

## ACCEPTANCE REVIEW MEMO (ARM)

**Licensee:** Pacific Radiopharmacy Ltd.

**License No.:** 53-16991-01MD

**Docket No.:** 030-12031

**Mail Control No.:** 471005

**Type of Action:** Amend

**Date of Requested Action:** 05-18-06

**Reviewer Assigned:**

**ARM reviewer(s):** Torres

*RSTC*

Response	Deficiencies Noted During Acceptance Review
	1. [ ] Open ended possession limits. Submit inventory. Limit possession. [ ] Inform licensee that we are limiting possession limits. [ ] Ask the licensee if they have any type-amount of EPAct Material.
	2. <i>Note to reviewer: As per N-1556 add License condition</i>
	3. <i>#20 on page E-5 of N-1556 Vol. 13</i>

**Reviewer's Initials:** \_\_\_\_\_

**Date:** \_\_\_\_\_

- Yes  No Request for unrestricted use for Group 2 or higher category should be transferred by memo to FCDB within 10 days of receipt.
- Yes  No Decommissioning notification should be completed within 30 days.
- Yes  No Termination request < 90 days from date of expiration
- Yes  No Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)
- Yes  No TAR needed to complete action.

**Branch Chief's and/or Sr. HP's Initials:** \_\_\_\_\_

**Date:** \_\_\_\_\_

### SUNSI Screening according to RIS 2005-31

Yes  ~~No~~ **Non-Publicly Available, Sensitive** if any item below is checked

General guidance:

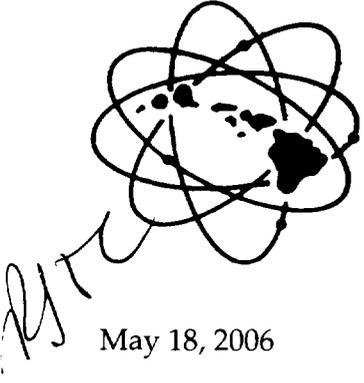
- RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule
- Exact location of RAM (whether = or > than Category 3 or not)
- Design of structure and/or equipment (site specific)
- Information on nearby facilities
- Detailed design drawings and/or performance information
- Emergency planning and/or fire protection systems

Specific guidance for medical, industrial and academic (above Category 3):

- RAM quantities and inventory
- Manufacturer's name and model number of sealed sources & devices
- Site drawings with exact location of RAM, description of facility
- RAM security program information (locks, alarms, etc.)
- Emergency Plan specifics (routes to/from RAM, response to security events)
- Vulnerability/security assessment/accident-safety analysis/risk assess
- Mailing lists related to security response

**Branch Chief's and/or Sr. HP's Initials:** *RSTC*

**Date:** *6/21/06*



**PACIFIC RADIOPHARMACY, LTD.**

347 NORTH KUAKINI STREET \* HONOLULU, HAWAII 96817  
TELEPHONE (808) 547-9580

May 18, 2006

U.S. Nuclear Regulatory Commission, Region IV  
611 Ryan Plaza Drive, Suite 400  
Arlington, TX 76011-8064

RECEIVED  
JUN 05 2006  
DNMS

Subject: License Amendment  
NRC License No. 53-16991-01MD  
Docket No. 030-12031

Dear License Reviewer:

We wish to amend our byproduct materials license to allow us to receive radioactive waste from customers.

We have developed and will implement and maintain written procedures for customer return of pharmacy supplied syringes and vials and their contents, to specify that:

- Only pharmacy supplied syringes and vials and their contents may be returned to the pharmacy;
- Instructions will be provided to radiopharmacy customers for the proper preparation and packaging of radioactive waste for return to the radiopharmacy; and
- Instructions will be provided to pharmacy staff for the pick-up, receipt, and disposal of the returned radioactive waste that meet the requirements in 10 CFR 20.2001(a), 10 CFR 30.33, 10 CFR 71.5, as applicable.

If you require any additional information please contact our radiation safety officer, Ronald Frick at 808-373-7009.

Sincerely,  
  
Gregg Oishi  
President

Estimated burden per response to comply with this mandatory information collection request, 7.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-6 EB), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjs1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NE08-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

# APPLICATION FOR MATERIAL LICENSE

**INSTRUCTIONS:** SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

**APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:**

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY  
 OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS  
 U.S. NUCLEAR REGULATORY COMMISSION  
 WASHINGTON, DC 20555-001

**ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:**

**IF YOU ARE LOCATED IN:**  
 CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND,  
 MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA,  
 RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION  
 NUCLEAR MATERIALS SAFETY BRANCH  
 U.S. NUCLEAR REGULATORY COMMISSION, REGION I  
 475 ALLENDALE ROAD  
 KING OF PRUSSIA, PA 19406-1415

**ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA,  
 PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR  
 WEST VIRGINIA, SEND APPLICATIONS TO:**

SAM NUNN ATLANTA FEDERAL CENTER  
 U.S. NUCLEAR REGULATORY COMMISSION, REGION II  
 61 FORSYTH STREET, SW, SUITE 23T85  
 ATLANTA, GA 30303-8931

**IF YOU ARE LOCATED IN**  
**ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN,**  
**SEND APPLICATIONS TO:**

MATERIALS LICENSING SECTION  
 U.S. NUCLEAR REGULATORY COMMISSION, REGION III  
 801 WARRENVILLE RD.  
 LISLE, IL 60532-4351

**ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS,  
 LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA,  
 OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH,  
 WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:**

NUCLEAR MATERIALS LICENSING SECTION  
 U.S. NUCLEAR REGULATORY COMMISSION, REGION IV  
 611 RYAN PLAZA DRIVE, SUITE 400  
 ARLINGTON, TX 76011-8084

**PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.**

1. THIS IS AN APPLICATION FOR (Check appropriate item)

A. NEW LICENSE

B. AMENDMENT TO LICENSE NUMBER 53-16991-01MD

C. RENEWAL OF LICENSE NUMBER \_\_\_\_\_

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)

Pacific Radiopharmacy  
 347 North Kuakini St.  
 Honolulu, HI 96817

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Same as 2.

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Ronald Frick, M.S., CHP, DABR

TELEPHONE NUMBER

808-373-7009

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL  
 a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY	3C	AMOUNT ENCLOSED	\$0
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13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Gregg Oishi, President

SIGNATURE



DATE

5/19/06

**FOR NRC USE ONLY**

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
APPROVED BY			\$	DATE	47-05

JUN 21 2006

DATE

This is to acknowledge the receipt of your letter/application dated 05-18-06, and to inform you that the initial processing, which includes an administrative review, has been performed.

There were no administrative omissions. Your application will be assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card:

The action you requested is normally processed within 90 days.

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 471005.  
When calling to inquire about this action, please refer to this mail control number.  
You may call me at 817-860-8103.

Sincerely,

*Colleen Murahan*  
Licensing Assistant

BETWEEN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

(FOR LEMS USE)  
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INFORMATION FROM LTS  
-----  
: : : : :  
: Program Code: 02500  
: Status Code: 0  
: Fee Category: 3C  
: Exp. Date: 20150630  
: Fee Comments:  
: Decom Fin Assur Regd: N  
: : : : :  
: : : : :  
: : : : :

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED  
Applicant/Licensee: PACIFIC RADIOPHARMACY LTD.  
Received Date: 20060605  
Docket No: 3012031  
Control No.: 471005  
License No.: 53-16991-01MD  
Action Type: Amendment

2. FEE ATTACHED

Amount: \_\_\_\_\_  
Check No.: \_\_\_\_\_

3. COMMENTS

Signed \_\_\_\_\_  
Date 07/27/06

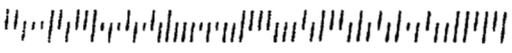
B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / \_\_/)

1. Fee Category and Amount: \_\_\_\_\_

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

3. OTHER

Signed \_\_\_\_\_  
Date \_\_\_\_\_



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RECEIVED  
JUN - 5 2006  
DNMS

FIRST CLASS MAIL

**PACIFIC RADIOPHARMACY, LTD.**  
47 North Kalia Street  
HONOLULU HAWAII 96817  
(808) 547-9580

U.S. Nuclear Regulatory  
Commission, Region IV  
611 Ryan Plaza Drive, Suite 400  
Arlington, TX 76011-8064