

RYDER MEMORIAL HOSPITAL, INC.

RECEIVED
A Growing Community Institution



P.O. BOX 489
HUMACAO, PUERTO RICO
00661

MAY 10 AM 8 49

May 4, 1982

Mrs. Patricia C. Vacca
Material Licensing Branch
Division of Fuel Cycle and
Material Safety
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Control No. 10911

Dear Mrs. Vacca:

Thank you for your letter dated April 23, 1982 in which you request additional information in support of our application for a new license.

For the sake of clarity, I shall reply in the same order, item per item.

Item 1a.

1. Licenses in which Mrs. M.M. Palacios de Lozano has fulfilled the responsibilities of Radiation Safety Officer are:

I. González Martínez Oncologic Hospital

Byproduct Material License No. 52-00544-02
" " " No. 52-00544-03
" " " No. 52-13471-01

Pavia Hospital

Byproduct Material License No. 52-15139-01

Auxilio Mutuo Hospital

Byproduct Material License No. 52-08827-02

Bayamón Nuclear Medicine Laboratory - José T. Medina, M.D.

Byproduct Material License No. 52-14931-01

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REG2 LIC30
52-21026-01 PDR

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INSPECTION AND ENFORCEMENT

San Juan City Hospital

Byproduct Material License No. 52-06121-02

St. Luke's Episcopal Hospital

Byproduct Material License No. 52-16061-01

Hospital General Guadalupe 2000

Byproduct Material License No. 52-17704-01

In addition please find enclosed a copy of Mrs. Lozano's curriculum vitae.

Item 1b.

Mrs. Lozano is not a full-time employee but a consultant. She will visit the nuclear medicine laboratory once a week, once we obtain the license and the laboratory starts to operate as such.

Dr. Angel L. Torres-Noya is the Deputy Radiation Safety Officer who will assume the duties on a day to day basis.

Item 2

Enclosed please find a copy of a memorandum from the Division of Physics of the Department of Radiological Sciences, University of Puerto Rico Medical Sciences Campus which provides the requested information.

We intend to use the survey instrument calibration services described in said memorandum.

Item 3

As indicated under Item 11 of our application, we are purchasing New England Nuclear Cat. No. 362 dose calibrator reference sources which consist of:

Co - 57 - 5 m Ci
Co - 60 - 50 uCi
Cs - 137 - 200 uCi

Each source is calibrated with $\pm 5\%$ accuracy at the 99% confidence level, NBS traceable.

Item 4

Hematologist - Jorge W. Perdomo, M.D.
Nursing Staff Member - Carmen M. Gómez, M.N.S.
Director Nursing Department

0736

Item 5

Enclosed please find a copy of our revised procedures for ordering and receiving radioactive material, which we hope will meet your approval.

Item 6a

Enclosed please find copy of memorandum to the carrier to be posted at the Nuclear Medicine Laboratory door and inside the imaging room.

Item 6b

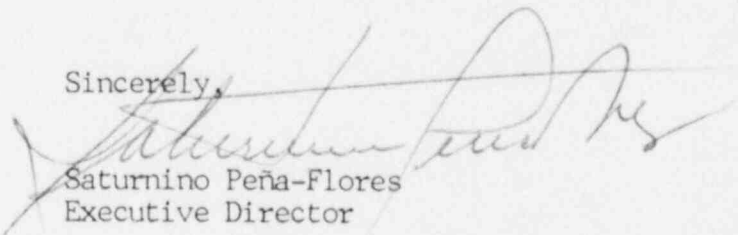
The "other buildings" referred to are part of the same hospital; they are buildings other than the one where the Nuclear Medicine Laboratory is to be located. There might be occasions in which the condition of the patient merits that the administration of the radiopharmaceutical be carried out in the patient's room.

Item 7

Since it seems inescapable to provide a hood for the opening of bottles containing more than 50 mCi of I-131, we have decided to postpone authorization to treat carcinoma of the thyroid with doses that require hospitalization. We need time to decide where to locate the hood, etc. and we cannot afford to delay the license petition any further. Hence, we wish to be authorized to treat carcinoma of thyroid with doses up to 30 mCi.

Please advise if any additional information is required.

Sincerely,


Saturnino Peña-Flores
Executive Director

CURRICULUM VITAE

NAME: Palacios de Lozano, María M.

FIELD: Physics; Industrial Health; Radiological Physics

EDUCATION: B. S. (Physics) University of Puerto Rico
-----1958

M. S. (Industrial Health) University of Cincinnati-----1960

M. S. (Health Physics)- University of Rochester
-----1961

EXPERIENCE: Head, Physics Department, I. González Martínez Hospital-----July 1970-Feb. 1980

Hospital Physicist, I. González Martínez Hospital-----1968-70

Hospital Physicist, I. González Martínez Hospital (Ad Honorem)-----1963-68

Head, Physics Section, Radiotherapy and Cancer Division, Puerto Rico Nuclear Center
-----1967-70

Senior Associate, Radiotherapy and Cancer Division, Puerto Rico Nuclear Center 1961-70

Instructor in College Physics
University of Puerto Rico-----1958-59

Assistant Instructor in Physical Sciences,
University of Puerto Rico-----1957-58

OTHER: Radiological Physicist (Consultant)
Radiotherapy
V. A. Hospital-----Oct. 1980 to present

Radiation Safety Officer (Consultant)
Nuclear Medicine Laboratory
Guadalupe Hospital-----Jan. 1978 to present

Radiation safety Officer (Consultant)
Nuclear Medicine Laboratory
San Juan City Hospital----July 1976 to present

Radiation Safety Officer (Consultant)
Nuclear Medicine Laboratory
Auxilio Mutuo Hospital----March 1976 to present

Radiation Safety Officer (Consultant)
Nuclear Medicine Laboratory
San Lucas Hospital-----March 1974-Aug. 1975

Radiation Safety Officer (Consultant)
Nuclear Medicine Laboratory
Hermanos Meléndez Hospital----1971-June 1979

Radiation Safety Officer (Consultant)
Matilde Brenes Hospital
Nuclear Medicine Laboratory --1971-June 1979

Radiation Safety Officer (Consultant)
Nuclear Medicine Laboratory
CT Radiology Complex-----1971 to present

Radiation Safety Officer (Consultant)
Pavía Hospital----- July 1970 to present

President, Puerto Rico Chapter of the
Health Physics Society-----1970-71

Puerto Rico Nuclear Center
Alternate representative, Standards
Committee N-44, American National Standards
Institute-----1968-70

PUBLICATIONS:

"Early Effects of Irradiation of the
Normal Thyroid Gland", A. Bosch, M. D.
A. Lanaro, M. D., S. Irizarry, M. D. and M. M.
Palacios, M. S., Rev. Interam. Radiol.,
Vol. III, No. 2, Peru, 1968

SOCIETIES:

Health Physics Society
American Public Health Association
American Association of Physicists in Medicine
Member, Academy of Kettering Fellows
Puerto Rico Nuclear Medicine Society
Honorary Member, Radiological Society of Colombia



SCHOOL OF MEDICINE
DEPARTMENT OF RADIOLOGICAL SCIENCES

DIVISION OF PHYSICS

MEMORANDUM

TO : All users of Instruments Calibration
facilities of the UPR-Medical Sciences Campus

FROM : Dr. Heriberto Torres, Head
Division of Physics

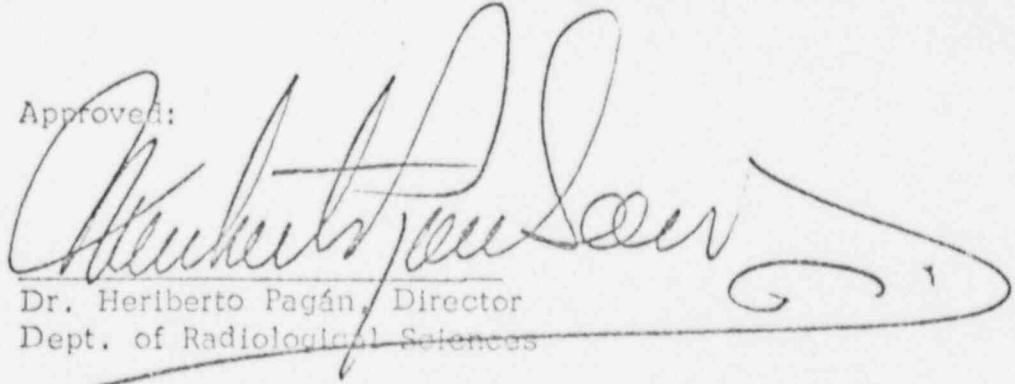
SUBJECT : Access to Cs-137 Calibration Source

DATE : March 22, 1982

The University of Puerto Rico (UPR) Medical Sciences Campus through the Division of Physics of the Department of Radiological Sciences is organizing the Instruments Calibration Services for any outside NRC Licensee or X-Ray Department who may need a gamma or X-Ray survey meter calibration. A calibration fee will be charged.

You are authorized to have access to the calibration facilities and use the Cs-137 source (100 mCi - 12/69 Nuclear Associates - Mod. 64-764 Serial No. 166). This source can not be removed from the Medical Sciences Campus and the Radiation Protection Officer will supervise the calibration procedures to comply with the Radiation Protection Program of the UPR - Medical Sciences Campus NRC - Lic. No. 52-01946-07 and Appendix D of the USNRC - Regulatory Guide 10.8

Approved:


Dr. Heriberto Pagán, Director
Dept. of Radiological Sciences

PROCEDURES FOR ORDERING AND
RECEIVING RADIOACTIVE MATERIAL

C-738

1. The Head Nuclear Medicine Technologist will place all orders for radioactive materials and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.
2. A system for ordering and receiving radioactive materials will be established and maintained.
 - a. Ordering of routinely used materials
 1. Written records that identify the isotope, compound, activity levels, and supplier, etc., will be used.
 2. The written records will be referenced when opening or storing radioactive shipment.
 - b. Ordering of specially used materials (e. g. therapeutic uses)
 1. A written request will be obtained from the physician who will perform the procedure. In the case of special orders, the physician's written request and appropriate shipping/receipt records will be referenced and the dose assayed prior to its administration.
 2. Persons ordering the materials will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, etc.
 3. The physician's written request will be referenced when receiving, opening, or storing the radioactive material.
 - c. It is essential that written records be maintained for all ordering and receipt procedures.
3. Radioactive shipments are shipped to Puerto Rico by the supplier by aircraft. A commercial carrier, employed by the supplier's local distributor, brings the shipment to the Nuclear Medicine Laboratory. Hence, the control on the part of the Laboratory over incoming radioactive shipment starts upon its arrival at our premises. Most radioactive shipments arrive during off-duty hours, on Sundays. The carrier brings shipment over to the Nuclear Medicine Laboratory; he

opens up the door to the isotope camera room (he has his own copy of the key) and leaves the shipment inside the isotope camera room, in front of door to "hot" room (he does not have key to "hot" room); he then locks the door to the isotope camera room and leaves. Specific instructions are outlined in attached memorandum which is to be posted at main lab door and inside camera room. In this manner, said shipments are secured against unauthorized removal. These shipments are then removed on the next working day by the technician, who then proceeds as per instructions given under the section "Instructions to Personnel Receiving and Opening Package of Radioactive Material".

4. Byproduct material to be administered to humans shall be procured:
 - a. in prepackaged, precalibrated form from a supplier who manufactures or repackages the product under appropriate pharmaceutical controls related to assay, identity, quality, purity, sterility and pyrogenicity; or,
 - b. in the form of duly authorized generators, which will provide radionuclides to be used in conjunction with duly authorized kits to yield the radiopharmaceutical to be administered to humans.
5. In the preparation of radiopharmaceuticals using generators as the source of the radioactive component, the manufacturer's elution procedures shall be strictly followed. Likewise, the preparation of the radiopharmaceutical shall be carried out strictly following the manufacturer's instructions for the specific kit involved.
6. All patient doses will be assayed prior to administration using the dose calibrator, whose calibration will be routinely checked with a Co-57, a Cs-137 and a Co-60, standard source. Syringe shields shall be used for preparation and administration of patient's doses, without exception.

7. RECORD BOOK ON PROCUREMENT AND UTILIZATION:

As a further safeguard in the protection of personnel and in order to properly furnish information on the procurement and utilization of radionuclides to individuals responsible for conducting inspections regarding observance of safety measures dealing with such hazardous materials, the following information will be officially recorded:

- a. Type of radionuclide procured
- b. Amount of radionuclide procured
- c. Amount of radionuclide authorized by the Nuclear Regulatory Commission
- d. Amount of radionuclide administered, in toto, per human subject
- e. Disposition of excreta from human subjects involved in clinical procedures using radionuclides.
- f. Level of activity of radionuclide in the excreta
- g. General statements as to the potential hazard of feces and urine disposed of.
- h. A register will be maintained of all radionuclide material on hand and an accounting will be made of material procured.
- i. Samples transferred to other buildings shall never exceed 2.5mCi; samples up to 2.5mCi may be transferred only if their half-life is less than 10 days.
- j. Radionuclides in solution should be stored in a metal container so that, in case of leakage, the contents will be contained therein.

RYDER MEMORIAL HOSPITAL, INC.

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P.O. BOX 489
HUMACAO, PUERTO RICO
00661

April 30, 1982

MEMORANDUM

To: Delivery Personnel Who Deliver
Packages Containing Radioactive Material
to the Nuclear Medicine Laboratory

From: Mr. Saturnino Peña Flores
Executive Director

Subject: Delivery of Packages Containing Radioactive Material

Any packages containing radioactive material that arrive outside of working hours, or on Sundays shall be brought immediately to the Nuclear Medicine Laboratory camera room. Unlock the door to the camera room, place the package on top of the counter immediately to the right of the door and next to the camera control; relock the door as you leave.

If the package is wet or appears to be damaged, immediately contact the hospital Radiation Safety Officer and/or the Deputy Radiation Safety Officer. The carrier must remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

Radiation Safety Officer: Mrs. M. M. Palacios de Lozano, MS -
Home Phone: 789-5637.

Deputy Radiation Safety Officer: Angel Torres Noya, M. D.,
Home Phone: 789-5364.