

ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Pacific Radiopharmacy **License No.:** 53-16991-01MD
Docket No.: 030-12031 **Mail Control No.:** 471246
Type of Action: Amend **Date of Requested Action:** 01-29-07
Reviewer Assigned: Roberto **ARM reviewer(s):** Torres

Response	Deficiencies Noted During Acceptance Review
	[] Open ended possession limits. Limit possession. Submit inventory. [] Submit copies of most recent leak test results. [] Add - delete IC license condition. Add IC paragraph in cover letter. [] Split license from cover letter. Add SUNSI marking to license. [] Ask the licensee if they have any type-amount of EPAct Material.
	1. Need copy of active license of Mr. Caplan to practice pharmacy.

Reviewer's Initials: _____ **Date:** _____

- Yes No Unrestricted release Group 2 or >: Transfer memo to FCDB within 10 days.
- 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: RT **Date:** 2/8/07

Pre-Licensing Screening

Applicant Information:

Control No. 471246

Name: Pacific Radiopharmacy	Type of Request: Amend Program Code(s):	
Location: HI	License No.: 53-16991-01MD	Docket No.: 030-12031

STEP 1—Radioactive Materials and Quantities Requested:

Instructions for Step 1: Complete Step 1 for all applications. If all your responses in Step 1 are "No" then do not complete Step 2 (Screening Criteria). Sign and date the completed step-sheet and add it as the sensitive and non-publicly available OAR in ADAMS. If a "yes" response is indicated for any item in Step 1, also complete Step 2. If the type of use is subject to a Security Order or the requirements for increased controls, complete Step 3 (Item A or Item B) without delay.	Yes or No
A. The request is from a new applicant.	N
B. NUREG-1556, Volume 20, Section 4.9 indicates a licensing site visit is needed for the requested type of use, e.g., (1) Type A broad scope license, (2) panoramic irradiator containing > 10000 curies, (3) manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material, (4) radioactive waste brokers, (5) radioactive waste incinerators, (6) commercial nuclear laundries, and (7) any other application that in the judgement of the reviewer and cognizant supervisor involves complex technical issues, complex safety questions, or unprecedented issues that warrant a site visit.	N
C. The applicant requested certain radionuclides and quantities that equal or exceed the Risk Significant Quantity (TBq) values in the table, below, that have been "highlighted" by the reviewer	N

Table of Risk Significant Quantities

(Category 2 Quantities, IAEA Safety Guide No. RS-G-1.9, Categorization of Radioactive Sources, August 2005)

Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant Quantity (Ci ¹)	Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant Quantity (Ci ¹)
Am-241	0.6	16	Pm-147	400	11,000
Am-241/Be	0.6	16	Pu-238	0.6	16
Cf-252	0.2	5.4	Pu-239/Be	0.6	16
Cm-244	0.5	14	Ra-226 ²	0.4	11
Co-60	0.3	8.1	Se-75	2	54
Cs-137	1	27	Sr-90 (Y-90)	10	270
Gd-153	10	270	Tm-170	200	5,400
Ir-192	0.8	22	Yb-169	3	81

¹ The primary values are TBq. The curie (Ci) values are for informational purposes only.

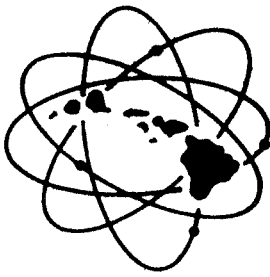
² The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC is in the process of amending its regulations for discrete sources of Ra-226.

Calculations of the Total Activity or the Unity Rule are attached to document whether or not the screening criteria in Step 2 were also completed to evaluate the application. NOTE—If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s).	Yes, No, or Not Applicable (NA)
Total Activity—multiple activities are requested for a single radionuclide and the sum of the activities equals or exceeds the quantity of concern for the radionuclide	—
Unity Rule—multiple radionuclides are requested and the sum of the ratios equals or exceeds unity, e.g., [(total activity for radionuclide A) ÷ (risk significant quantity for radionuclide A)] + [(total activity for radionuclide B) ÷ (risk significant quantity for radionuclide B)] ≥ 1.0.	—

Signature and Date for Step 1:

RTZ 2/8/07

License Reviewer and Date



PACIFIC RADIOPHARMACY, LTD.

347 NORTH KUAKINI STREET * HONOLULU, HAWAII 96817

TELEPHONE (808) 537-9580

RECEIVED

FEB - 2 2007

DNMS

January 29, 2007

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

RTU

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 add Steven Caplan, R.Ph. as an Authorized Nuclear Pharmacist. We have enclosed NRC Form 313A(ANP), which details his training and experience.

If you require any additional information please contact our Radiation Safety Officer, Ronald Frick at 808-373-7009.

Sincerely,



Gregg Oishi
President

No 471246

(10-2005)
10 CFR 30, 32, 33,
34, 35, 36, 39, and 40

APPLICATION FOR MATERIAL LICENSE

Estimated burden per response to comply with this mandatory collection request: 4.4 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 and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-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, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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 20555-0001

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

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:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-4005

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, Ltd.
347 North Kuakini Street
Honolulu, HI 96817

3. ADDRESS 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. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 3C AMOUNT ENCLOSED \$ 0.00

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

1/29/07

FOR NRC USE ONLY

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

471246

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND
EXPERIENCE AND PRECEPTOR ATTESTATION
[10 CFR 35.55]**

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized Nuclear Pharmacist
Steven Caplan, R.Ph.

State or Territory Where Licensed
Hawaii

PART I -- TRAINING AND EXPERIENCE
(Select one of the two methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the nuclear pharmacy uses.

1. Board Certification

- a. Provide a copy of the board certification.
- b. Skip to and complete Part II Preceptor Attestation.

2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist

- a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	Purdue University - Nuclear Pharmacy Certificate Program		4/15/06 - 9/21/06
Radiation protection	Purdue University - Nuclear Pharmacy Certificate Program		4/15/06 - 9/21/06
Mathematics pertaining to the use and measurement of radioactivity	Purdue University - Nuclear Pharmacy Certificate Program		4/15/06 - 9/21/06
Chemistry of byproduct material for medical use	Purdue University - Nuclear Pharmacy Certificate Program		4/15/06 - 9/21/06
Radiation biology	Purdue University - Nuclear Pharmacy Certificate Program		4/15/06 - 9/21/06

Total Hours of Training: >200 hours

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION (continued)**

2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist (continued)

b. Supervised Practical Experience in a Nuclear Pharmacy.

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Shipping, receiving, and performing related radiation surveys	Pacific Radiopharmacy, Ltd. NRC License #53-16991-01MD		March 2006 - January 2007
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides	Pacific Radiopharmacy, Ltd. NRC License #53-16991-01MD		March 2006 - January 2007
Calculating, assaying, and safely preparing dosages for patients or human research subjects	Pacific Radiopharmacy, Ltd. NRC License #53-16991-01MD		March 2006 - January 2007
Using administrative controls to avoid medical events in administration of byproduct material	Pacific Radiopharmacy, Ltd. NRC License #53-16991-01MD		March 2006 - January 2007
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	Pacific Radiopharmacy, Ltd. NRC License #53-16991-01MD		March 2006 - January 2007
Total Hours of Experience:		>500 hours	
Supervising Individual <p align="center">Trent T. Phan, Ph.D.</p>			

c. Go to and complete Part II Preceptor Attestation.

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION (continued)**

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section

Check one of the following:

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized Nuclear Pharmacist

10 CFR 35.55(a)(1), (a)(2), and (a)(3) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

OR

Structured Educational Program

I attest that Steven Caplan, R.Ph. has satisfactorily completed a 700-hour structured
Name of Proposed Authorized Nuclear Pharmacist

educational program consisting of both 200 hours of classroom and laboratory training, and practical experience in nuclear pharmacy, as required by 10 CFR 35.55(b)(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Second Section

Complete the following for preceptor attestation and signature:

I am an Authorized Nuclear Pharmacist for Pacific Radiopharmacy, Ltd.,
Nuclear Pharmacy or Medical Facility

53-16991-01MD
License/Permit Number

Name of Preceptor Trent T. Phan, Ph.D.	Signature <i>Trent Phan</i>	Telephone Number 808-547-9580	Date Jan 29, 2007
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*2/12/07 Reviewer's assessment
Steve Caplan meets the training and experience required
by 10 CFR 35.55 (b)(1) and (b)(2) and can be named
as ANP on license 53-16991-01MD.*

Roberto J. Torres

PURDUE UNIVERSITY
WEST LAFAYETTE, INDIANA

SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES
DEPARTMENT OF INDUSTRIAL AND PHYSICAL PHARMACY
DIVISION OF NUCLEAR PHARMACY

This certificate is awarded to

Steven Caplan

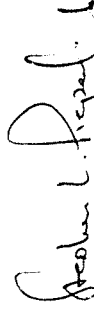
as evidence of completion of the

NUCLEAR PHARMACY CERTIFICATE PROGRAM

September 28, 2006



John M. Pezzato
Dean, School of Pharmacy
and Pharmaceutical Sciences



Stephen L. Pieperbrink
Director of Nuclear Pharmacy Engagement

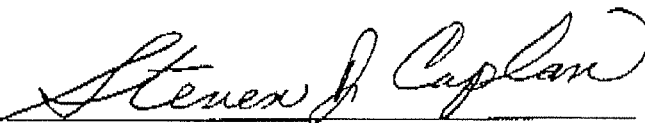
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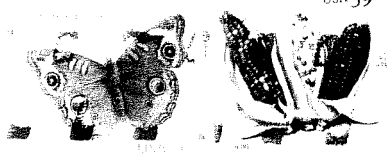
EXPIRATION DATE
12/31/07

STATE OF HAWAII DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
PHARMACIST

STEVEN J. CAPLAN
HONOLULU HI

(SIGNATURE
OF LICENSEE)





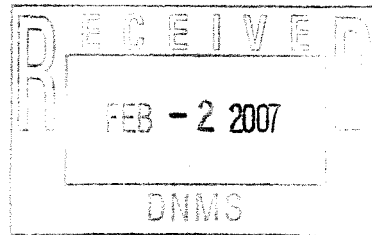
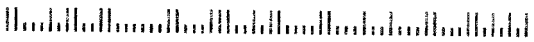
2007 PM HONOLULU HI 968 30 JAN 2007 PM HONOLULU HI 968 30



Gamma Corporation

P.O. Box 240370, Honolulu, HI 96824

U.S.N.R.C., Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064



4 7 1 2 4 6

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
Exp. Date: 20150630
Fee Comments:
Decom Fin Assur Req'd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: PACIFIC RADIOPHARMACY LTD.
Received Date: 20070202
Docket No.: 3012031
Control No.: 471246
License No.: 53-16991-01MD
Action Type: Amendment

2. FEE ATTACHED

Amount: _____
Check No.: _____

3. COMMENTS

Signed *Colleen Thumala*
Date _____

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 _____