Fundación Hospital Metropolitano, Inc.

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January 5, 1994

Mr. J. Philip Stohr, Director
Division of Radiation Safety
and Safeguards
N.R.C. Region II
101 Marietta Street, N.W. Suite 2900
Atlanta, Georgia 30323-0199

SUBJECT: CONFIRMATORY ACTION LETTER

Dear Mr. Stohr:

This is in response to your letter dated 12-30-93 (Confirmatory Action Letter).

1. My understanding does not differ from that set forth.

2. We cannot complete the actions within the specified schedule. Our due date to complete the retraining program will be 2-28-94.

3. We will notify you as soon as we complete the actions addressed by you in the letter.

4. We enclose the plan for the implementation of the retraining program.

Thanks.

Cordially,

Víctor R. Marrero, MHSA
Administrator

VM/ida

cc: Dr. José Díaz
Mr. Milton Maldonado
Dra. Jeanne Ubiñas
Dra. Ada Miranda
Mr. Santiago Gómez

· DCS

RADIATION ONCOLOGTY CENTER
FUNDACION HOSPITAL METROPOLITANO

RE: Docket No. 030-11155
License No. 52-16033-01

Mr. Hector Bermúdez
NRC Region II
101 Marietta Street,
NW Suite 2900
Atlanta Georgia

MISADMINISTRATION WRITTEN REPORT

LICENSEE'S NAME: Jeanne Ubiñas, MD

PRESCRIBING PHYSICIAN'S NAME: Jeanne Ubiñas

DESCRIPTION OF THE EVENT:

On December 9, 1993 at 5:20 PM, a patient with an adenocarcinoma of endometrium, Stage III, post operative and post irradiated, had a brachytherapy procedure. The procedure consisted of the insertion in the vagina of a plastic tandem of 2 cms. in diameter and containing three sources of 10 mg radioactive material of Cesium 137. The vagina was closed at the introitus by means of two surgical stitches. After having localization films and dosimetry done, the patient was told by the Radiotherapist that the sources were to remain in place until Saturday, December 11 at 5:30 PM when they would be removed and she will be discharged.

On saturday December 11 at 9:50 AM, the Radiotherapist in charge visited the patient and found out that the cylinder was out and that the patient had placed it at the side of her body at probably 2 or 3 inched from her hip. The sources were inmediately placed in the portable safe and the radioactivity checked in the patient and room with the Geiger counter. The Radiation Oncologist Center's physicist was contact by phone around 11 AM, also, the Hospital's Radiation Safety Officer, who at the time was at the institution, was personally told about the event. The Physicist checked the cylinder and the radioactive sources; all three sources were accounted for and stored at the safe box.

The Physicist called the NRC's Hot Line early in the afternoon and informed the event. The patient was released at 1:30 PM after having the stitches removed and a pelvic examination performed. The examination revealed no bleeding nor visible or palpable anormalities in the vagina or external genitalia.

On requesting information from the patient, she told the Radiotherapist that the sources were out by approximately 8 AM and that she notified the event to a nurse that entered her room to take the vital signs. No action was taken by the nursing personnel either by notifying the Radiotherapist in charge or the Radiation Safety Officer.

The refering physician was called by the Radiotherapist in charge in the morning of December 12, 1993. She notified the event and disscused the management of the case with him; both agreed in considering the treatment complete.

IMPROVEMENTS NEEDED TO PREVENT RECURRENCE OF THE EVENT

To prevent further recurrence of the event the following improvements are recommended: (1) Continue and reinforce the educational activities for nursing personnel; (2) Admit patients to only one of the Hospital's wards to enable the personnel involved with this type of patient to become more familiar with the procedure.

ACTION TAKEN TO PREVENT THE RECURRENCE OF THE EVENT

At present we are in the process of coordinating a more energetic program of education for nursing and other pertinent personnel regarding the handling of the brachytherapy patient.

NOTIFICATION OF THE PATIENT

The patient was notified verbally both at the moment of the event occurance and in the follow up visits (Dec. 16, Dec. 24, Dec. 31, 1993). The patient was informed that the sources, when inside her body, were beneficial for her condition but outside the body were potentially harmful; that the treatment was not delivered as prescribed by the Radiotherapist but was considered complete after disscusing the case with her gynecologist. The patient was also told that in the near future she will receive a letter informing about the event.

Jeanne Ubiñas, MD

Victor Marrero, MHSA

DATE OF REPORT December 29, 1993