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UNIVERSIDAD DE PUERTO RICO, RECINTO DE CIENCIAS MEDICAS
UNIVERSITY OF PUERTO RICO, MEDICAL SCIENCES CAMPUS

OFICINA DEL RECTOR
OFFICE OF THE CHANCELLOR

August 30, 1990

Stewart D. Ebneter
Regional Administrator
Office of Enforcement
U.S. Nuclear Regulatory Commission
Office of Governmental and Public Affairs
Region II
101 Marietta Street, N.W.
Atlanta, GA 30323

Docket NOS 030-13584
030-31462

License No. 52-01946-07
52-01946-09

Re: Reply to a Notice of Violation

Dear Mr. Ebneter:

According to the provisions of 10CFR.2.201, the University of Puerto Rico Medical Sciences Campus is required to submit a written explanation to the Nuclear Regulatory Commission regarding the alleged violations stated in your Notice of Violation of July 18, 1990.

A detailed explanation of the alleged violations and the corrective measures taken are:

9404130219 930614
PDR FOIA
VAZQUEZ93-312 PDR

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APTDO. 5067 CORREO GENERAL, SAN JUAN, PUERTO RICO 00936 — TEL. (809) 758-2525
G.P.O. BOX 5067, SAN JUAN, PUERTO RICO 00936 — PHONE (809) 758-2525

I. Violations of License 52-01946-07 (Broad Scope)

A. 1. Violation is admitted.

2. The reason for these violations were as follow:

<u>April 13, 1989</u>

The previous Radiation Safety Officer resigned on April 10, 1989 and the new RSO was appointed on April 11, 1989. The implant was performed without notifying the newly appointed RSO due to a lag in the communique notifying the Radiotherapy personnel of the appointment.

<u>October 11, 1989</u>

The RSO was not notified by the Radiotherapy personnel of this implant. This was due to inadequate performance on the part of the Radiotherapy personnel.

<u>January 4, 1990</u>

The Campus was on Christmas recess. The Radiation Safety Office technician (Mr. José Robles) was on vacation. The Radiotherapy personnel did not notify the RSO even though he was on call. This was due to inadequate performance on the part of the Radiotherapy personnel.

3. Corrective steps

a) Concerning these violations a meeting was held on April 10, 1990 with Mr. Onelio Núñez, Dean of Administration, Dr. Petra Burke, Acting Dean of Medicine, Dr. Víctor Marcial, Director of Radiotherapy, Dr. Frieda Silva, Director of Nuclear Medicine and Chair of the Radiological Sciences Department and the Radiation Safety Committee, Mr. José A. San Inocencio, Assitant Dean of Administration, Mrs. Ida Nilsa Guzmán, Associate Dean of Administration and Dr. Heriberto Torres, Campus RSO. Dr. Marcial was notified that these violations were unacceptable, and a corrective action plan was drafted to prevent recurrence.

b) These violations (particularly 10/11/89 and 1/4/90) were isolated cases. The previous record on implant surveys has been satisfactory.

c) The following written procedures have been established to prevent further violations.

- The Radiation Safety Office will be notified at least 2 days in advance of any planned implant therapy by the Radiotherapy Division.

- When the patient is admitted to the hospital, the nursing supervisor will notify the Radiation Safety Office within 4 hours of admission.

- The physcist in charge of performing the dose calculation, will notify, in writing, the Radiation Safety Office before the implant is performed.

- The Radiation Safety Office will perform the survey after implanting the material and will record the date when source(s) will be removed.

- Violation of this procedure will be submitted to disciplinary sanctions, that may result in the termination of employment of the personnel involved.

4. Corrective steps for prevention of future violations.

- Refer to 1A3.c

5. Compliance: September 4, 1990

B. 1. Violation is admitted.

2. Reason for violation: The RSO was not notified by the Radiotherapy Personnel of the removal of the implant. This was due to the inadequate performance of the Radiotherapy personnel.

3. Corrective steps

a) The RSO will be notified of the date and time of the implant removal. The RSO will perform the appropiate surveys.

b) Violation of this procedure will be submitted to disciplinary sanctions that may result in the termination of employment of the personnel involved.

4. Corrective steps to prevent future violations

   - Refer to 1B3b

5. Compliance: September 4, 1990

C. 1. Violation is admitted.

2. Reason for violation: The Nuclear Medicine Technologist in charge of the Hot Laboratory left the door opened and the area unattended. Lack of air conditioning in the room contributed to this behavior.

3. Corrective steps

   All Nuclear Medicine Technologist were informed of the violation and the serious implication of these actions.

   Written reprimands will be issued if the violation is detected by the Nuclear Medicine Physicist. Violations will be submitted to disciplinary sanctions that may result in termination of employment.

4. Corrective steps to prevent future violations

   In addition to the corrective actions taken previously, the following steps were taken:

   a) A central air conditioning unit was installed inside the room.

   b) A mechanical device was installed in the door to prevent it from being left open.

   c) A glass viewing section was installed in the door to look inside without the need to open it.

5. Compliance already achieved

D. 1. Violation is admitted.

2. Reason for violation: The RSO did not perform the leak tests when required. There was inadequate supervision of the RSO pesonnel. There was lack of a written working plan for the year.

3. Corrective steps

a) The leak test for all sealed sources were done on April 19, 1990. All of them showed less than 0.005 mCi of removable contamination.

b) An annual working plan was prepared by the RSO stating all activities to be done during the year.

4. Corrective steps to prevent future violations
- An annual work plan will be prepared by the RSO. The plan will be submitted for approval to the Campus Radiological Safety Committee. Proper implementation of the plan will be the responsability of the RSO and his Office.

5. Compliance already achieved.

E. 1. Violation is admitted.

2. Reason for violation: The RSO did not perform the quarterly inventory, instead he performed a biannual inventory.

3. Corrective steps

a) The physical inventory is now in compliance with 10CFR35.59 (g).

b) From April 2, 1990 to present, the inventory has been conducted every 3 months as required by the regulations.

4. Corrective steps to prevent future violations
- The physical inventory is included in the annual working plan.

- The Radiological Safety Committee will perform a quarterly review of the activities presented in the annual working plan.

5. Compliance already achieved.

F. 1. Violation is admitted.

2. Reason for violation: No written records of the surveys were kept in the Radiological Safety Office or elsewhere. The ambient dose measurements were performed biannualy during the physical inventories.

3. Corrective action

The ambient dose measurements are performed during the quarterly physical inventories. Record of this measurement is kept in the same document used for the physical inventories.

4. Corrective steps to prevent future violations
   - The ambient dose measurements is part of the annual working plan of the RSO. It will be reviewed by the Radiological Safety Committee on a quarterly basis.

5. Compliance already achieved.

G. 1. Violation is admitted.

2. Reason for violation: The Radiation Safety Office failed perform fume hood air velocity measurements.

3. Corrective actions

a) The air velocity measurement at different points on the chemical hood at the Nuclear Medicine hot room were performed by the Radiation Safety Office on August 31, 1990.

4. Corrective steps to prevent future violations

   - The air flow measurement at the Nuclear Medicine hot room will be performed every six months or more frequently if needed. Results will be presented to the Radiation Safety Committee by the RSO.

5. Compliance September 4, 1990.

H. 1. Violation is admitted.

2. Reason for violation: The RSO failed perform air flow measurements at the Nuclear Medicine Laboratory.

3. Corrective actions

   a) The air flow measuremnts for Xe-133 were performed by the Radiation Safety Office on August 31, 1990.

4. Corrective steps to prevent future violations

   - The measurements will be performed together with all other necessary test, as scheduled in the annual work plan. Measurements will be performed every six months, or more frequently if needed. This activities will be reviewed in the Radiation Safety Committee meetings.

I. 1. Violation is admitted.

2. Reason for violation: The Campus RSO resigned April 10, 1990. The Radiotherapy personnel opened the packages without notifying the newly appointed RSO. This was due to lack of communication.

3. Corrective actions

   a) Radiotherapy staff was instructed on the importance of complying with the requirements of the license. Violation of this procedure will be submitted to disciplinary sanctions that may result in the termination of employment of the personnel involved.

4. Corrective steps to prevent future violations
   - The established procedure will be published and distributed to all Radiotherapy personnel and staff. It will included a statement regarding the penalty for violating the procedure.

5. Full compliance already achieved.

J. 1. Violation is admitted.

2. Reason for violation: The new RSO failed to performed the annual review of the Radiation Safety Program with the Committee.

3. Corrective actions

   a) The revision of 1989 was performed on May 1990, and the 1990 revision will be presented on the first meeting on 1991.

4. Corrective steps to prevent future violations
   - The review of the program is part of the annual working plan. The Radiation Safety Committee, on its first quarterly meeting will include as part of its agenda the revision of the program presented by the RSO.

5. Full compliance already achieved.

K. 1. Violation is admitted.

2. Reason for violation: All the required test were performed by the Nuclear Medicine Physicist, and the RSO failed to sign the records.

3. Corrective action

   a) All records were reviewed and signed by the RSO as required by 10CFR35.

4. The Nuclear Medicine Physicist will notify the RSO in writting when the test are performed. The RSO will review and sign all the records required for the dose calibrator. He shall report to the Radiation Safety Committee on the status of the testing and the records.

5. Full compliance already achieved.

II. Violations of License No. 52-01946-09

A. 1. Violation is admitted.

2. Reason for violation: The spot checks were adequately performed by the Assistant Physicist, the Radiotherapy Physicist failed to review them as required.

3. Corrective action

   a) All spot checks from April to date were reviewed by the Radiotherapy Physicist.

4. Corrective steps to prevent future violations

   - Dr. Heriberto Torres, will only have the duties of Radiotherapy Physicist, as soon as the new RSO is certified by NRC. An ammendment to the license, will be submitted with the documentation of the newly appointed RSO. He will continue on the position until a final full time appointment is made.

5. Full compliance already achieved.

B. 1. Violation is admitted.

2. Reason for violation: The teletherapy physicist failed to perform the required calibration.

3. Corrective action

   a) Full calibration was performed by the the teletherapy on April 6, 1990.

4. Corrective steps to prevent future violations

   - Dr. Heriberto Torres will continue as Radiotherapy Physicist until a full time appointment is made.

5. Full compliance already achieved.

C. 1. Violations is admitted.

2. Reason for violation: The teletherapy physicist and his staff failed to perform the leak test of the teletherapy unit.

3. Corrective actions

   a) The leak test were performed on April 19, 1990 and it was satisfactory.

4. Corrective steps to prevent future violations

   - The teletherapy physicist and his staff will perform the test every 6 months and report the results to the RSO. The RSO will report to the Radiation Safety Committee.

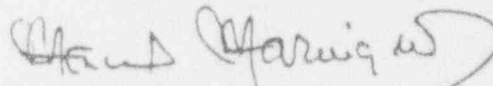
5. Full compliance already achieved.

We hereby request that the proposed civil penalties be decreased or eliminated due to the fact that the alleged violations were corrected, and the University of Puerto Rico has taken the necessary steps to avoid future violations.

In your evaluation of our response to the Notice of Violation, please consider, that the University of Puerto Rico is a non-profit organization dedicated to higher education. In particular, the University of Puerto Rico Medical Sciences Campus provides the services for medically indigent patients which would otherwise not receive these services anywhere else in Puerto Rico.

The University of Puerto Rico in its commitment to public health, teaching and research has a vital interest in mantaining to its fullest extent this license. Therefore, it has committed itself to a comprehensive action plan, that will prevent the occurrence of these type of incidents.

Cordially yours,



Manuel Marina, MD
Acting Chancellor
Medical Sciences Campus

I hereby certify that the above information is true to the extent of my knowledge.

Manuel Marina, MD
Acting Chancellor
Medical Sciences Campus