

June 2, 1998

Hospital Regional Dr. Ramón E. Betances  
Centro Medico De Mayaguez  
ATTN: Miguel A. Sepúlveda, MHSA  
Administrator  
410 Hostos Avenue  
Mayaguez, PR 00680

SUBJECT: TRANSMITTAL AND EXPLANATION OF AMENDMENT TO LICENSE NO. 52-13598-01  
(REFERENCE: CONTROL NO. 25 871; DOCKET NO. 030-00571)

Dear Sr. Sepúlveda:

Enclosed please find Amendment No. 16 to your NRC material license. Changes to the license are printed in **BOLD** typeface. We have issued this amendment in response to your letters dated March 18, 1998 and August 18, 1997. Specifically, we have added Dr. Rodríguez as an authorized user, and deleted Dr. Padilla. We have also removed the license condition which specified the keeping of records for decommissioning. This requirement is in 10 CFR 30.35(g).

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 to 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.
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 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

Hospital Regional  
 Dr. Ramón E. Betances

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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,

/s/

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

- Enclosures: 1. Amendment No. 16  
 License No. 52-13598-01
- 2. NRC Form 313

|           |                   |                  |               |        |        |        |        |        |        |
|-----------|-------------------|------------------|---------------|--------|--------|--------|--------|--------|--------|
| OFFICE    | RII:DNMS          | RII:DNMS         | RII:DNMS      |        |        |        |        |        |        |
| SIGNATURE | <i>DJ Collins</i> | <i>MS Lesser</i> | <i>CHosey</i> |        |        |        |        |        |        |
| NAME      | DCollins          | MSLesser         | CHosey        |        |        |        |        |        |        |
| DATE      | 6/1/98            | 6/1/98           | 6/2/98        | 5/ /98 | 5/ /98 | 5/ /98 | 5/ /98 | 5/ /98 | 5/ /98 |
| COPY?     | YES NO            | YES NO           | YES NO        | YES NO | YES NO | YES NO | YES NO | YES NO | YES NO |

OFFICIAL RECORD COPY

DOCUMENT NAME: G:\NMSSII\DNMS\COVLTR\257B71.DJC

BETWEEN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

Program Code 02300  
Status Code 0  
Fee Category 7A 2B  
Exp Date 20010228  
Fee Comments 000E 12  
Decom Fin Assur Req'd N

LICENSE FEE TRANSMITTAL

A. REGION II

1. APPLICATION ATTACHED

Applicant/Licensee: HOSPITAL RAMON DE BETANCES  
Received Date: 980325  
Docket No.: 3000571  
Control No.: 257871  
License No.: 52-13598-01  
Action Type: Amendment

2. FEE ATTACHED

Amount: 400.00  
Check No.: 2205

3. COMMENTS

Signed DIANE HEIM  
Date 3/31/98

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

1. Fee Category and Amount: 7A 2B \$400

2. Correct Fee Paid. Application may be processed for:  
Amendment 1  
Renewal \_\_\_\_\_  
License \_\_\_\_\_

3. OTHER \_\_\_\_\_

Signed [Signature]  
Date 4/7/98

|                   |             |
|-------------------|-------------|
| Log               | Apr 1 II    |
| Remitter          |             |
| Check No.         | 2205        |
| Amount            | 400.00      |
| Fee Category      | 7A 2B       |
| Type of Fee       | Amend       |
| Date Check Rec'd. | 4/7/98      |
| Date Completed    |             |
| By:               | [Signature] |

**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. Hospital Ramón E. Betances<br/>Centro Médico de Mayagüez</p> <p>2. 410 Road #2</p> <p>Mayagüez, Puerto Rico 00680-1522</p> | <p>In accordance with the application dated March 18, 1998</p> <p>3. License number 52-13598-01</p> <p>is amended in its entirety to read as follows:</p> <p>4. Expiration date February 28, 2001</p> <p>5. Docket No. 030-00571</p> <p>Reference No.</p> |
|--|---|

|  |   |  |
|--|---|--|
| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Cobalt 60</p> <p>B. Uranium (depleted in the isotope Uranium 235)</p> | <p>7. Chemical and/or physical form</p> <p>A. Teletherapy sealed sources registered pursuant to 10 CFR 32.210 or an equivalent Agreement State regulation</p> <p>B. Metal</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 495.8 terabequerels (TBq) [13,400 curies] (2 sources of not more than 247.9 TBq [6,700 curies] each)</p> <p>B. 250 kilograms</p> |
|--|---|--|

9. Authorized Use:
- A. One source to be used in a compatible teletherapy unit (registered pursuant to 10 CFR 32.210 or an equivalent Agreement State regulation) for medical use identified in 10 CFR 35.600. One source in its shipping container to be in possession of the licensee as necessary for the replacement of the sources in the teletherapy unit only.
  - B. For use as contained shielding in teletherapy units, storage containers and/or related teletherapy components.

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
52-13598-01Docket or Reference Number  
030-00571

Amendment No. 16

**CONDITIONS**

10. Licensed material shall be used only at the licensee's facilities located in the cobalt teletherapy room at Hospital Ramón E. Betances, Centro Médico de Mayagüez, 410 Road #2, Mayagüez, Puerto Rico.
11. The Radiation Safety Officer for this license is Alison de Hoyos, M.S.
12. The Teletherapy Physicist for this license is Pedro J. Montes, M.S.
13. Licensed material shall be used by, or under the supervision of, the following individuals for the materials and uses specified:
  - A. Gloria Arroyo Bosch, M.D. uses identified in 10 CFR 35.600.
  - B. Edwin Rodríguez, M.D. uses identified in 10 CFR 35.600.
14. Sealed sources containing licensed material shall not be opened or removed from the teletherapy device by the licensee.
15. The licensee is exempted from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits in 10 CFR 30.35 for the purpose of source changes only. This exemption is granted for no more than 30 days for any one source change.
16. The licensee shall maintain the Radiation Safety Program staffing (including a Dosimetrist) and maintain oversight of the Radiation Safety Program, in accordance with Items 1 and 2 of licensee's Performance Improvement Program submitted to the NRC in a letter dated August 21, 1992.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
52-13598-01

Docket or Reference Number  
030-00571

Amendment No. 16

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.

A. Letters dated:

- |                       |  |
|-----------------------|--|
| (1) January 18, 1991  | [with attachments]   |
| (2) February 11, 1991 | [with attachments]   |
| (3) August 22, 1992   | [Performance Improvement Program]  |
| (4) December 2, 1992  | [fax to change hospital name]  |
| (5) March 10, 1993    | [Change RSO]   |
| (6) December 3, 1993  | [Teletherapy Survey]   |
| (7) March 31, 1994    | [Teletherapy Survey]   |
| (8) March 2, 1994     | [Correct Condition 18]   |
| (9) March 20, 1996    | [Addition of Dr. Diaz Padilla, elimination of PIP items 3 & 5 (consultant audits and 6 months training interval) and extension of expiration date in accordance with 10 CFR 30.36] |
| (10) June 3, 1996     | [Revise corrections of Dr. Diaz preceptor statement]   |
| (11) July 11, 1997    | [Change teletherapy physicist]   |
| (12) March 18, 1998   | [Nominate Dr. Rodriguez as authorized user]  |

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DAVID J. COLLINS

DATE \_\_\_\_\_

JUN 02 1998

BY \_\_\_\_\_

*David J. Collins*

Region II, Division of Nuclear Materials Safety  
61 Forsyth Street, S.W., Suite 23T85  
Atlanta, GA 30303