

OFFICIAL RECORD COPY
MATERIALS LICENSE

Amendment No. 5

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		In accordance with the letter dated January 10, 1997	
1.	Syncor de Puerto Rico, Inc.	3. License Number	52-16345-02MD
2. P.O. Box 4408 Carolina, Puerto Rico 00984		is amended in its entirety to read as follows:	
		4. Expiration Date	April 30, 2005 (extended)
		5. Docket or Reference No.	030-19134
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 Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State requirements	A. Any form initially distributed in accordance with a specific license issued pursuant 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 requirements	A. M o l y b d e n u m 9 9 - 1.85 terabecquerels (TBq) (50 curies); Technetium 99m - 1.85 TBq (50 curies); Iodine 131 - 33.3 gigabecquerels (GBq) (900 millicuries); All others combined, 18.5 GBq (500 millicuries)	
B. Any byproduct material authorized under 10 CFR, 35.57(a).	B. Any sealed source listed in paragraph 10 CFR 35.57(a) of 10 CFR Part 35 that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	B. 555 megabecquerels (MBq) (15 millicuries) total	
C. Any byproduct material identified in 10 CFR, Part 31.11(a)	C. Prepackaged units for <u>in vitro</u> diagnostic tests	C. 1.85 GBq (50 millicuries)	
D. Uranium (depleted in the isotope uranium 235)	D. Metal enclosed in stainless steel	D. 180 kilograms	

180276

9706190110 970221
PDR ADOCK 03019134
C PDR011
ML20

MATERIALS LICENSE
SUPPLEMENTARY SHEETLicense Number
52-16345-02MDDocket or Reference Number
030-19134

Amendment No. 5

9. Authorized Use:

- A. Preparation and distribution of radioactive drugs (includes Mo99/Tc99m generators) to authorized recipients.
- B. Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to Section 32.74 of 10 CFR Part 32, the licensee is authorized to redistribute sources to persons licensed pursuant to Section 10 CFR 35.57(a) of 10 CFR Part 35 or under equivalent licenses of Agreement States.
- C. Distribution to specific licensees or general licensees pursuant to 31.1 of 10 CFR Part 31 provided the packaging and labelling remain unchanged.
- D. Shielding for molybdenum 99/technetium 99m generators.

Pursuant to Sections 32.72 and 32.74 of 10 CFR Part 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 A. through C. of this license to persons licensed pursuant to Sections 35.100, 35.200, and 35.300 of 10 CFR Part 35, or under equivalent Agreement State licenses.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at WA 15 Los Angeles, Carolina, Puerto Rico.
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 32.72(b)(2) and 32.72(b)(3) of 10 CFR Part 32, or
 - (2) authorized on Byproduct Materials License 04-26507-01MD;
- B. The Radiation Safety Officer for this license is Jay R. Simon, R.Ph., and in his absence, James S. Hilton, R.Ph.
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. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

52-16345-02MD

Docket or Reference Number

030-19134

Amendment No. 5

CONDITIONS

Continued -

12. D. 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.
- E. 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.
- F. 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 St. NW, Atlanta, Georgia 30323-0199. The report shall specify the source involved, the test results, and corrective action taken.
- G. 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 or detector cells by the licensee.
14. The licensee shall conduct a physical inventory every six months to account for all sources and/or devices received and possessed under this license.
15. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."
16. Radioactive waste (e.g., syringes, vials) that contains or is contaminated with radioactive materials that the licensee originally supplied to its customers may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements, and representations in the application dated December 7, 1988.
17. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

52-16345-02MD

Docket or Reference Number

030-19134

Amendment No. 5

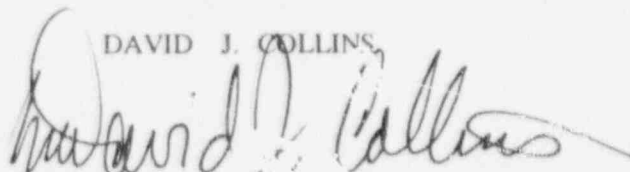
CONDITIONS

Continued -

17. 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 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.
18. In addition to the possession limits in condition 8, the licensee shall further restrict the possession of licensed material so that at no time is a quantity of radioactive material possessed in excess of a quantity that requires decommissioning funding in accordance with 10 CFR 30.35(d), 10 CFR 40.36(e) or 10 CFR 70.25(d).
19. The licensee shall maintain records of information related to decommissioning at the licensee's facilities located at WA 15 Los Angeles, Carolina, Puerto Rico as specified in 10 CFR 30.35(g) until this license is terminated by the Commission.
20. 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 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 December 7, 1988
- B. Letters dated:
1. April 20, 1989 [alternate RSO qualifications]
 2. March 2, 1994 [renewal application]
 3. April 5, 1995 [survey instruments, calibration of dose calibrator, safe use procedures]
 4. July 19, 1996 [transfer of assets to Syncor de P.R. (IAW IN 89-25 Rev. 1); changes to facility; incineration; I-131 authorization; I-131 handling procedures; dose container and labels; bioassay procedures]
 5. September 28, 1996 [approval of transfer by both Dr. Caamaño and Syncor de P.R., Inc.]
 6. October 24, 1996 (fax) [qualifications of Alicia Alpert]
 7. January 10, 1997 [delete Ms. Alpert, add J.S. Hilton as alternate RSO]
- C. Reference NRC Letter dated March 1, 1996, extension of expiration date per 10 CFR 30.36(a)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DAVID J. COLLINS



FEB 21 1997

DATE

BY

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

N:\MLICENSE\52-16345.A05

J 2/24/97



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199
FEB 24 1997

INFORMATION FOR NRC MATERIAL LICENSEES

Please find enclosed: _____ Your NRC material license
CORRECTED COPY _____ Amendment to your NRC material license
AMENDMENT #4 (sp) _____ Amendment renewing your NRC material license
AMENDMENT #5 _____ 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; or
 - 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.

g:\dnms\mlib2\infofor.mat

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 20555-0001SYNCOR DE PUERTO RICO, INC.
ATTN: JAY SIMON
RADIATION SAFETY OFFICER
P. O. BOX 4408
CAROLINA, PR 00984

TYPE OF ACTION

- ☐ NEW LICENSE
☐ RENEWAL OF LICENSE
☒ AMENDMENT TO LICENSE

REQUESTED DATE

1-10-97

LICENSE NUMBER

52-16345-02MD

CONTROL NUMBER

257343 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
3C	\$	\$	\$ 520.00
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(S) DUE	\$	520.00
PAYMENT RECEIVED	\$	
AMOUNT DUE	\$	520.00

☒ Your request was received without the prescribed application fee.

☐ We received your Check No. _____ in the amount of \$ _____. 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.

SIGNATURE - LICENSE FEE ANALYST

RITA MESSIER

LFDCB

REMessier

1/22/97

LFDCB

Rita Messier

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 I 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 I of this form.

Distribution:

Pending Fee File OC/DAF/SF(LF-3 2 7)
LFARB R/F (2) Region II

DATE

1-22-97

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: 20050430
: Fee Comments: 3C OK-SEE 1984 NOTES
: Decom Fin Assur Req'd: N
:

1997 JAN 21 PM 4:00

LICENSE FEE TRANSMITTAL

A. REGION II

1. APPLICATION ATTACHED

Applicant/Licensee: SYMOR DE PUERTO RICO, INC.
Received Date: 970115
Docket No: 3019134
Control No.: 257343
License No.: 52-16345-02MD
Action Type: Amendment

2. FEE ATTACHED

Amount: NONE
Check No.: _____

3. COMMENTS

Signed DIANE HEIM
Date 1/17/97

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

1. Fee Category and Amount: 3C 2B \$520

2. Correct Fee Paid. Application may be processed for:

Amendment /
Renewal _____
License _____

3. OTHER _____

Signed Lita S. Sosa
Date 2/10/97

Log	<u>Jan 2 II</u>
Remitter	<u>NPI/Symcor</u>
Check No.	<u>1532</u>
Amount	<u>\$520</u>
Category	<u>3C 2B</u>
Type of Fee	<u>Amend</u>
Date Check Rec'd.	<u>2/21/97</u>
Date Completed	<u>2/21/97</u>
By	<u>RLS</u>



The Service Difference™

Syncor International Corporation

January 10, 1997

Mr. David J. Collins
Nuclear Regulatory Commission
Region II
Division of Nuclear Materials Safety
101 Marietta Street, NW, Suite 2900
Atlanta, Georgia 30323-0199

RE: License 52-16345-02MD


Dear Mr. Collins,

This is to request a change in the alternate RSO for the above license. The change is to list James S. Hilton, RPh as alternate RSO replacing Alicia Alpert, RPh. Further, please remove Ms. Alpert from our license in total.

Mr. Hilton is listed under the Syncor NRC master license 04-26507-01MD which is attached as an authorized user-authorized nuclear pharmacist. Mr. Hilton is now a staff pharmacist of Syncor de Puerto Rico.

If you have any questions, feel free to contact me.

Sincerely,


Jay R. Simon, RPh
RSO

257343

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

04-26507-01MD

Docket or Reference Number

030-33224

CORRECTED COPY

(Continued)

Ronald Gonzales
Armen Gostanian
Richard Green
Robert Grobinski

Fred L. Goodman
Paul R. Gotti
Carla Grider

David Goss
Ellen L. Graham
Brent Griggs

Gary Hamilton
Craig Hansen
Stephanie Hasan
Sidney S. Heath
Kenneth R. Hetzel
Russell Hildebrandt
James S. Hilton
Bradley Holmgren
Dennis Hoogland
James G. Horner
Mechelle Howser

Paul Hamilton
Edward Harrison
Zeta Lyn Hayes
Mark J. Henn
Bettina Hickman
Keith Higa
Lisa A. Hofmann
Walter Holst
Gary D. Hoogland
Larry Horvath
Joseph Huber

Melissa K. Hampton
Darren L. Hartman
Gregory Kyle Haynes
Steve Herlich
Laura Hicks-Konicke
Nicki Hillard
Jeff Hogan
John Holstein
Wade M. Hopkins
Steve Horvath
David Hurwitz

Blaine Ikeda

Hossein Izadjoo

Sharon Jackson
Brady M. Jens
Glenn Jones
Karen Juergens

Donald Jacoby
Sean Jeppesen
Mason M. Jones
Louis Juliano

Christina D. James
Thomas Johnson
Michael D. Jorgensen
Charles A. Julin

Gavin Kahn
Abdul Kamara
Russell K. Kawamura
Thomas Keefe
Delvin D. Kendrick
Alan Kim
Terry L. King
Eugene L. Kochert
James W. Korb
Lora Kozak
Robert Kuntz

Charles P. Kaiser
Deborah Kaminsky
Percy L. Kea
Richard Keesee
Kaveh Khadivi
Joseph Kim
Linda C. Kloss
Dennis Kobienski
Christopher Korherr
Betty Ku, Ph.D.

Joseph Kalinowski
Richard J. Kassal
L. Jason Keck
Margaret Faye Kelly
Lori Jo Kiewel
Bynum Kimmons
Paul Knapp
Keith Koontz
Gregory Korte
Jerry Kuhs

Blaise Lachowicz
E. Todd Landry
Tuan L. Le
Piyamas Lerdvoratavee
Joseph Lofaro
Kelli Love

Katherine A. Lamielle
Susan Lardner
Merle Leiker
Leslie Leshen
George Lomax
Tamara D. Lowery

David Lamont
Pasquale LaVallo
Christopher M. Leon
Daniel D. Littlefield
Jon Long
Joseph E. Lukacs

Anthony A. Macaluso

Nancy Mack

Anne Mahaffey

257343