

DL-050498-02

May 4, 1998

Caribbean Nuclear Pharmaceuticals, Inc.
ATTN: Mr. William J. Cox
President
P. O. Box 984
Ponce, PR 00733-0984

SUBJECT: CORRECTED COPY OF LICENSE NO. 52-16061-02MD

Dear Mr. Cox:

As we discussed on April 2, 1998, enclosed is a corrected copy of your NRC materials license which removes St. Luke's Episcopal Hospital from the licensee's name. This change was necessary to correct an error made by the NRC when the original license was issued.

If you have any questions concerning the canceled license, please contact Ms. Diane Heim at (404) 562-4723.

Sincerely,

Charles M. Hosey, Deputy Director
Division of Nuclear Materials Safety

Enclosure: Corrected copy of Amendment No. 3
License No. 52-16061-02MD

OFFICE	RTI:DNRS													
SIGNATURE														
NAME	CHosey													
DATE	5/	7/98	5/	7/98	5/	7/98	5/	7/98	5/	7/98	5/	7/98	5/	7/98
COPY?	YES	NO	YES	NO	YES	NO	YES	NO	YES	NO	YES	NO	YES	NO

OFFICIAL RECORD COPY

DOCUMENT NAME: G:\DNRS\COVLTR\CMP.CC

RECEIVED

MATERIALS LICENSE

CORRECTED COPY

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>Licensee</p> <p>1. Caribbean Nuclear Pharmaceuticals, Inc.</p> <p>2. P.O. Box 984</p> <p>once Puerto Rico 00733-0984</p>	<p>In accordance with letter received November 5, 1996</p> <p>3. License number 52-16061-02MD is amended in its entirety to read as follows:</p> <p>4. Expiration date August 31, 2001</p> <p>5. Docket No. 030-34161</p> <p>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 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) Technetium-99m 925 gigabecquerels (GBq) (25 Ci) Xenon-133 37 GBq (1 Ci) Strontium-89 36.63 GBq (990 millicuries (mCi)) Phosphorus-32 1.85 GBq (50 mCi) Rhenium-186 18.5 GBq (500 mCi) 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)

Handwritten signature/initials

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SUPPLEMENTARY SHEET**

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030-34161

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| <p>6. Byproduct, source, and/or special nuclear material</p> <p>J. Any byproduct material authorized under 10 CFR 35.57(a)</p> <p>K. Any byproduct material listed in 10 CFR 35.400 and §35.500</p> <p>L. Uranium (depleted in the isotope Uranium 235)</p> | <p>7. Chemical and/or physical form</p> <p>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</p> <p>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</p> <p>L. Metal encased in stainless steel</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>J. 1.85 gigabecquerels (50 millicuries)</p> <p>K. 1.85 GBq (50 mCi)</p> <p>L. 110 kilograms</p> |
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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.

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9. 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.

CONDITIONS

10. Location for use: **Caribbean Nuclear Pharmaceuticals, Inc.**
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:
 - (a) James B. Hudson, R.Ph.
 - (b) William J. Cox, N.P.
 - (c) Kurt A. Boesger, N.P.
 - (d) Jeffrey M. Bruhl, N.P.
 - (e) 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.

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12. 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.

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.

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16. 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.
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.

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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]
- (4) April 2, 1998 (remove St. Luke's Episcopal Hospital from name)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DAVID J. COLLINS

David J. Collins

DATE _____

BY _____

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

5/4/98