

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.

301849

Licensee

1. Radiopharmacy Incorporated
2. 600 N. Weinbach
Suite 910
Evansville, IN 47711

In accordance with letter dated
September 16, 1996

3. License Number 13-26246-01MD is amended in
its entirety to read as follows:

4. Expiration Date January 31, 2001

5. Docket or
Reference No. 030-31910

6. Byproduct, Source, and/or
Special Nuclear Material7. Chemical and/or Physical
Form8. Maximum Amount that Licensee
May Possess at Any One Time
Under This License

- A. Any unsealed byproduct material, except iodine-131, technetium-99m and xenon-133 used to prepare radioactive drugs for medical use.

- B. Molybdenum-99

- C. Technetium-99m

- A. Any unsealed byproduct material used to prepare radioactive drugs for medical use, except iodine-131, technetium-99m and xenon-133.

- B. Any molybdenum-99/technetium-99m generator initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or equivalent Agreement State regulations.

- C. Unsealed

- A. 550 millicuries

- B. 35 curies

- C. 35 curies

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9610280024 960930
PDR ADOCK 03031910
C PDR

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2^{ml}
30
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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

13-26246-01MD

Docket or Reference Number

030-31910

Amendment No. 07

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

D. Xenon-133

D. Unit dose containers
of gas or gas in
solution initially
distributed in
accordance with a
specific license
issued pursuant to 10
CFR 32.72 or
equivalent Agreement
State regulations

D. 400 millicuries

E. Iodine-131

E. Any form initially
distributed in
accordance with a
specific license
issued pursuant to 10
CFR 32.72 or
equivalent Agreement
State regulations

E. 900 millicuries

F. Any byproduct material
authorized under 10
CFR 35.57(a)

F. 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

F. 15 millicuries

G. Uranium (depleted in
the isotope Uranium-
235)

G. Metal encased in
stainless steel

G. 400 kilograms

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SUPPLEMENTARY SHEET**

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9. Authorized Use:

- A. through E. Preparation and distribution of radioactive drugs (includes Mo-99/Tc-99m generators) to authorized recipients.
- F. 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.
- G. Shielding for Mo-99/Tc-99m 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 G. of this license to persons licensed pursuant to Sections 35.100, 35.200, and 35.300 of 10 CFR Part 35, or under equivalent licenses of Agreement States.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 600 N. Weinbach, Suite 910, Evansville, Indiana and at 1409 East Virginia Avenue, Evansville, Indiana.
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 (4), or
 - (2) Authorized nuclear pharmacists: Timothy M. Quinton, Trenton Rees, Mark E. Brown, Leroy G. Candelaria, David Newbaker, E. Dean Dome, Lynette M. Schaefer, Jeffrey A. Albrecht, Nicole M. Braun, or Matthew O. Broshears.
- B. The Radiation Safety Officer for this license is Timothy M. Quinton.
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.

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- C. 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.
- 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 III, ATTN: Chief, Nuclear Materials Safety Branch, 801 Warrenville Road, Lisle, Illinois 60532-4351. 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 containing licensed material shall not be opened.

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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. Records of inventories shall be maintained for 2 years from the date of each inventory.
15. The licensee may transport licensed material 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 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.
 - B. Before disposal as normal waste, radioactive waste shall be surveyed 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.
17. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements and representations in application dated September 17, 1990.
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(d) for establishing decommissioning financial assurance.
19. 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. Applications dated September 17, 1990, October 2, 1991 (with attachments), July 5, 1995 (with attachments) and June 6, 1996; and
 - B. Letters dated October 23, 1990 (with attachments), May 10, 1991, July 17, 1991, August 28, 1991, October 2, 1991, June 6, 1996 and August 29, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date September 30, 1996

By

Colleen C. Casey
Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02500
Status Code: 0
Fee Category: 3D
Exp. Date: 20010131
Fee Comments:
Decom Fin Assur Req'd: N

56
21

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: RADIOPHARMACY INCORPORATED
Received Date: 960920
Docket No: 3031910
Control No.: 301849
License No.: 13-26246-01MD
Action Type: Amendment

2. FEE ATTACHED

Amount: 0
Check No.: 0

3. COMMENTS

Signed D. Hersey
Date 9-24-96

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

1. Fee Category and Amount: 3D \$430

2. Correct Fee Paid. Application may be processed for:
Amendment ☒
Renewal ☐
License ☐

3. OTHER

Signed SC
Date 10/8/96

1996 SEP 27 AM 11:00

OCT 15 1996

Log	<u>Sep 10 III</u>
Remitter	
Check No.	<u>21931</u>
Amount	<u>\$430</u>
Fee Category	<u>3D</u>
Type of Fee	<u>AMD</u>
Date Check Rec'd	<u>10/8/96</u>
Date Completed	
By:	<u>SC</u>



RADIOPHARMACY, INC.

600 N. WEINBACH, STE. 910
EVANSVILLE, IN 47711
(812) 474-1242

September 16, 1996

United States Nuclear Regulatory Commission
Region III
801 Warrenville Rd.
Lisle, IL 60532-4351

I am writing to request that the I-131 possession limit, item 8.E. of NRC Material License No. 13-26246-01MD issued to Radiopharmacy, Inc., be increased to 900 millicuries. I also request that this change be made as soon as possible.

If you need additional information or have any questions, please call me. Thanks for your help.

Sincerely,

Timothy Quinton
Radiation Safety Officer

RECEIVED

SEP 20 1996

REGION III

301849

SEP 20 1996

PM 9/17/96

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 20555-0001

RADIOPHARMACY, INC.
ATTN: TIMOTHY QUINTON
RADIATION SAFETY OFFICER
600 N. WEINBACH
SUITE 910
EVANSVILLE, INDIANA 47711

TYPE OF ACTION

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

REQUESTED DATE

9-16-96

LICENSE NUMBER

13-26246-01MD

CONTROL NUMBER

301849

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
3D	\$	\$	\$ 430.00
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(s) DUE	\$	430.00
PAYMENT RECEIVED	\$	0.00
AMOUNT DUE	\$	430.00

☒ 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

LFDCB

LFDCB

SHIRLEY CRUTCHFIELD

9/30/96

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

LFARB R/F (2)

OC/DAF/RF

OC/DAF/SF(LF-3.2.7)

Region _____

DATE

Sept. 30, 1996

OCT 16 1996

Timothy Quinton
Radiation Safety Officer
600 N. Weinbach
Suite 910
Evansville, IN 47711

Dear Mr. Quinton:

Enclosed is Amendment No. 07 to your NRC Material License No. 13-26246-01MD in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 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 Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days:
 - a. When the 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(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.
4. Request and obtain a license amendment before you:
 - a. Change Radiation Safety Officers;

301849

- b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - d. 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. 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 Policy and Procedures for NRC Enforcement Actions. 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 when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Colleen C. Casey
Nuclear Materials Licensing Branch

License No. 13-26246-01MD
Docket No. 030-31910

Enclosure: Amendment No. 07

DOCUMENT NAME: M:\03031910.CL6

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure
"N" = No copy

OFFICE	DNMS/RIII <i>ckc</i>						
NAME	CCCASEY:sjd						
DATE	09/24/96						

OFFICIAL RECORD COPY



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

September 25, 1996

Timothy M. Quinton, President
Radiation Safety Officer
Radiopharmacy Incorporated
600 N. Weinbach, Suite 910
Evansville, IN 47711

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE (Letter Dated 09/16/96)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

☐ New License ☒ Amendment ☐ Renewal
☐ Termination ☐ Auth User (Amendment not required)

Administrative deficiencies were identified during this initial review as outlined below. However, it should be noted that a technical review may identify additional omissions in the submitted information.

It appears that your request is nonroutine and has been assigned to Colleen Casey for an expedited review. If you should have any questions please contact Ms. Casey at (630) 829-9887.

Incomplete information is as follows: In order for us to complete your request the required fee is necessary. Please contact our License Fee & Debt Collection Branch, located in our headquarters office, as referenced below.

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
2. Renewal actions are normally processed within 180 days, however under timely filing (before expiration) you may continue to operate under your existing license.
3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 301849
License No. 13-26246-01MD