MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee			
1.	Hospital Oncológico Andrés Grillasca	3. License Number	52-11832-02
2.	P.O. Box 1324 Ponce, Puerto Rico 00733-1324	4. Expiration Date	January 31, 2002
		5. Docket or Reference No.	030-34175

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material identified in 10 CFR 35.400	A. Any brachytherapy sources identified in 10 CFR 35.400	A. 111 Gigabecquerels (3 Curies)

9. Authorized Use:

A. Medical use identified in 10 CFR 35.400.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at Hospital Oncológico Andrés Grillasca, Centro Médico Ponce, Ponce, Puerto Rico 00733.

11. The Radiation Safety Officer for this license is José N. Correa, M.D., assisted by Daniel Torres, Consultant.

12. Licensed material listed in Item 6 above shall be used by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users		Material and Use
A.	José N. Correa, M.D.	Medical uses specified in 10 CFR 35.400.
B.	Santiago N. Sallaberry, M.D.	Medical uses specified in 10 CFR 35.400.
C.	Carlos Remedios, M.D.	Medical uses specified in 10 CFR 35.400.

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13. Sealed sources containing licensed material shall not be opened by the licensee.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 52-11832-02

Docket or Reference Number 030-34175

14. In addition to the possession limits in item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35 for establishing decommissioning financial assurance.

15. The licensee shall maintain records of information important to safe and effective decommissioning at the licensee's facilities listed in Condition 10 pursuant to the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

16. A. The licensee may not possess and use materials authorized in Items 6, 7, and 8 until: (1) the licensee has constructed facilities and obtained the equipment described in the application and supporting documentation; and (2) the U.S. Nuclear Regulatory Commission, Region II, ATTN: Chief, Nuclear Materials Licensing/Inspection Branch 2, Suite 2900, 101 Marietta Street N.W., Atlanta, GA 30323-0199, has been notified in writing that activities authorized by the license will be initiated.

B. In accordance with the requirements set forth in 10 CFR 30.36(b), the licensee shall promptly notify the Nuclear Regulatory Commission, in writing, of a decision not to complete the facility, acquire equipment, or possess and use authorized material.

17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- Application dated July 31, 1996

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

HECTOR BERMUDEZ

Date JAN 9 1997

By _____

Region II, Materials Licensing/Inspection Branch 2
101 Marietta Street, Suite 2900
Atlanta, GA 30323-0199

1/9/97

N:\MLICENSE\52-11832.N01

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

JAN 9 1997

INFORMATION FOR NRC MATERIAL LICENSEES

Please find enclosed:
- ✓ Your NRC material license
- ____ Amendment to your NRC material license
- ____ Amendment renewing your NRC material license
- ____ Amendment terminating your NRC material license
- ____ Notice for Radiographer Quality Assurance Approval Program

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify this office (ATTN: Ms. Diane Heim at (404) 331-4673) so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day in the month and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR 19, "Notice, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Not possess and use materials authorized in Items 6, 7, and 8, on the license until:

   a. you have constructed the facilities and obtained the equipment described in the license application and supporting documentation; and

   b. you have notified the U. S. Nuclear Regulatory Commission, Region II, ATTN: Materials Licensing\Inspection Branch, in writing, that activities authorized by the license will be initiated.

   c. you have submitted and certified implementation of a Quality Management Program (10 CFR 35.32) for radiotherapy, or for administering >30 uCi of I-125 or I-131.

3. Notify NRC, in writing, within 30 days:

   a. when an authorized user, Radiation Safety Officer, or Teletherapy Physicist permanently discontinues performance of duties under the license or has a name change; or

   b. when the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

4. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:

   a. when you decide to terminate all activities involving materials authorized under the license; or

   b. if you decide not to complete the facility, acquire equipment, or possess and use authorized material.

(Rev. 3/96)

5. Request and obtain a license amendment before you:

   a. receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this part.

   b. permit anyone, not authorized under 10 CFR 35, Subpart J, to work as an authorized user under a license for medical use of byproduct material.

   c. permit anyone, not authorized under 10 CFR 35, Subpart J, to work as a Radiation Safety Officer, Teletherapy Physicist, or Nuclear Pharmacist, under a license for medical use of byproduct material.

   d. order byproduct material in excess of the amount, or a different radionuclide or form, other than authorized on the license;

   e. add or change the areas of use or address (or addresses) of use identified in the license application or on the license; or

   f. change ownership of your organization.

6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. Transfer of licensed materials must be consistent with 10 CFR 30.41, 40.51 or 70.42, as applicable. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a Notice of Violation, or imposition of a Civil Penalty, or an order suspending, modifying or revoking your license as specified in the "General Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600, (7/95). Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken against those who do not achieve the necessary attention to detail and standard of compliance expected of licensees.

Thank you for your cooperation.

Enclosures:
1. NRC License
2. Category Marked Below for:
   [ ] New licenses: NUREG-1600 (7/95); 19; 20; 30; 40 or 70, as appropriate; 71; 170; NRC Form 3; Agreement State list; and NRC Form 313.
   [ ] New radiography licenses: Parts 34; 150.
   [ ] New medical and teletherapy licenses: Part 35.
   [ ] Amendments and renewals: NRC Form 313.

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(Rev. 3/96)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

JAN 9 1997

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(Rev. 3/96)

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   d. order byproduct material in excess of the amount, or a different radionuclide or form, other than authorized on the license;

   e. add or change the areas of use or address (or addresses) of use identified in the license application or on the license; or

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   [ ] New radiography licenses: Parts 34; 150.
   [ ] New medical and teletherapy licenses: Part 35.
   [ ] Amendments and renewals: NRC Form 313.

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(Rev. 3/96)

OFFICIAL RECORD COPY

January 9, 1997

Hospital Oncológico Andrés Grillasca
ATTN: Mr. Angel Franceschi
Administrator
P.O. Box 1324
Ponce, Puerto Rico 00733-1324

SUBJECT: TRANSMITTAL AND EXPLANATION OF A MATERIALS LICENSE (REFERENCE: 257096, 030-34175)

Dear Mr. Franceschi:

Enclosed is License No. 52-11832-02 issued in response to your application dated July 31, 1996. Please review this document carefully and be sure that you understand all of its provisions. In particular, please note that Condition No. 16 requires, in part, that you notify us when you decide to initiate licensed activities.

In order to prevent delaying issuance of this license, please note that during our review of your application and supporting documentation, apparent weaknesses were identified. Specifically:

1. Your Quality Management Program (QMP) for brachytherapy does not appear to contain procedures:

   a. to ensure that radioactive source(s) will not move or dislodge while implanted,

   b. that describe the method(s) used to identify and evaluate any unintended deviations from a written directive,

   c. that describe the corrective action(s) that will be taken after the deviation has been identified, and

   d. that specify that a record of <u>each</u> administration will be maintained in an <u>auditable form for at least three years</u>.

2. It is our understanding that your use of the word "revised" in Item C of your QMP is intended to mean "reviewed", as "revise" in the English language means "to change, alter or modify." If your understanding is different, please let us know as soon as possible.

3. Please be aware that there is a slight difference in the requirements regarding capability of your survey meters between those used under your teletherapy license and those you will use under this license (see 10 CFR 35.420 and 10 CFR 35.620). Please ensure that the instruments used under this license meet 10 CFR 35.420.

4. Item 9 of your application states that you will use a survey instrument calibration contractor. It is still your responsibility to ensure that

your contractor will calibrate your instruments in accordance with the provisions of 10 CFR 35.51.

If you desire to revise your QMP to address the apparent weaknesses identified above, you are reminded that you will be required to submit to us a copy of the revised QMP within 30 days of the revision.

The above issues are likely to be reviewed during future inspections. If you have questions, please call me at 404/331-7880.

Sincerely,

Héctor Bermúdez
Nuclear Materials Licensing/Inspection Branch 2

Enclosure:
License No. 52-11832-02

SEND	OFC	RII:DNMS	RII:DNMS			
TO	NAME	HBermúdez	JPotter			
PDR?	DATE	1 / 9 /97	1 / 9 /97	/ /97	/ /97	/ /97
Yes No	COPY?	Yes No	Yes No	Yes No	Yes No	Yes No

OFFICIAL RECORD COPY DOCUMENT NAME: G:\DRSS\NMLS\LICLTR\257096T.HB

HOSPITAL ONCOLOGICO ANDRES GRILLASCA
DE LA
ASOCIACION PARA LA LUCHA CONTRA EL CANCER
CENTRO MEDICO DE PONCE, PONCE, PUERTO RICO

APARTADO 1324
PONCE, P.R. 00733-1324

TELEFONO
(809) 848-0800

October 21, 1996

U. S. Nuclear Regulatory Commission
Region II Nuclear Materials Safety Branch
101 Marietta St. N. W. Suite 2900
Atlanta Georgia 30323-

Re: License no. 52-11832

Subject: Quality Management Program for Brachytherapy

Gentlemen:

The following policies and procedures are to be implemented during Brachytherapy radiation doses are administered to any patient as directed by an authorized user.

A. Prior to the Administration of any prescribed Brachytherapy dose a written directive shall be completed by an authorized user. It shall include the following.

a) Patient name
b) Total Dose
c) Sources (Isotopes) to be used
d) Total activity of sources (strengths)
e) The specific treament site or volume

B) All ptients considered for brachytherapy shall be identified by more than one method; among them are:

a) Patient photograph
b) Hospital I.D. number
c) Social security number
d) Patient name, address and age.

This information will be documented in the patient record.

C) Each written directive will be revised before administering the brachytherapy dose to verify the details of the treatment plan. Among the items to be check are:

a) Radioisotope to be used
b) Number of sources
c) Sources strengths
d) Method and route of treatment

D) If any brachytherapy personnel have a question on how to carry out written directive (what to do or how it should be done) they should ask first rather than continuing a procedure.

E) Another authorized user or a qualifield individual under supervision of an authorized user, such as; (a therapy physicist, dosimetrist or senior therapy technologist) shall verify that the authorized user written directive and plan of treatment are in agreement before implanting the radioactive sealed sources.

F) To verify the identity of sources and strength of each one the following appropiate method will be used:

1. Check serial number of sources
2. Use a radiation detector and dose calibrator
3. Use of color-coded sources and locations-clearly mached for storage.

G) All temporary and permanent brachytherapy implants will be cheched by means of radiographs to verify the position of each source and for calculation purposes. In some cases if fixed geomety applicators are use the radiographs are not mandatory.

H). An authorized user shall after insertion of a temporary or permanent implant verify and record the actual loading sequence of the radioactive sources implanted and sign the patients chart or patient appropiate record.

I.) The dose calculations shall be checked before the total prescribed dose is administered. An authorized user or a qualified person under the supervision of an authorized user (eg. radiotherapy physicist, dosimetrist) whenever possible not the same person who make the original calculations should check the calculations. The brachytherapy dose should be manually calculated to a single point and the results compared to the computer-dose calculations. Manual dose calculations will be checked for at least the following.

a) Arithmetric errors
b) Appropiate transfer of data
c) Appropiate use of monograms, and graphs.

J) An authorized user will sign a written record in the patient's chart after insertion of the brachytherapy sources and prior to the completion of the procedure. The written record should include at least the radioisotope, the treatment site, total source strength and exposure time or total dose.

K) If the authorized user determines that delaying the treatment in order to perform the check of dose calculations would jeorpardize the patient's health, the authorized user will
make a notation of this determination in the record of the calculated administered dose, and the physical measurements will be performed within the next two working days of completion of the brochytherapy treatment.

L) A qualified person as a teletherapy physicist will perform an acceptance test on each treatment computer program used for brachytherapy dose calculations. The acceptance test will assess each treatment planning based on the authorized user specific needs and applications.

M) A brachytherapy Q.M. program review will be in effect. A biannually review of cases will be done by means of randomized sample. A total of 20% of the cases if the number is greater than 100 (20 cases if the number of sample cases is betwen 20 and 100 or all the cases if less than 20) will be checked.

The review will be performed by a qualified person under the supervision of the authorized user. Whenever possible the person conducting the review should not review his own work.

N) Record of the spot reviews and a summary of the findings and actions taken will be maintained for three years.

The above policies are in addition to the policies in effect for the Radiotherapy Section.

We hope this information satisfies the requirement for the Q.M. program.

Sincerely,

Daniel Torres-M.S.
Assistant R.S.O.
Physicist

HOSPITAL ONCOLOGICO ANDRES GRILLASCA
DE LA
ASOCIACION PARA LA LUCHA CONTRA EL CANCER
CENTRO MEDICO DE PONCE, PONCE, PUERTO RICO

APARTADO 1324
PONCE, P.R. 00733-1324

TELEFONO
(809) 848-0800

July 31, 1996

U.S. Nuclear Regulatory Commission
Region II License Division
101 Marietta Street, N.W. Suite 2900
Atlanta, Georgia 30323-0199

Gentlemen:

This is an application for a license to use by product material for Brachytherapy as in section 35.400. Previouly the same request was made as an amendment to our license52-11832 and a fee of $550.00 was paid. Enclosed find a check for $850.00 to complete the total fee of $1,400.00. See the documentation from office of Accounting and Finance, Office of the Controller-N.R.C..

Enclosed find application form 313 with addendums and check in the amount of $850.00.

Please let us know if additional information is needed.

Sincerely,

Angel Franceschi-M.S.H.A.
Administrator

NRC FORM 313 (10-94)
10 CFR 30, 32, 33, 34, 35, 36, 39 and 40

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120
EXPIRES 6-30-96

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (T-6 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1 THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2 NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip code)*

HOSPITAL ONCOLOGICO - PONCE
P.O. BOX 1324
PONCE, P.R. 00733-1324

3 ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

HOSPITAL ONCOLOGICO ANDRES GRILLASCA
CENTRO MEDICO PONCE
PONCE, P.R. 00733

4 NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dr. Jose N. Correa

TELEPHONE NUMBER
(787) 848-0800

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5 RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6 PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7 INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8 TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9 FACILITIES AND EQUIPMENT.

10 RADIATION SAFETY PROGRAM.

11 WASTE MANAGEMENT.

12 LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 7 C
AMOUNT ENCLOSED $ 850.00

13 CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Angel Franceschi MSHA Administrator		

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

HOSPITAL ONCOLOGICO ANDRES GRILLASCA
DE LA
ASOCIACION PARA LA LUCHA CONTRA EL CANCER
CENTRO MEDICO DE PONCE, PONCE, PUERTO RICO

APARTADO 1324
PONCE, P.R. 00733-1324

TELEFONO
(809) 848-0800

APPLICATION FOR MATERIAL LICENSE

Addendum: Items 5 thru 11 N.R.C. Form 313

Items 5&6 Radioactive Material

5.d Inplant Material in Sec. 35.400
Amount: 3 Ci Puspose: Medical use

7 Dr. Jose N. Correa: R.S.O. under license 52-11832
Mr. Daniel Torres-M.S. Physicist Assintant RSO
The same situation existing under lic. 52-11832

7.1 Authorized Users:
Dr. Jose N. Correa
Dr. Neftaly Sallaberry
Dr. Carlos Remedios
The authorized users under NRC licenses 52-11832-01 and 52-10270

8.1 We will establish and implement the model training program that was published in Appendix A to Regulatory Guide 10.8 Rev 2.

9 Instrument Calibration will be perfoimed by an authorized Contractor as at the present time: Calibration Services by RMC Company has been provided for the last two years.

9.1 Annotated drawing is enclosed.

9.4 Personnel Monitor:
We will establish and implement the model personnel external exposure monitoring program published in Appendix D Guide 10.8 Rev. 2. At present time we are using Landauer film and ring dosimetry system.

10 Radiation Safety:
At present time we have under license #52-11832-01 a Radiation Safety Committee and also the ALARA concept is implemented.

10.3 Leak Test
We will establish and implement the model procedure for leak-testing sealed sources as in appendix H to Regulatory Guide 10.8 Rev. 2.

10.6 Ordering and Receiving

We will establish and implement the model guidance for ordering, receiving and opening packages that was published in Appendix K & L to Regulatory Guide 10.8 Rev. 2.

10.11 Implant Sources and Surveys:

We will establish and implement the model procedure for keeping an inventory of implant sources and area surveys that was published in Appendix M.4 and N to Regulatory Guide 10.8 Rev. 2.

10.15 Implant Therapy

We will establish and implement the model procedure for radiation safety during implant therapy that was published in Appendix Q to Regulatory Guide 10.8 Rev. 2.

11. Waste Management

We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.2 Rev. 2.

NRC FORM 577
(1-95)

U.S. NUCLEAR REGULATORY COMMISSION

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

HOSPITAL ONCOLOGICO ANDRES GRILLASCA
ATTN: ANGEL FRANCESCHI, M.S.H.A.
ADMINISTRATOR
P. O. BOX 1324
PONCE, PR 00733-1324

TYPE OF ACTION

- [X] NEW LICENSE
- [ ] RENEWAL OF LICENSE
- [ ] AMENDMENT TO LICENSE

REQUESTED DATE: 4-18-96

LICENSE NUMBER:

CONTROL NUMBER: 257096 ATTN: RITA MESSIER, LFARB, T9E10

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
7C	$ 1,400.00	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE	$ 1,400.00
PAYMENT RECEIVED	$ 550.00
AMOUNT DUE	$ 850.00

- [ ] Your request was received without the prescribed application fee.
- [X] We received your Check No. 23463 in the amount of $ 550.00. Payment of the additional fee noted above is required.
- [ ] Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).
- [ ] Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

- [ ] Enclosed is Check No. _____ which accompanied your request. The fee is not required because:
  - [ ] We received your Check No. _____ in payment of the fee.
  - [ ] The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.
  - [ ] Your request was combined, prior to review, with your _____ request, Control No. _____.

III. CHECK RETURNED

- [ ] Enclosed is Check No. _____ which was returned to us by the bank for:
  - [ ] INSUFFICIENT FUNDS
  - [ ] ACCOUNT CLOSED
  - [ ] OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

- [ ] License No. _____, Amendment No. _____, issued on _____ was issued without the required fee being collected. The fee required is noted in Section I of this form.
- [ ] The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).
- [ ] Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

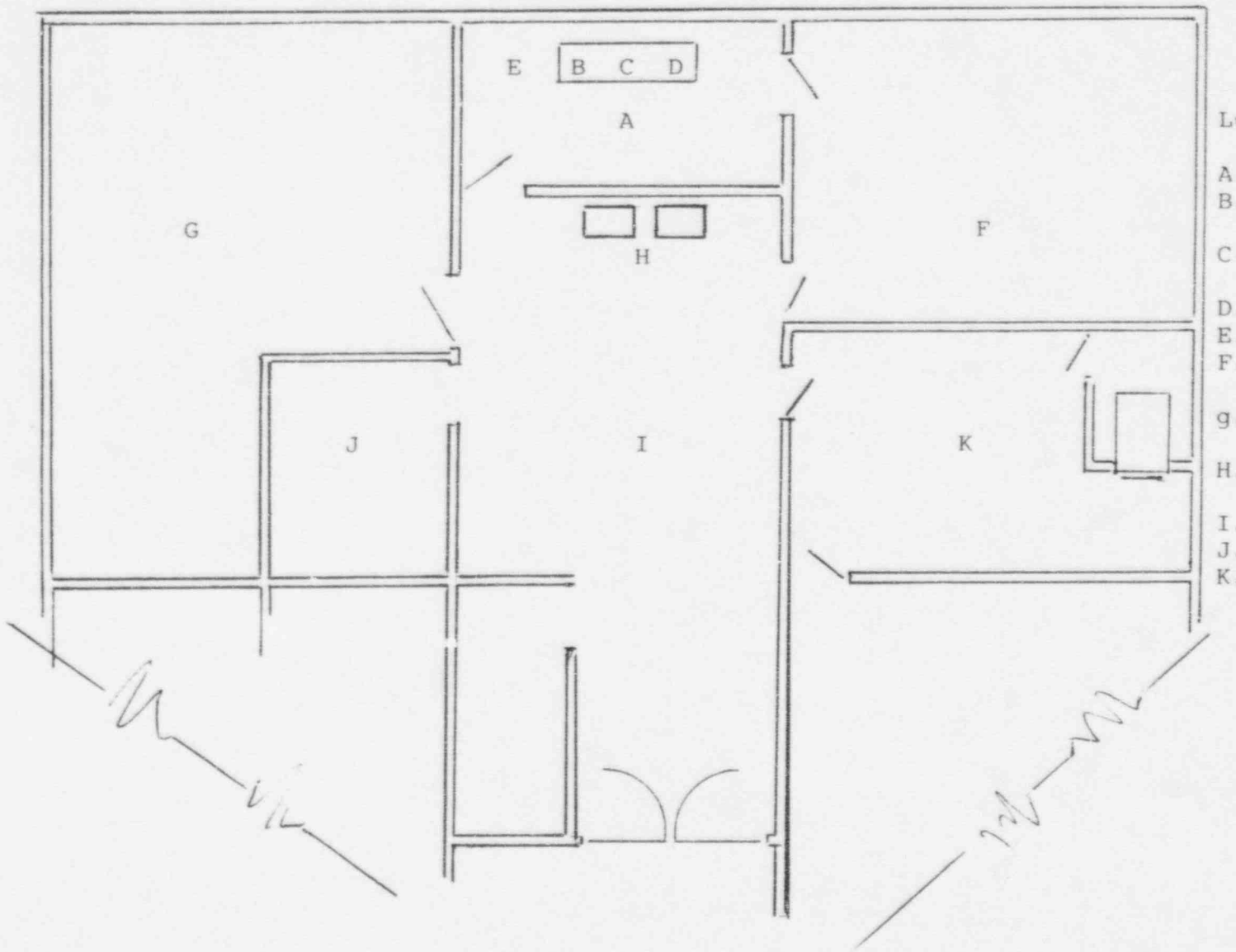
SIGNATURE – LICENSE FEE ANALYST
Rita Messier
RITA MESSIER

(LEAVE BLANK)

DATE
6-13-96

HOSPITAL ONCOLOGICO ANDRES GRILLASCA - PONCE

OPERATING ROOMS & RADIUM PREPARATION AND STORAGE

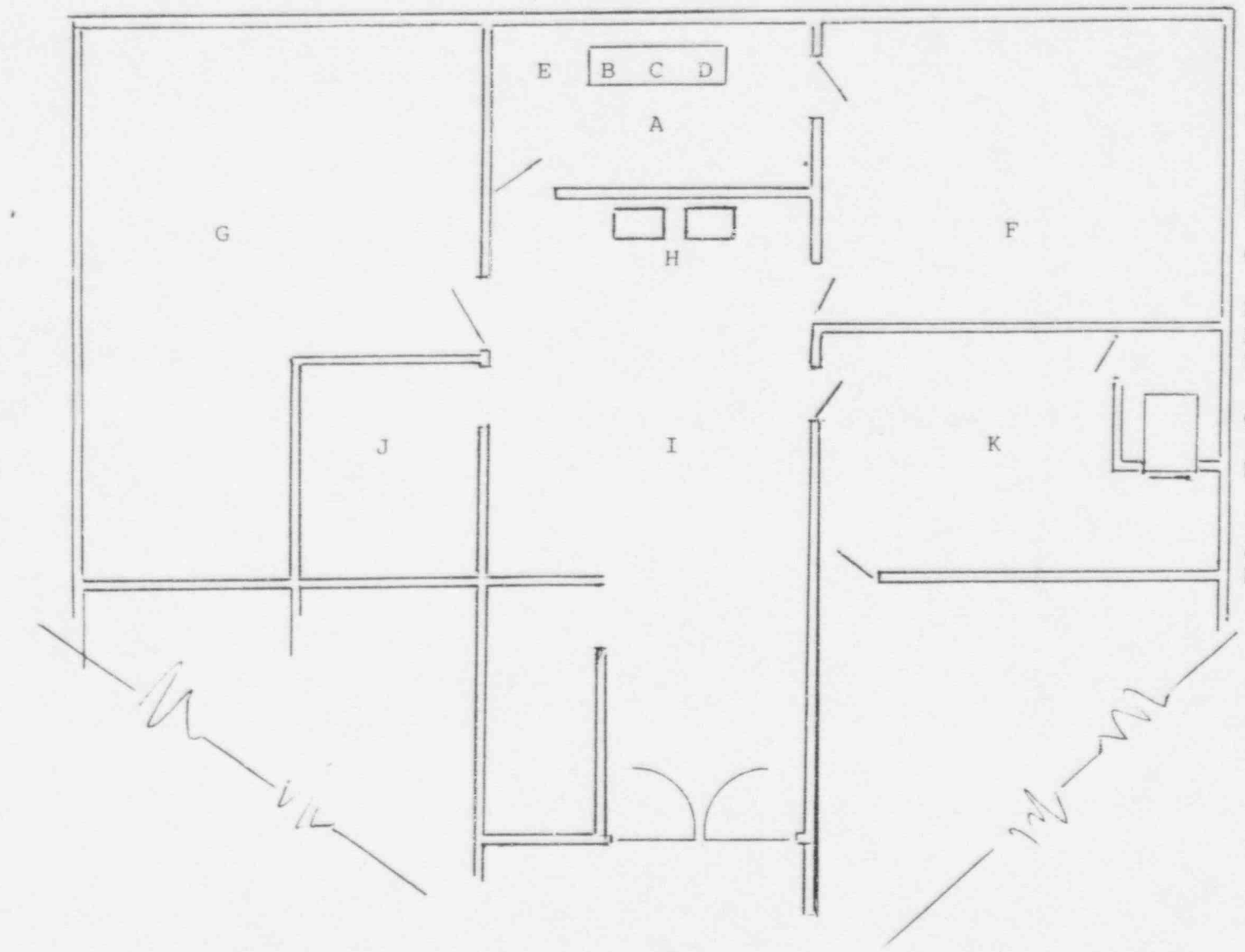


Legend:

A. Working Bench
B. Safe-Radium Storage
C. L. Block (Lead)
D. Lead Well
E. Lead Storage
F. Operating Room
g. Operating Room
H. Lavatory (Sink)
I. Aisle
J. Office
K. Sterilization Room

HOSPITAL ONCOLOGICO ANDRES GRILLASCA - PONCE

OPERATING ROOMS & RADIUM PREPARATION AND STORAGE



Legend:

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K. Sterilization Room

HOSPITAL ONCOLOGICO
ANDRES GRILLASCA
De La Asociación Para La Lucha
Contra El Cáncer
Ponce, Puerto Rico 00731

23788

30 de julio de 19 96 101-234/215

PÁGUESE A LA ORDEN DE US NUCLEAR REGULATORY COMMISSION $ 850.00

THE SUM 850 DOLLARS 00 CTS DÓLARES

BS PR BANCO DE SANTANDER PUERTO RICO
SUCURSAL PLAZA DE PONCE
PONCE, PUERTO RICO

Asociación Para La Lucha Contra el Cáncer

⑈02150234⑈ 051⑈010161⑈

DESPRENDA Y RETENGA ESTE INFORME ANTES DE DEPOSITAR.

Asociación Para La Lucha Contra el Cáncer No. 23788

FECHA DE FACTURA	FACTURA NO.	DESCRIPCION	
7/30/96		By concept of "Amount Due" for license Fee Requirements Radiotheraphy Service	$850.00

ATTN: Rita

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LIS

Program Code: ____
Status Code: 3
Fee Category: ___ _____
Exp. Date: 0
Fee Comments: _____
Decom Fin Assur Reqd: _

LICENSE FEE TRANSMITTAL

A. REGION II

1. APPLICATION ATTACHED
   Applicant/Licensee: HOSPITAL ONCOLOGICO
   Received Date: 960613
   Docket No: 3034175
   Control No.: 257096
   License No.:
   Action Type: New License

2. FEE ATTACHED
   Amount: 550.00
   Check No.: 23463

3. COMMENTS
please apply this check from
control 257054 to this control.
257054 has been voided

Signed diane heim
Date 6/13/96

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /LT)

1. Fee Category and Amount: 1C $1400

2. Correct Fee Paid. Application may be processed for:
   Amendment ____
   Renewal ____
   License ✓

3. OTHER _____

Signed Rita Messier
Date 8/13/96

Log Jun 1 II
Remitter
Check No. 23463/23788
Amount $550 + $850
Fee Category 1C
Type of Fee Export
Date Check Rec'd. 8/9/96
Date Completed 8/13/96
By: Rita

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02300
Status Code: 0
Fee Category: 7A 2B
Exp. Date: 20030131
Fee Comments: CODE 23
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION II

1. APPLICATION ATTACHED
   Applicant/Licensee: HOSPITAL ONCOLOGICO
   Received Date: 960503
   Docket No: ~~3000570~~ 03175
   Control No.: 257054
   License No.: 52-11832-~~01~~ 02
   Action Type: ~~Amendment~~ New.

2. FEE ATTACHED
   Amount: $550
   Check No.: 23463

3. COMMENTS

Signed N.Witt
Date ~~MAY 08 1996~~

4. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

Fee Category and Amount: _____

Application may be processed for:

[redacted]

Signature

Date

ATTN Rita Messier

VOID SHEET

TO: License Fee Management Branch

FROM: RTL

SUBJECT: VOIDED APPLICATION

Control Number: 26-1054

Applicant: Hospital Oncologico

Date Voided: 6/13/96

Reason for Void: Please void this control and apply fee to 25709G as a separate license is needed for brachytherapy license

Duane Hoins 6/13/96
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

☐ Refund Authorized and processed

☑ No Refund Due

☐ Fee Exempt or Fee Not Required

Comments:

Log completed ☑

Processed by: Lisa

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02300
Status Code: 0
Fee Category: 7A 2B
Exp. Date: 20030131
Fee Comments: CODE 23
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION II

1. APPLICATION ATTACHED
   Applicant/Licensee: HOSPITAL ONCOLOGICO
   Received Date: 960503
   Docket No: 3000570
   Control No.: 257054
   License No.: 52-11832-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: $550
   Check No.: 23463

3. COMMENTS

Signed N.Witt
Date MAY 08 1996

$550 applied to new license 257096

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered)

1. Fee Category and Amount: 7A 2B Verified 6/13/96

2. Correct Fee Paid. Application may be processed for:
   Amendment ✓
   Renewal
   License

3. OTHER

Signed Rita Messier
Date 6/13/96

Log May 1 II
Remitter
Check No.
Amount
Fee Category 7A 2B
Type of Fee amd
Date Check Rec'd. 6/13/96
Date Completed
By: RM

HOSPITAL ONCOLOGICO ANDRES GRILLASCA
DE LA
ASOCIACION PARA LA LUCHA CONTRA EL CANCER
CENTRO MEDICO DE PONCE, PONCE, PUERTO RICO

APARTADO 1324
PONCE, P.R. 00733-1324

TELEFONO
(809) 848-0800

April 18, 1996

U. S Nuclear Regulatory Commission
Region II License Division
101 Marietta Street, N. W. Suite 2900
Atlanta, Georgia 30323-0199

Subject: License Amendment
Lic: 52-11832-01

Gentlemen:

This is to request an amendment to our Radiotherapy License # 52-11832-01 in order to add intracavitary sources.

At present time we have Radium 226 needles and tubes, that we are planning to dispose.

Our requests is for Implant Material for Brachytherapy as in 35.400 in the following amounts.

Sources: Cs 137	Iridium 192	Iodine 125	Gold-198	Palladium 103
10 tubes of 10 mg.	1 Curie	1 Curie	1 Curie	1 Curie
5 tubes of 15 mg.				
3 tubes of 20 mg.				

At present time we have the following facilities and equipmet used with Radium 226.

2. L-shape blocks

1. Radium storage safe 3" Lead
Lead blocks 2" 4" X 8" to form protective well

1. Minimonitor II Survey Meter Model-571
The following equipment will be obtained.

257054

1. Source calibrator, 1 extra survey meter, several applicators.

The authorize users for the intracavitary sources will be our Radiation Oncologist Dr. José N. Correa, Dr. Neftaly Sallaberry, and Dr. Carlos Remedios. They are the authorize users or Lic. 52-11832-01 and License 52-10270-01 for intracavitary therapy.

We will implement the model proceduce for Radiation Safety During Implant Therapy as in appendix Q in Regulatory Guide 10.8

Enclosed find the corresponding check for the amendment fee in the amount of $550.00.

Your prompt answer to this request will be apreciated.

Sincerely,

Angel Franceschi M.S.H.A.
Administrator

257054

From: Diane Heim
To: REM1
Date: 5/24/96 4:31pm
Subject: JOSE

JOSE IS GONE FOR THE DAY BUT WILL BE IN TUESDAY A.M. HIS PHONE NUMBER IS 404-331-7438 AND HIS EMAIL INITIALS ARE JXD2. I'LL TELL HIM YOU CALLED.

Rita - I would call & ask Nancy to show the pending cy to a reviewer and ask him if the request is for the use of teletherapy devices, or human use, not teletherapy ~~use~~ devices.

2300

Licenses

have 2

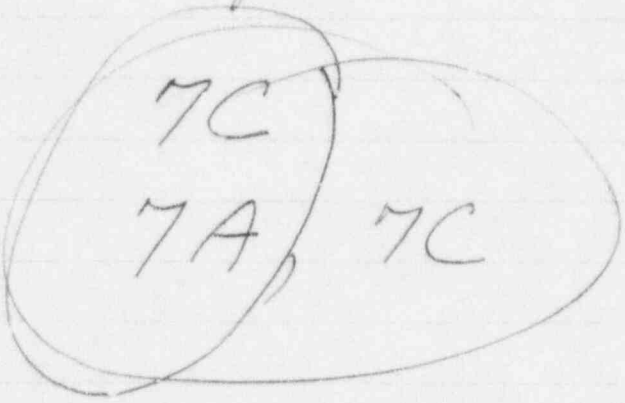
Nuc Med

tech

wants to move

Occupational Licenses -

from Nuc Med to



Rev Jose +

NMSS -

Cannot have

7A and 7C

on one Lic.

Must be separate

TRANSMISSION REPORT

08.01.1996 12:47

LFDCB

DATE TIME	DURATION	REMOTE ID	MODE	PAGES	RESULT
08.01 12:44	02'40"	787 843 2310	G3	2	O.K.

U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

HOSPITAL ONCOLOGICO ANDRES GRILLASCA
ATTN: ANGEL FRANCESCHI, M.S.H.A.
ADMINISTRATOR
P. O. BOX 1324
PONCE, PR 00733-1324

TYPE OF ACTION

- [x] NEW LICENSE
- [ ] RENEWAL OF LICENSE
- [ ] AMENDMENT TO LICENSE

REQUESTED DATE: 4-18-96

LICENSE NUMBER:

CONTROL NUMBER: 257096 ATTN: RITA MESSIER, LFARB, T9E10

I. APPLICATION FEE DUE

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7C	$ 1,400.00	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE	$ 1,400.00
PAYMENT RECEIVED	$ 550.00
AMOUNT DUE	$ 850.00

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II. FEE NOT REQUIRED

- [ ] Enclosed is Check No. _____ which accompanied your request. The fee is not required because:
  - [ ] We received your Check No. _____ in payment of the fee.
  - [ ] The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.
  - [ ] Your request was comb_d, prior to review, with your _____ request, Control No. _____.

III. CHECK RETURNED

- [ ] Enclosed is Check No. _____ which was returned to us by the bank for:
  - [ ] INSUFFICIENT FUNDS
  - [ ] ACCOUNT CLOSED
  - [ ] OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

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- [ ] Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE – LICENSE FEE ANALYST	(LEAVE BLANK)	DATE
Rita Messier RITA MESSIER		6-13-96

NRC FORM 577 (1-95)

This form was electronically produced by Elite Federal Forms, Inc.

NRC FORM 386 (12-92)

U.S. NUCLEAR REGULATORY COMMISSION

DATE 8/1/96

TIME

TELECOPIER TRANSMITTAL

WARNING: Most facsimile machines produce copies on thermal paper. The image produced is highly unstable and will deteriorate significantly in a few years. Reproduce copies onto plain paper prior to filing as a record.

TO

NAME: Angel Franceschi

TELEPHONE:

NAME AND LOCATION OF COMPANY (If other than NRC): Hospital Oncologico Andres Grillasca

TELECOPY NUMBER:

VERIFICATION NUMBER:

FROM

NAME: Rita Messier

TELEPHONE: 301-415-6067

MAIL STOP:

TELECOPY DATA

NUMBER OF PAGES: THIS PAGE + 1 PAGES = 2 TOTAL

PRIORITY

- [ ] IMMEDIATE
- [ ] OTHER (Specify)

SPECIAL INSTRUCTIONS

Please let me know if you wish to pursue your new license request. If you do please submit the additional $850 requested on 6/13/96. I can be reached on 301-415-6067 Fax 301-415-5387

PROBLEMS

If any problems occur or if you do not receive all the pages, call:

TELEPHONE

DISPOSITION OF ORIGINAL

After telecopy has been sent, process the original as requested below. (If none are checked, the original will be discarded.)

- [ ] RETURN TO SENDER
- [ ] CALL AND SENDER WILL PICK UP
- [ ] DISCARD

PROCESSED BY (INITIALS):

VERIFIED BY (INITIALS):