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# MATERIALS LICENSE

Amendment No. 2

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. St. Luke's Episcopal Hospital<br>Caribbean Nuclear Pharmacy | In accordance with letter received November 5, 1996<br>3. License Number 52-16061-02MD<br>is amended in its entirety to read as follows: |
| 2. P.O. Box 984<br>Ponce, Puerto Rico 00733-0984 | 4. Expiration Date August 31, 2001 |
| | 5. Docket or Reference No. 030-34161 |

| 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 initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or equivalent Agreement State regulations | A. Any form initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or equivalent Agreement State regulations | A. Molybdenum-99 4.625 terabecquerels (TBq) (125 Ci)<br>Technetium-99m 925 gigabecquerels (GBq) (25 Ci)<br>Xenon-133 37 GBq (1 Ci)<br>Strontium-89 36.63 GBq (990 millicuries (mCi))<br>Phosphorus-32 1.85 GBq (50 mCi)<br>Rhenium-186 18.5 GBq (500 mCi)<br>Iodine-131 18.5 GBq (500 mCi) |
| B. Molybdenum-99 | B. Any | B. 4.625 TBq (125 Ci) |
| C. Technetium-99m | C. Any | C. 925 GBq (25 Ci) |
| D. Xenon-133 | D. Any | D. 3.7 GBq (1 Ci) |
| E. Strontium-89 | E. Any | E. 33.63 GBq (990 mCi) |
| F. Phosphorus-32 | F. Any | F. 1.85 GBq (990 mCi) |
| G. Rhenium-186 | G. Any | G. 18.5 GBq (500 mCi) |
| H. Iodine 131 | H. Any | H. 18.5 GBq (500 mCi) |
| I. Any byproduct material listed in 10 CFR 31.11(a) | I. Prepackaged units for <u>in vitro</u> diagnostic tests | I. 370 MBq (10 mCi) |



MLdo 1/1

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

| 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 |
|---|---|---|
| J. Any byproduct material authorized under 10 CFR 35.57(a) | J. Any sealed source listed in 10 CFR 35.57(a) that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to 10 CFR 32.74 or equivalent Agreement State regulations | J. 1.85 gigabecquerels (50 millicuries) |
| K. Any byproduct material listed in 10 CFR 35.400 and §35.500 | K. Any sealed source that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to 10 CFR 32.74 or equivalent Agreement State regulations | K. 1.85 GBq (50 mCi) |
| L. Uranium (depleted in the isotope Uranium 235) | L. Metal encased in stainless steel | L. 110 kilograms |

9. Authorized use:

A. through H. Preparation and distribution of radioactive drugs (includes Mo99/Tc99m generators) to authorized recipients.

I. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labelling remain unchanged.

J. Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to 10 CFR 32.74, the licensee is authorized to redistribute sources to persons licensed pursuant to 10 CFR 35.57(a) or under equivalent licenses of Agreement States.

K. Redistribution of sealed sources as received from the manufacturer in the manufacturer's original packaging and shielding and accompanied by the manufacturer's approved instructions to authorized recipients for use and storage.

L. Shielding for Mo99/Tc99m generators.

Pursuant to 10 CFR 32.72 and 32.74, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 A. through J. of this license to persons licensed pursuant to Sections 35.100, 35.200, 35.300, 35.400, and 35.500 of 10 CFR Part 35, or under equivalent licenses of Agreement States.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 52-16061-02MD

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## CONDITIONS

10. Location for use: San Lucas (St. Luke's) Episcopal Hospital
Calle Guadalupe Final - Apartado 2027
Ponce, Puerto Rico 00733

11. A. Licensed material shall be used by, or under the supervision of:

1) a pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2) and (3), or

2) authorized nuclear pharmacists:
(1) James B. Hudson, R.Ph.
(2) William J. Cox, N.P.
(3) Kurt A. Boesger, N.P.
(4) Jeffrey M. Bruhl, N.P.
(5) Roberto Gonzalez, R.Ph.

B. The Radiation Safety Officer is Roberto Gonzalez, R.Ph., and in his absence, Kurt A. Boesger, N.P.

12. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.

B. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

C. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

D. Sealed sources need not be leak tested if:

(i) they contain only hydrogen-3; or
(ii) they contain only a radioactive gas; or
(iii) the half-life of the isotope is 30 days or less; or
(iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
(v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

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**CONDITIONS**

Continued -

12. E. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region II, ATTN: Chief, Materials Licensing/Inspection Branch, 101 Marietta Street NW, Suite 2900, Atlanta, Georgia 30323-0199. The report shall specify the source involved, the test results, and corrective action taken.

F. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to Perform such services.

13. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

14. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.

15. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

16. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 days for decay-in-storage before disposal in ordinary trash provided:

A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels on the outermost openable container shall be removed or obliterated.

C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

D. Radioactive wastes with half-lives greater than 65 days shall be packaged separately from those with half-lives of 65 days or less.

E. Radioactive waste forms shall be compatible with the storage containers.

F. Each record of disposal shall include the date on which the byproduct material was placed in storage; the radionuclides disposed; the survey instrument used; the background dose rate; the dose rate measured at the surface of each waste container; and, the name of the individual who made the disposal.

17. Radioactive waste resulting from licensee originated materials may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements, and representations in application dated May 29, 1996.

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**CONDITIONS**

Continued -

18. 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.

19. 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.

20. 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, Materials Licensing/Inspection Branch, Division of Nuclear Materials Safety, 101 Marietta Street NW, Atlanta, Georgia 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.

21. 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. The U.S. 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. Application dated June 5, 1996

B. Letters dated
   1. July 19, 1996 [additional supporting information]
   2. September 9, 1996 [add authorized nuclear pharmacist, change Radiation Safety Officer]
   3. **November 5, 1996 (received) [change mailing address]**

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DAVID J. COLLINS

DATE NOV 27 1996 BY

Region II, Division of Nuclear Materials Safety
101 Marietta Street, N.W., Suite 2900
Atlanta, Georgia 30323-0199

11/22/96 N:\MLICENSE\52-16061.A02

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

## 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 & 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; o

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

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.

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02500
Status Code: 0
Fee Category: 3C 2B
Exp. Date: 20010831
Fee Comments: _____
Decom Fin Assur Reqd: N

1996 NOV -8 AM 10:40

LICENSE FEE TRANSMITTAL

A. REGION II

1. APPLICATION ATTACHED
   Applicant/Licensee: ST. LUKE'S EPISCOPAL HOSPITAL
   Received Date: 961105
   Docket No: 3034161
   Control No.: 257258
   License No.: 52-16061-02MD
   Action Type: Amendment

2. FEE ATTACHED
   Amount: _NONE_____
   Check No.: _____

3. COMMENTS
   MAILING ADDRESS ONLY-NO FEE

Signed _____DIANE HEIM_____
Date _____11/6/96_____

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

1. Fee Category and Amount: 3C 2B FEE NOT REQUIRED
   mailing address change only

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

3. OTHER _____

Signed Rita Messier
Date 11/13/96

RECEIVED BY LFMS
Date 11/8/96
Log NOV 2 II
By Ron
Date Completed 11/13/96

Caribbean
Nuclear Pharmaceuticals, Inc.
Calle Guadalupe Final
Ponce P. R. 00731

Ponce (787) 842-5788
(800) 94-NUCLEAR

Mobile (800) 269-6825
Fax (334) 471-4620
Phone (334) 471-5445

Mr. David J. Collins
Region II Division of Nuclear Material Safety
101 Marietta Street, N.W., Suite 2900
Atlanta, Georgia 30329-0199

Dear Mr. Collins:

I like to intrduce my self to you, I am Roberto Gonzalez the Pharmacist and RSO on Caribbean Nuclear Pharmaceuticals in Ponce, Puerto Rico. I want to take this oportunity to announce two new changes.

1. Our new postal address is; Caribbean Nuclear Pharmaceuticals
   P.O. Box 984
   Ponce, P.R. 00733-0984

2. We started dispensing nuclear products on ; October 21, 1996.

Thank you for all your help. I will notify you of any changes at the appropriate time.

Sincerely,

Roberto Gonzalez RPh

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