UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-4005

August 20, 2007

Pacific Radiopharmacy, Ltd.
ATTN: Gregg Oishi
President
347 North Kuakini Street
Honolulu, Hawaii 96817

SUBJECT: LICENSE AMENDMENT AND NOTIFICATION PER 10 CFR 35.14(b)(1)

Please find enclosed Amendment No. 18 to NRC License No. 53-16991-01MD, **acknowledging your notification dated June 21, 2007, to remove Richard H. Naito as an authorized nuclear pharmacist from your license.** An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14)(iii). You should review the enclosed document carefully and be sure that you understand all of the conditions. If there are any questions, please contact me at 817-276-6552.

The NRC medical list server has been set up. The list server will send automatic e-mail notifications of medical-related generic communications, Federal Register Notices, and NMSS/FSME newsletters as they are published. Anyone may subscribe/unsubscribe to the new medical list server by sending an e-mail to medical-gc@nrc.gov with "Subscribe" or "Unsubscribe" in the subject line.

NRC expects licensees to conduct their programs with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your radiation safety program according to the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate by NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. In accordance with 10 CFR 35.14, notify the NRC no later than 30 days after:

   a. The date that the licensee permits an individual to work as an authorized nuclear pharmacist under 10 CFR 35.13(b)(1) through (b)(4);

   b. An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues duties under the license or has a name change;

   c. The licensee's mailing address changes;

   d. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 10 CFR 30.34(b); or

e. Add or change the areas or addresses of use identified in the license application or on the license.

In addition, please note that NRC Form 313 requires the applicant, by 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. Since the NRC also accepts a letter requesting amendment of an NRC license, the signatory for such a request should also be the licensee or certifying official rather than a consultant.

NRC will periodically inspect your radiation safety program. Failure to conduct your program according to NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action against you. This could include issuance of a notice of violation; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available on the following internet address: http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf.

The NRC no longer publishes the NRC Rules and Regulations loose leaf supplements. However, an electronic version of the NRC's regulations is available on the NRC Web site at www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web site at: http://www.nrc.gov/materials/miau/med-use-toolkit.html. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Thank you for your cooperation.

Sincerely,

/RA/

Rachel S. Browder, Health Physicist
Nuclear Materials Licensing Branch

Docket: 030-12031
License: 53-16991-01MD
Control: 471418

Enclosure:
1) NRC License Amendment No. 18

Amendment No. 18

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.

Licensee	In accordance with letter dated June 21, 2007
1. Pacific Radiopharmacy, Ltd.	3. License number 53-16991-01MD is amended in its entirety to read as follows:
2. 347 North Kuakini Street Honolulu, Hawaii 96817	4. Expiration date June 30, 2015
	5. Docket No. 030-12031 Reference No.

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
A. Any byproduct material with atomic numbers 1 through 83, except molybdenum-99, technetium-99m, iodine-131 and xenon-133	A. Any	A. 300 millicuries per radionuclide and 1 curie total
B. Molybdenum 99	B. Any	B. 100 curies
C. Technetium 99m	C. Any	C. 100 curies
D. Iodine 131	D. Any	D. 900 millicuries
E. Xenon 133	E. Any	E. 1 curie
F. Any byproduct material authorized under paragraph 35.65(a) of 10 CFR Part 35	F. Sealed sources	F. 10 millicuries
G. Any byproduct material listed in paragraph 31.11(a) of 10 CFR Part 31	G. Prepackaged units for *in vitro* diagnostic tests	G. 10 millicuries
H. Depleted Uranium	H. Metal	H. 600 kilograms

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9. Authorized use:

A. through E. Preparation and distribution of radioactive drugs in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals to authorized recipients for non-medical use.

F. Calibration and checking of the licensee's instruments. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 to authorized recipients and to authorized recipients for non-medical use.

G. Redistribution to specific licensees or general licensees pursuant to 31.11 of 10 CFR Part 31 provided the packaging and labeling remain unchanged.

H. Shielding for molybdenum 99/technetium 99m generators.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 347 North Kuakini Street, Honolulu, Hawaii.

11. Licensed material shall be used by, or under the supervision of:

A. A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2)(i) or (4).

B. Authorized nuclear pharmacists: Trent T. Phan, Ph.D. and Steven J. Caplan, R.Ph.

12. The Radiation Safety Officer for this license is Ronald Frick, M.S., CHP, DABR.

13. 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.

14. This license does not authorize distribution to persons exempt from licensing.

15. A. Sealed sources 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 or by an Agreement State.

B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the NRC under 10 CFR 32.210 or by an Agreement State prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

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C. 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.

D. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(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 IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.

E. Tests for leakage and/or contamination shall be performed by the licensee or other persons specifically licensed by the NRC or an Agreement State to perform such services. In addition, the licensee is authorized to collect leak test samples for analysis by persons specifically licensed by the NRC or an Agreement State to perform such services.

16. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.

17. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the NRC, to account for all sources and/or devices received and possessed under the license.

18. Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from the NRC before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective Registration Certificates issued either by the NRC pursuant to 10 CFR 32.210 or by an Agreement State.

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19. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

20. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

    A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

    B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

    C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

21. The licensee is authorized to retrieve, receive and dispose of radioactive waste from it's customers limited to radiopharmacy supplied syringes and vials and their contents.

22. 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. The U.S. 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. Application dated February 23, 2005 (ML050810163)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

/RA/

Date: August 20, 2007

By: _____

Rachel S. Browder, Health Physicist
Nuclear Materials Licensing Branch
Region IV
Arlington, Texas 76011