action by the NRC. All of the information contained in this response and the Nov. 20, 1996 report of misadministration can be placed in the public document room without redaction.

Sincerely,

Michael D'Agnes
President

encl: Misadministration Checklist

cc: Regional Administrator, NRC Region I
P. Giordano, Chairman, RSC
K. La Placa, Director of Oncology Services
N. Mehta, M.D.

BAYONNE HOSPITAL

Department of Radiology / Radiation Oncology
Misadministration Reporting Checklist

FOR INTERNAL USE ONLY

I. Discovery/Identification:

A. Misadminstration discovered on _____ (date)

B. Misadminstration involved procedure/dose delivered on _____(date)

C. Type of Misadministration defined under 10 CFR 35.2:

D. Authorized user _____, M.D.

E. Reported by _____, RSO

II. Telephone/verbal notification:	**Y**	**N**
1. Was the NRC Operations Center notified on the next business day?	___	___
2. Was an attempt made to notify the referring physician within 24 hours of IA?	___	___
3. Did the referring physician decide to inform the patient? (If affirmative then either 4 or 5 must be affirmative)	___	___
4. Did the referring physician inform the patient within 24 hours of IA or as soon as practicable?	___	___
5. Did the authorized user inform the patient within 24 hours of IA or as soon as practicable?	___	___
6. Did the RSO confirm the answers of questions 2-5?	___	___

Misadministration Reporting Checklist (cont.)

III. Written Notification/Archiving:

	Y	N
1. Was a written report of the misadministration sent to the NRC region I office within 15 days of IA?	___	___
2. Did the report contain all of the information specified in 10 CFR 35.33(a)(2), including reasons for a negative response to question 3 in section II above?	___	___
3. Was care taken not to disclose the patient's identity?	___	___
4. If the patient was verbally notified, was a copy of the report sent to the patient within 15 days of IA?	___	___
5. Are the records pertaining to the misadminstration available for review?	___	___

IV. Internal Verification:

	Y	N
1. Were **all** reporting requirements of 10 CFR 35.33 met?	___	___
2. Are explanations for negative answers attached?	___	___

Submitted to RSC by: _____, RSO, _____Date

Reviewed by: _____

Title: _____

Date: _____