

DL-042398-07

April 23, 1998

Hato Rey Community Hospital
ATTN: Sr. Teodoro Muñiz, MHA
Administrator
435 Ponce de Leon Avenue
Hato Rey, PR 00917

SUBJECT: TRANSMITTAL AND EXPLANATION OF AMENDMENT TO LICENSE NO 52-17704-01
(REFERENCE CONTROL NO. 257774; DOCKET NO. 030-13199)

Dear Sr. Muñiz:

Enclosed please find Amendment No. 13 to your NRC material license. Changes to the license are printed in **BOLD** typeface. We have registered the change of ownership documents dated December 29, 1998. These documents reflect the ownership transfer and acceptance of all license commitments by the new owner and administration. These documents do not have any bearing or authorization regarding the near-future transfer to Pavia Healthcare. As explained in our telephone conversation on April 17, 1998, NRC Regional management feels that it is most important to have the December 29, 1997 documents regarding the transfer of control included in the license.

As I further explained, a review by NRC of the forthcoming transfer to Pavia Healthcare is required by 10 CFR 30.41 prior to the effective date of the transfer. The purpose is to allow NRC to determine the status of materials, violations of regulations, prior liabilities and acceptance of past liabilities and commitments to follow all the existing license conditions and commitments. The transfer document should be signed by executive members of both the selling and acquiring organizations. It is our understanding that the transfer to Pavia Healthcare may occur in the next 90 days, as stated in your March 2, 1998, letter.

Please review the 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) 562-4723) so that we can provide appropriate corrections and answers.

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 and Investigations," 10 CFR 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:
 - a. when an authorized user or Radiation Safety Officer 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).
3. In accordance with 10 CFR 30.36(d) 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. when you decide to terminate licensed activities in a separate building or outdoor area identified on your license
4. Request and obtain a license amendment before you:
 - a. receive or use byproduct material for a clinical procedure permitted under 10 CFR 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 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 as permitted on the license; or
 - f. change ownership of your organization.
5. 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 signature on the application should be the licensee or a 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.

Sincerely,

D.J. Collins

David J. Collins, License Reviewer
Division of Nuclear Materials Safety

- Enclosures: 1. Amendment No. 13
License No. 52-17704-01
2. NRC Form 313

OFFICE	R11:DNMS	R11:DNMS	R11:DNMS						
SIGNATURE	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>						
NAME	DJCollins	RELesser	CMosey						
DATE	4/23/98	4/26/98	4/27/98	4/ /98	4/ /98	4/ /98	4/ /98	4/ /98	4/ /98
COPY?	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

OFFICIAL RECORD COPY

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.

<p style="text-align: center;">Licensee</p> <p>1. Hato Rey Community Hospital Nuclear Medicine Laboratory</p> <p>2. 435 Ponce de Leon Avenue</p> <p>Hato Rey, Puerto Rico 00917</p>	<p>In accordance with letter dated December 29, 1997</p> <p>3. License number 52-17704-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date January 31, 2004</p> <hr/> <p>5. Docket No. 030-13199 Reference No</p>
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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 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200, except radioactive gases	B. As needed
C. Iodine 131	C. Any unsealed form for preparation and administration as specified in §35.300	C. 55.5 gigabecquerels (1.5 curies)
D. Any byproduct material with a half-life less than 120 days, except iodine 131	D. Any form for uses described in §35.300 initially distributed in accordance with a specific license issued to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations.	D. As needed
E. Any byproduct material identified in 10 CFR 35.500	E. Any diagnostic sealed source identified in 10 CFR 35.500 and registered pursuant to 10 CFR 32.210 or an equivalent Agreement State regulation	E. As needed (See Item 9 E.)

Handwritten initials: MLJ

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PDR ADOCK 03013199
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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

52-17704-01

Docket or Reference Number

030-13199

Amendment No. 13

9. Authorized Use:

- A. Medical use identified in 10 CFR 35.100.
- B. Medical use identified in 10 CFR 35.200.
- C. and D. Medical use identified in 10 CFR 35.300.
- E. Sealed source contained in a compatible device (registered pursuant to 10 CFR 32.210 or an equivalent Agreement State regulation) for medical use identified in 10 CFR 35.500. The licensee may also possess one additional source in its shipping container for use incident to source exchange.

CONDITIONS

10. Licensed material shall be used at the licensee's facilities located at Hato Rey Community Hospital, 435 Ponce de Leon Avenue, Hato Rey, Puerto Rico, 00917.

11. The Radiation Safety Officer for this license is Irma L. Molina-Vicenty, M.D.

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 User

Material and Use

- | | |
|-------------------------------------|---|
| A. Carlos D. Garcia-Rodriguez, M.D. | Uses described in 10 CFR 35.100, §35.200, §35.300 and §35.500 |
| B. Sandra C. Gracia-López, M.D. | Uses described in 10 CFR 35.100, §35.200, §35.300 and §35.500 |
| C. Irma L. Molina-Vicenty, M.D. | Uses described in 10 CFR 35.100, §35.200, §35.300 and §35.500 |
13. Sealed sources containing licensed material shall not be opened by the licensee
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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

52-17704-01

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15. 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.

A. Letter (with application) dated December 20, 1992

B. Letters (and facsimilies as noted) dated:

- (1) October 18, 1993 [supplemental information for 12/20/92 application]
- (2) September 25, 1995 [change RSO and user]
- (3) April 7, 1997 [add 3 authorized users, change RSO to Dr. Garcia]
- (4) June 23, 1997 (fax) [delete Dr. Vieras]
- (5) October 7, 1997 (received) [changes RSO to Dr. Molina-Vicenty]
- (6) December 29, 1997 [Change of ownership and commitments to support license continuance]

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

for DAVID J COLLINS

DATE

APR 23 1998

BY

David J. Collins

Region II, Division of Nuclear Materials Safety
61 Forsyth Street SW, Suite 23T85
Atlanta, GA 30303-8931