

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 EPAct Material.

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

<input type="checkbox"/> Yes	<input type="checkbox"/> No	Unrestricted release Group 2 or >: Transfer memo to FCDB within 10 days.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Decommissioning notification should be completed within 30 days.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Termination request < 90 days from date of expiration
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)
<input type="checkbox"/> Yes	<input type="checkbox"/> 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: *JAC* **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:

<p>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.</p>		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

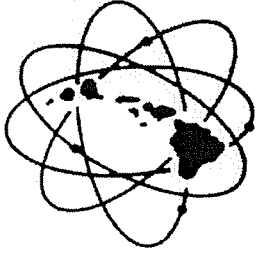
¹ The primary values are TBq. The curie (Ci) values are for informational purposes only.
² The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC is in the process of amending its regulations for discrete sources of Ra-226.

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:

Jacqueline A. Cook 7/10/07
 License Reviewer and Date

Handwritten initials



PACIFIC RADIOPHARMACY, LTD.

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

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JUL 2 2007
DABAC

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,

Handwritten signature of Gregg Oishi
Gregg Oishi
President

Aug. 1, 2007
DATE

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.

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 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,

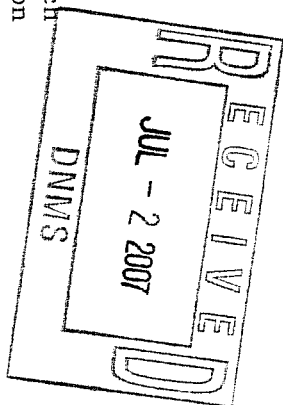
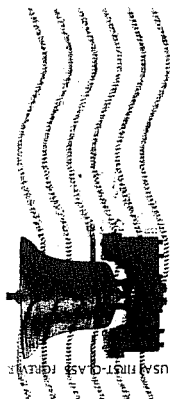


Licensing Assistant

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

HONOLULU HI 96817

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Arlington, TX 76011-4005

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