

## ACCEPTANCE REVIEW MEMO (ARM)

**Licensee:** Pacific Radiopharmacy Ltd.

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

**Docket No.:** 030-12031

**Mail Control No.:** 471418

**Type of Action:** Notify

**Date of Requested Action:** 06-21-07

**Reviewer  
Assigned:**

**ARM reviewer(s):** Cook

Response	Deficiencies Noted During Acceptance Review
	<input type="checkbox"/> Open ended possession limits. Limit possession. Submit inventory. <input type="checkbox"/> Submit copies of most recent leak test results. <input type="checkbox"/> Add - delete IC license condition. Add IC paragraph in cover letter. <input type="checkbox"/> Split license from cover letter. Add SUNSI marking to license. <input type="checkbox"/> Ask the licensee if they have any type-amount of EAct Material.

**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:** 

**Date:** 7/10/07

## Pre-Licensing Screening

### Applicant Information:

Control No. 471418

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

### STEP 1—Radioactive Materials and Quantities Requested:

<b>Instructions for Step 1: Complete Step 1 for all applications.</b> 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)

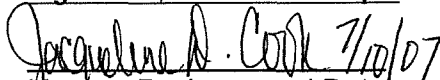
Radionuclide	Risk Significant Quantity (TBq <sup>1</sup> )	Risk Significant Quantity (Ci <sup>1</sup> )	Radionuclide	Risk Significant Quantity (TBq <sup>1</sup> )	Risk Significant Quantity (Ci <sup>1</sup> )
Am-241	0.6	16	Pm-147	400	11,000
Am-241/Be	0.6	16	Pu-238	0.6	16
Cf-252	0.2	5.4	Pu-239/Be	0.6	16
Cm-244	0.5	14	Ra-226 <sup>2</sup>	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

<sup>1</sup> The primary values are TBq. The curie (Ci) values are for informational purposes only.

<sup>2</sup> 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.

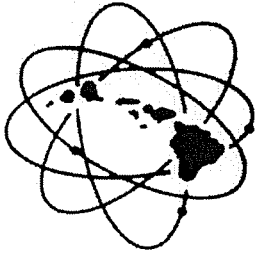
Calculations of the Total Activity or the Unity Rule are attached to document whether or not the screening criteria in Step 2 were also completed to evaluate the application. <b>NOTE—If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s).</b>	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:

  
 License Reviewer and Date 7/10/07

**PACIFIC RADIOPHARMACY, LTD.**

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



RECEIVED

JUL 2 2007

DAIIC

June 21, 2007

Nuclear Materials Licensing Branch  
U.S. Nuclear Regulatory Commission, Region IV  
611 Ryan Plaza Drive, Suite 400  
Arlington, TX 76011-4005

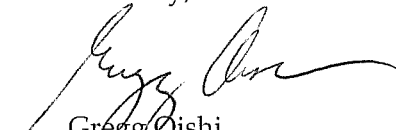
Subject: Notification  
NRC License No. 53-16991-01MD  
Docket No. 030-12031

Dear License Reviewer:

Please remove Richard H. Naito from our list of authorized nuclear pharmacists.

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

Sincerely,



Gregg Oishi  
President

This is to acknowledge the receipt of your letter/application dated  
6-21-07, and to inform you that the initial processing,  
which includes an administrative review, has been performed.

Aug. 1, 2007  
DATE

☒ 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:

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The action you requested is normally processed within      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** 471418.  
When calling to inquire about this action, please refer to this mail control number.  
You may call me at 817-860-8103.

Sincerely,

*Celeen Murahan*

Licensing Assistant

(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
.....
```

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: Decom Fin Assur Reqd: N
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: Decom Fin Assur Reqd: N
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- Applicant/Licensee: PACIFIC RADIOPHARMACY LTD.  
 Registered Address: 20070702


20070702  
2012021

3012031  
471410

53-16991

## Notifications

- Amount:



- Signed \_\_\_\_\_  
Date 7-6-07

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 \_\_\_\_\_

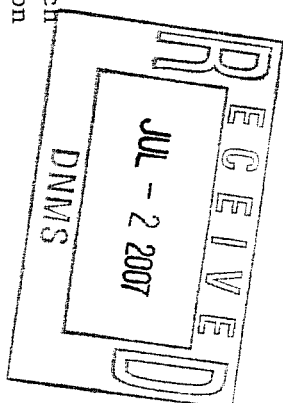
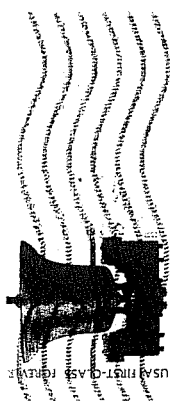
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- ### 3. OTHER

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

Pacific Radiopharmacy, Ltd.  
347 N. Kuakini Street  
Honolulu, HI 96817

HONOLULU HI 968  
26 JUN 2007 PM 2 L



Nuclear Materials Licensing Branch  
U.S. Nuclear Regulatory Commission  
Region IV  
611 Ryan Plaza Drive, Suite 400  
Arlington, TX 76011-4005

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