U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 20

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 and E-mail dated January 27, 2010 and March 17, 2010
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 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 shall 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) and (4).

B. Authorized Nuclear Pharmacist(s): Trent T. Phan, Ph.D. and James A. Fuselier, 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) and 40.36(b) for establishing financial assurance for decommissioning.

14. This license does not authorized 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 specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 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 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 and the results received.

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C. Sealed sources need not be leak tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or 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 they are not designed to emit alpha particules, 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 and the results received. 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 microcuries (185 Becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcuries (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 Regulator Commission, Region IV, 612 East Lamar Boulevard, Suite 400, Arlington, Texas 76011-4125, 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 U.S. Nuclear Regulatory Commission 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 Commission 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 sealed 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 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 Commission pursuant to 10 CFR 31.210 or by an Agreement State.

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

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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 its 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)
B. Letter dated December 28, 2009 (ML100120802)
C. E-mails dated January 13, 2010 (ML100131298)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date March 18, 2010

By **/RA/**

Roberto J. Torres, Senior Health Physicist
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Region IV
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