MC # 252361

HOSPITAL SAN PABLO

CALLE SANTA CRUZ NO. 70
URB. SANTA CRUZ
P. O. BOX 236
BAYAMON, PUERTO RICO 00621-6036

TEL. 786-7474

September 21, 1988.

U.S. Nuclear Regulatory Commission, Region II
Nuclear Materials Safety Section
101 Marietta Street, Suite 2900
Atlanta, Georgia 30323

To whom it may concern:

This letter represents an application for material license renewal. Our license number is 52-21325. We are proceeding according to comunication sent by FAX and mail on August 19, 1988 (see copies attached).

As instructed on the "Instruction for Preparation of Application for License Renewal" leaflet (Form FCML:A, Enclosure 1), we proceed as follows:

1. There have been no changes in our licensed activities. There have been no changes in authorized users. There have been no changes in our activities according to ammendments of regulations.

2. Information and documents submitted in March 15 and June 30, 1983, describes all activities in our laboratory. No changes have occured since then.

3. If any further information is needed, please contact:

Mr. Jorge Torres, MHSA
Associate Administrator
Hospital San Pablo
Tel.(801)740-4747 Ext. 234

Mrs. Nilsa Guzmán, C.N.M.T.
Radiology and Nuclear Medicine Department Manager
Hospital San Pablo
Tel. (801)740-4747 Ext. 337

Thanks for your cooperation and prompt response to this matter.

Cordially yours,

Jorge A. Torres, MHSA
Associate Administrator

Enclosure:

1. Copy of License
2. Copies of previous communications
3. Fees for license renewal

030-20510

MS12 0937

HOSPITAL SAN PABLO

'83 JUL 11 P3:35

June 30, 1983

Mr. Earl. G. Wright
Material Certification and Procedures Branch
U. S. Nuclear Regulatory Commission
Washington, DC 20555

RE: Control No. 14270

Gentlemen:

This is in reference to your request for additional information about our application for a materials license dated March 11, 1983. Each item, as indicated on June 7, 1983 letter, is answered as follows:

A. ITEM 5 - The Radiation Safety Officer (RSO) in a day to day basis will be Dr. René Dietrich.

B. ITEM 8 - At the present time the only material considered to be used from Group IV and V is Iodine 131. Both Dr. Dietrich and Dr. Medina, are authorized under License No. 52-14931 to use I-131 as Iodine to treat hyperthyroidism and thyroid carcinoma. Additional information will be provided by these doctors, if needed, for other material under Group IV and V.

C. ITEM 11 & 19 - We do not have a fume hood in our laboratory. But the only circumstance that workers will be exposed to fumes from Iodine 131 is when treatment of thyroid carcinoma is carried out. This procedure is not a routine, it is the exception. When a patient is considered for treatment he is hospitalized. The total dose to be given is requested from the supplier and the same patient drinks the I-131 dose from the shielded vial using a plastic straw, under the supervision of

Reg Guide 8.30

COPY SENT REGION

P.O. Box 236, Bayamón, Puerto Rico 00621-6036 – (809) 786-7474

the authorized medical licensee. This procedure will be carried not more than one (1) per month or less. As a routine, surveys in each patient room will be conducted and thyroid uptake for each worker in the laboratory carried out every six months. With this limited working time the probability of exceeding the maximum intake of radioactive material is negligible. When the dose to be given is less that ten (10) millicuries the use of capsules is preferable and implemented.

D. ITEM 12 - The training program for our Nuclear Medicine employees and related personnel was revised and covers all the pertinent items indicated in 10 CFR Part 19 and in the Regulatory Guide Page 10.8 - 8. When implemented, lesson plans and participation records will be available for inspection.

E. ITEM 13 - Procedures for ordering and receiving radioactive material:

The following additional instructions and controls are included in the hospital procedures for ordering and receiving radioactive material.

1. Ordering radioactive material:

   a. Provide written records identifying the isotope, compound, activity and supplier.

   b. The written records will be reference when opening or storing radioactive shipment.

   c. All written request shall be signed by the authorized physician user.

   d. The same procedure applies to all orders of radioactive material.

5. During normal working hours carriers will be instructed to deliver radioactive packages directly to the nuclear medicine laboratory.

Please consider the above additional information in order to expedite the consideration of our license request in such a way that we can start providing the service our patients are demanding.

Cordially,

Santiago Rivera Ortiz, MHSA
Associate Administrator

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cc Mr. Daniel Torres
Physicist Consultant

Mr. Roberto Hernández
Administrator

Dr. José Anzalotta
Chief, Radiology Department

HOSPITAL SAN PABLO

25300 $190.00
Application
4/4/83
Brown

4/4/83
APRIL 5 D.L.
Brown

March 15, 1983

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

Gentlemen:

Enclosed please find, duly completed and signed, the Application for Materials License-Medical. Also, check #25300 for $190.00 corresponding to the application fee.

If additional information is needed, do not hesitate to contact with our offices. Thank you.

Cordially,

Santiago Rivera Ortiz, MHSA
Associate Administrator

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Enclosures

'83 MAR 23 P2:37

14270

P.O. Box 236, Bayamón, Puerto Rico 00621-6036 -- (809) 786-7474

FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION **APPLICATION FOR MATERIALS LICENSE – MEDICAL**	Approved: GAO R0557

INSTRUCTIONS – *Complete items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(Institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Hospital San Pablo
PO Box 236
Bayamón, PR 00621-6036

TELEPHONE NO.: AREA CODE (809) 786 - 7474

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

#70 Santa Cruz St. 02120
Urb. Santa Cruz
Bayamón, PR 00619

L E L 21325

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Mr. Santiago Rivera Ortiz

TELEPHONE NO.: AREA CODE (809) 786 - 7474

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*

a. ☒ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☐ RENEWAL OF LICENSE NO. 30-20510

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

Dr. René Dietrich
Dr. José T. Medina

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Mr. Daniel Torres, MS

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I	x	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	x	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		2 curies
10 CFR 35.100, SCHEDULE A, GROUP IV	x	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	x	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	x	100
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	x	150 mCi
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE

14270

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. 1 Date: October 1980

7. MEDICAL ISOTOPES COMMITTEE	
X	Names and Specialties Attached; and
X	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
	Supplements A & B Attached for Each Individual User; and See note
	Supplement A Attached for RSO. See note
9. INSTRUMENTATION *(Check One)*	
	Appendix C Form Attached; or
X	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
X	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
	Equivalent Procedures Attached; and
X	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
X	Appendix F Procedures Followed; or
	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X	Appendix G Rules Followed; or
	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
X	Appendix H Procedures Followed; or
	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
X	Appendix I Procedures Followed; or
	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
X	Appendix J Form Attached; or
	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
X	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	Detailed Information Attached; and
	Appendix L Procedures Followed; or *(Check One)*
	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon -- 133)	
	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

	TYPE (Check appropriate box)		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY		FILM	Landauer Co.	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER	X	FILM	Landauer Co.	Monthly
		TLD		
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

Pocket dosimeters will be available for visitors in the laboratory and also for nurses when I-131 be used for treatment of thyroid carcinoma.

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

(1) LICENSE FEE CATEGORY:
Human Use of Byproduct Material

(2) LICENSE FEE ENCLOSED: $ $190.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)*
Santiago Rivera Ortiz

(2) TITLE
Associate Administrator

c. DATE
March 15, 1983

FORM NRC-313M (8-78)

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on Form NRC-313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

HOSPITAL SAN PABLO
BAYAMON, PUERTO RICO

ADDITIONAL INFORMATION FOR LICENSE APPLICATION

ITEM #7 -- Radiation Safety Committee:

1. Dr. Rene Dietrich - Radiologist
2. Dr. José T. Medica - Radiologist
3. Mr. Santiago Rivera Ortiz - Associate Administrator
4. Mr. Daniel Torres - Medical Physicist
5. Miss Luz de Lourdes Rivera - Nurse
6. Mrs. Melania Santiago - Chief X-Ray Technologist
7. Ing. José L. Fortuño - Safety Committee President

ITEM #8 - Training and Experience

A. Individual Users

Dr. René Dietrich and Dr. José T. Medina are authorized users under N.R.C. License (#52-14931-01) at Bayamón X-Ray Laboratory.

B. Mr. Daniel Torres, MS, has N.R.C. License (#52-18306-01). Also he is R.S.O. for licenses #52-13598-03, #52-11832-02, #52-10270.

ITEM #9 - Instrumentation

Survey meters:
1. Victoreen Thyac III or Model 491
2. Nuclear Associates - Mini monitor II
3. Picker Dose Calibrator
4. Picker Dyna Camera 4/15
5. Picker Clinical Analyzer
6. Picker Counter (scaler) Probe for Iodine Up-take Purposes

ITEM #10 - Calibration of Instruments

All instrument calibrations will be made by our R.S.O., Mr. Daniel Torres, who is authorized by license and experience as shown in enclosed letters.

Appendix D Procedures followed

ITEM #11 - Facilities and Equipment

The Nuclear Medicine Laboratory will be localized in an annex building adjacent to the main hospital and designed to accomodate a C.T. Scanner and Ultrasound Unit and the Nuclear Medicine Laboratory. The total area is designed for special studies and only personnel involved in such activities will be around. Patients will be accepted by previous appointments.

All walls are made of concrete and the areas designed for storage and decay will have lead bricks nest. Also an "L-Shape block" will be available for technologist protection. A home-made lead nest will be available for waste area.

The hot laboratory room will have only one (1) entrance and only authorized personnel will have access to it. The environs ot the laboratory will be doctors' offices and the area of the C.T. Scanner.

The walls thickness has been evaluated considering the highest amount of radioactive material requested and the energy of such isotopes. Routine daily surveys will demonstrate if additional lead shielding is needed in the hot room.

ITEM # 12 - Personnel Training

Our laboratory personnel has been working in nuclear medicine laboratories for many years. Even though they will be instructed before assuming duties in our hospital as part of the continuous education program mandatory for all personnel.

The hospital R.S.O., Mr. Daniel Torres, will include the following topics during training periods:

a. Radiation Safety and Radiation Protection
b. License Limitations and Requirements
c. Safety Around Storage Areas
d. Pertinent N.R.C. Regulations and State Requirements
e. How to Report Incidents and Response to Emergencies
f. How to Use and Interpret Film Badges and Dosimeters
g. All Hospital Safety Regulations

ITEM # 13 - Procedure for Ordering and Receiving Radioactive Material

a. The Chief Nuclear Medicine Technologist with the authorization of the Medical Director will place all orders.

b. When accepting delivery, a log book will be kept giving date, time and isotopes received in addition to name of person receiving and delivering.

c. All deliveries of radioactive material shall be made during laboratory working hours. No delivery will be accepted during off-duty ours or holidays. This arrangement will be established with the supplier.

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

Hospital San Pablo

(Licensee's Name)

March 15, 1983

(Date)

1. Management Commitment

a. We, the management of this (medical facility, hospital, etc.), are committed to the program described in this paper for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC)[1] and a Radiation Safety Officer (RSO).

b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee (RSC)[2]

a. Review of Proposed Users and Uses

(1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

(2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

(3) The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

(1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

(2) The RSC will support the RSO in those instances where it is necessary for the RSO to assert his/her authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

[1] Private practice physician licenses do not include an RSC.

[2] The RSO on private practice physician licenses will assume the responsibilities of the RSC under Section 2.

c. Review of ALARA Program

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table 0-1 below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see Section 6).[3]

(3) The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. **Radiation Safety Officer (RSO)**

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of Section 6 of this program.

(3) Quarterly review of records of radiation level surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

4. **Authorized Users**

a. New Procedures Involving Potential Radiation Exposures

(1) The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.

(2) The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of Authorized User to Persons Under His/Her Supervision

(1) The authorized user will explain the ALARA concept and his/her commitment to maintain exposures ALARA to all persons under his/her supervision.

(2) The authorized user will ensure that persons under his/her supervision who are

[3] The NRC has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify further investigations.

subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. **Persons Who Receive Occupational Radiation Exposure**

a. The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions.

b. The worker will know what recourses are available if he/she feels that ALARA is not being promoted on the job.

6. **Establishment of Investigational Levels In Order to Monitor Individual Occupational External Radiation Exposures**

This institution (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The Investigational Levels that we have adopted are listed in Table 0-1 below. These levels apply to the exposure of individual workers.

Table 0-1

	Investigational Levels (mrems per calendar quarter)	
	Level I	*Level II*
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250

*Not normally applicable to nuclear medicine operations except those using significant quantities of beta-emitting isotopes.

The Radiation Safety Officer will review and record on Form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report), results of personnel monitoring not less than once in any calendar quarter as required by § 20.401 of 10 CFR Part 20. The following actions will be taken at the Investigational Levels as stated in Table 0-1:

a. Quarterly exposure of individuals to less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table 0-1 values for the Investigational Level I.

b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

d. Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in Table 0-1.

In cases where a worker's or a group of workers' exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The RSC will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds

the newly established Investigational Level II, those actions listed in paragraph 6.c above will be followed.

7. **Signature of Certifying Official**[4]

I hereby certify that this institution (or private practice) has implemented the ALARA Program set forth above.

Signature

Santiago Rivera Ortiz

Name (print or type)

Associate Administrator

Title

Institution (or Private Practice) Name and Address:

Hospital San Pablo
PO Box 236
Bayamón, PR 00621-6036

[4]The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator) or, in the case of a private practice, the licensed physician.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

MAR 13 1981

FCMLB:LWC
030-18227
(06759)

Mayaguez Medical Center
ATTN: Daniel Torres
Radiotherapy Department
Mayaguez, PR 00708

Gentlemen:

Enclosed is Amendment No. 11 to Byproduct Material License No. 52-13598-02 which relates to the information submitted in your January 19, 1981 letter concerning survey meter calibration procedures.

We have reviewed your procedure for performing survey meter calibrations and have found them to be acceptable for performing calibration of survey meters for outside clients.

You should advise your clients that when submitting correspondence (e.g., amendments, renewals or new applications) to the NRC which requires a reference to the calibration of the survey meters, that they should specifically list you as their consultant and reference your byproduct material license number.

Your name and license number are being added to our list of consultants whose procedures have been reviewed to determine that they are at least equivalent to the procedures outlined in Appendix D for the calibration of survey meters. Consequently, this should expediate the review process for your client with regard to this aspect of their license applications, etc.

Please note that we have amended Item 9.F. and Condition No. 18. of your byproduct material license in accordance with this licensing action.

We wish you continued success with your nuclear medicine service.

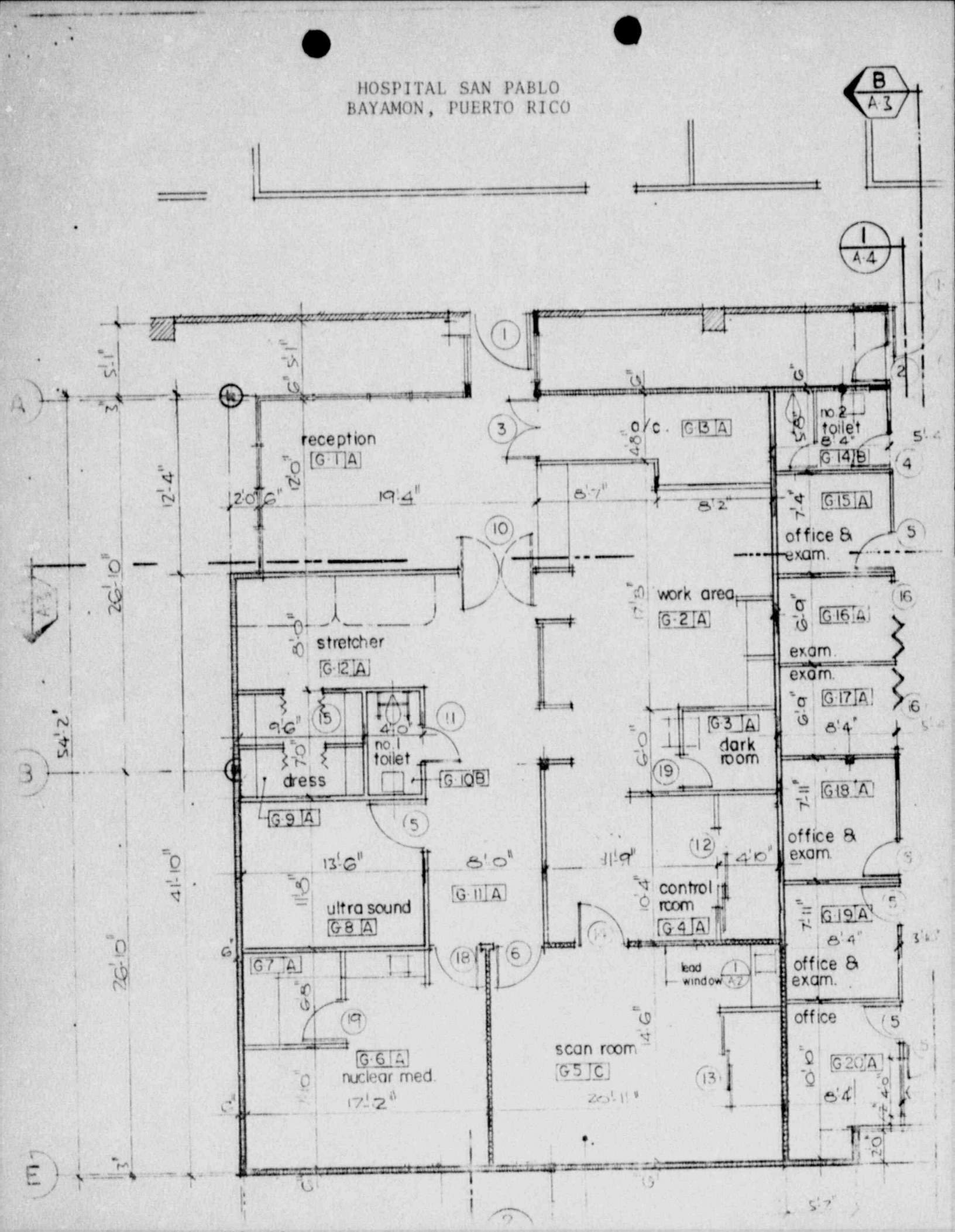
Sincerely,

Larry W. Camper

Larry W. Camper
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosure: As stated

HOSPITAL SAN PABLO
BAYAMON, PUERTO RICO



APPENDIX J

WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with § 20.303 of 10 CFR Part 20.

1. Liquid waste will be disposed of (check as appropriate)

__X__ In the sanitary sewer system in accordance with § 20.303 of 10 CFR Part 20.

_____ By commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

2. Mo-99/Tc-99m generators will be (check as appropriate)

_____ Returned to the manufacturer for disposal.

__X__ Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash.**

_____

* Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 17).

** These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

_____ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

3. Other solid waste will be (check as appropriate)

__X__ Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.

_____ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

4. The commercial waste disposal service used will be

_____

(Name) (City, State)

NRC/Agreement State License No. _____

34270