



# LABORATORIO MEDICINA NUCLEAR

HOSPITAL DEL MAESTRO

5to. PISO - AVENIDA DOMENECH

HATO REY, PUERTO RICO 00918

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Tel. 765-5160

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Ext. 1118

April 2, 1985

30-08602

Mr. J. Philip Stohr  
Director Division of Radiation  
Safety and Safeguards  
U. S. Nuclear Regulatory Commission  
101 Marietta Street, N. W.  
Atlanta, Georgia 30303

License No. 52-15086-01

Dear Mr. Stohr:

This is in response to your letter of March 6, 1985 regarding the violations identified during the inspection carried out on January 22, 1985 on the Nuclear Medicine Laboratory of the Teacher's Hospital.

Statement 1a.

- a. Although established procedures require the establishment of a Hospital Radiation Safety Committee with certain required members that will meet quarterly, such a committee had not been properly established and no meetings had been held.

This was true from the standpoint of the Hospital Radiation Safety Committee which had not been properly constituted after the appointment of Dr. Heriberto Pagán Saez as the new head of the Department of Radiology in June 1984. The laboratory, as a department has its own safety committee with the following members:

- 1- Mr. Santiago Gomez-Health Physics Consultant
- 2- Dr. Juan E Rizek-Nuclear Medicine Specialist
- 3- Mr. Pablo T. Collazo-Supervisor Nuclear Med. Technologist
- 4- Dra. Lillian Conde de Borrego-Consultant in Nuclear  
Medicine
- 5- Sra. Sonia Soto-Medical Technologist
- 6- Srta. Carmen Aida De León-Nuclear Medicine Administration

This committee had met quarterly and reviewed Safety precautions at the laboratory. Minutes of the meeting were kept and documented. It has met on two occasions since the inspection of January 22, 1985- (January 28, 1985 and February 4, 1985. Also on March 4, 1985 and April 1, 1985. Regular meetings are scheduled for May, August and December 1985).

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The Hospital has appointed a Hospital Radiation Safety Committee which will be composed of:

- 1- Dr. Heriberto Pagán Saez-Head, Dept of Radiology
- 2- Dr. A. A. Cintrón Rivera-M.D., F.A.C.N.P., Nuclear  
Medicine Specialist Director
- 3- Mrs. Maria T. Rivera-Nursing Department
- 4- Mr. Filiberto Garcia-Administrator of Teacher's Hospital  
B.A, M.P.H.A.
- 5- Mr. José Pacheco, M.S. - Hospital Health Physics  
Consultant
- 6- Dr. J. E. Rizek-M.D.-Director Nuclear Medicine Laboratory.

The committee had an organizational meeting and has a scheduled meeting for tuesday April 9, 1985 at 11:30 A.M.. This committee is schedule to meet on a quarterly basis: June, September and December 1985. Full compliance achieved by March 15, 1985.

### Statement 1b.

- b. Although established procedures require annual in-service training of ancillary personnel who work in or frequent restricted areas, such training had not been conducted.

This is true since training was offered on an informal basis and was not documented. Provisions have been made to give formal training to all personnel involved in bringing patients to and from the Laboratory and Wards of the Hospital including-nurses, nursing aides, maintenance and cleaning personnel, etc. Conference was given on March 5, 1985 by Dr. J.E. Rizek and Mr. Santiago Gomez on the general aspects of Handling, caring and transportation of patients receiving isotopes for diagnostic purposes.

Documentation of attendance to those conferences has been made.

Training, Documentation and Conferences will be schedule on a quarterly basis to present-careof patients receiving therapeutic doses of isotopes, Health Physics aspects of Radioisotopes; Low level Waste Disposal; and other subjects of interest as well as needed to run this laboratory. Full compliance achieved by March 5, 1985.

### Statement 1c

- c. Although established procedures require daily surveys of the Nuclear Medicine Department, such surveys had been conducted weekly.

This is true because of a misunderstanding from the part of the personnel involved. Surveys were performed on a weekly basis and were documented. However, Daily surveys of Hot laboratory, preparation area and patient's area were started to be performed and are being carried out on a daily basis by a properly trained person (Nuclear Medicine Technologist trained by Radiation Physicist) with proper written documentation since January 28, 1985.



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Full compliance achieved and maintained since that date up to present.

### Statement 1d.

- d. Although established procedures require swipes on final source containers of radioactive packages received, such swipes had not been performed on any packages received.

Visual inspection had always been performed. When no damage was observed grossly no swipe tests were performed, but only radiation levels were determined on every shipment. This was documented by chief technologist. Swipe tests were not performed on a routine basis. Starting on every shipment after February 3, 1985, swipe tests are being performed in addition to visual and radiation levels determinations and are properly documented.

Full compliance achieved and maintained since that date (February 3, 1985) up to present.

### Statement 1e.

- e. Although established procedures require weekly tests in the Nuclear Medicine Department, such surveys had been performed every two weeks instead of weekly.

True. This test had been performed on a biweekly and properly documented, due to a misunderstanding from the part of the radiation physicist. Starting on January 31, 1985, swipe tests are being performed in many potentially contaminated areas in the laboratory by the Radiation Physicist consultant on a weekly basis and is being properly documented. Full compliance achieved and maintained up to date since January 31, 1985 up to present

### Statement 1f

- f. Although established procedures require quarterly linearity checks on the dose calibrator, such checks had been performed semiannually.

Linearity tests were performed on February and July 1984 and also on January 1985 and were properly documented.

Linearity tests are being done on a quarterly basis using the manual method described in our application according to appendix D of the Nuclear Regulatory Commission guide for License application.

To facilitate the performance of the test we plan to use the Atomic Products Lineator, provided the Nuclear Regulatory Commission approves the change. Application for amendment of our License for this has already been submitted early in February 1985.

Full compliance achieved on January 28, 1985. Linearity tests will be performed on April, July, October 1985 and January 1986.



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### Statement 1g

- g. Although established procedures require the use of syringe shields, such shields had not been used recently since the shield was broken.

True. The shield was noted broken early in January 1985 before the inspection. A replacement was ordered from Atomic Products on January 15, 1985 and had not been received at the time of inspection. This has been received by the February 6, 1985 meeting. An additional shield has been procured in order to prevent that particular event from recurring.

Full compliance achieved by February 6, 1985.

### Statement 2.

2. 10 CFR 35.14 (B) (ii) requires a license, before administration to patients, to cause each elution or extraction of technetium-99m from a molybdenum-99/technetium-99m generator to be tested to determine either the total molybdenum-99 activity or the concentration of molybdenum-99.

True. Dose calibrator and was not adequate for the measurement of molybdenum and daily measurements had not been performed.

Daily determinations of molybdenum-99 breakthrough test is being performed on every elution obtained since February 11, 1985 and they are being properly documented.

An AccuCal Dose calibrator has been obtained from Nuclear Pharmacy, Inc. and will be installed in our laboratory. This will expedite our accurate and efficient compliance with this required activity.

Full compliance of this violation has been achieved as of February 11, 1985.

Corrective steps taken to avoid further violations include the preparation of a monthly overall check list of the radiation safety programs to be reviewed by the Director of the Laboratory-Dr. Juan E. Rizek, the Radiation Physicist Consultant to the Laboratory Mr. Santiago Gomez and the Nuclear Medicine specialist, Dr. A. A. Cintrón Rivera. The meeting schedule for the 2nd. Monday of each month will consider the previous month list and will require each person responsible for the compliance of the activities. All documents related to that activity. (Please see addendum A).

We hope that the above information will be of help.

Thanking you for your cooperation,

Cordially yours,

*A. A. Cintrón Rivera*  
Dr. A.A. Cintrón Rivera  
Nuclear Medicine Laboratory

*Filiberto Garcia*  
Approved: Filiberto Garcia, MHSA  
Administrator  
Hospital del Maestro



## RADIATION SAFETY INSPECTION CHECK LIST.-

No. \_\_\_\_\_

To: \_\_\_\_\_

From: \_\_\_\_\_

Date: \_\_\_\_\_

The following Items related to the Radiation Protection Program and NRC Regulations require your consideration to take immediate action, comply and document:

- \_\_\_\_\_ Copy of the Licenses and Amendments
- \_\_\_\_\_ Copies of 10CFR-Parts 19,20,21,30,35,40,50
- \_\_\_\_\_ Radioactive Materials shipments Radiation Survey and Records
- \_\_\_\_\_ Daily Radiation Survey to the "Hot Room"
- \_\_\_\_\_ Calibration check of the Dose Calibrator
- \_\_\_\_\_ Mo-99 Breakthrough Test
- \_\_\_\_\_ Linearity Test of the Dose Calibrator
- \_\_\_\_\_ Film Badges Service and Radiation Exposure Records
- \_\_\_\_\_ Radiation Sources Leak Test and Inventory
- \_\_\_\_\_ Instructions to Personnel and Continued Education
- \_\_\_\_\_ Weekly Radiation Survey and Contamination Control
- \_\_\_\_\_ I-131 Therapeutic Treatments radiation surveys and records
- \_\_\_\_\_ Radioactive Waste collection and disposal
- \_\_\_\_\_ Radiation Detection Instruments Calibration
- \_\_\_\_\_ Up-takes and/or Bioassays
- \_\_\_\_\_ Radiation Labels, Emergency Procedures, Notice to Employees...etc
- \_\_\_\_\_ Radiation Safety Committee meetings
- \_\_\_\_\_ OTHERS \_\_\_\_\_

REMARK: Full compliance due to \_\_\_\_\_

*Addendum A*