ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Straub Clinic & Hospital **License No.:** 53-18126-01

Docket No.: 030-14529 **Mail Control No.:** 471471

Type of Action: Notify **Date of Requested Action:** 08-13-07

Reviewer Assigned: **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.

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: RTC **Date:** AUG 28 2007

Pre-Licensing Screening

Applicant Information: **Control No.** 471471

Name: Straub Clinic & Hospital	Type of Request: Amend Program Code(s):
Location: HI	License No.: 53-18126-01 Docket No.: 030-14529

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.	No
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.	No
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	No

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:

AUG 28 2007

License Reviewer and Date

888 South King Street • Honolulu, HI 96813

Straub
CLINIC & HOSPITAL

(808) 522-4000 • straubhealth.org

August 13, 2007

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

RE: Notification
NRC License No. 53-19126-01
Docket No. 030-14529

Dear License Reviewer:

We have approved Sandi Kwee, M.D. as an authorized user for byproduct materials listed in 10 CFR 35.100, 35.200, and 35.300. Dr. Kwee is currently authorized for these uses on NRC License #53-16533-02 issued to The Queen's Medical Center. A copy of this license is enclosed.

Please contact our Radiation Safety Consultant, Ronald Frick, at 808-373-7009 if you require additional information.

Sincerely,

Art Gladstone
Chief Operating Officer

Enclosure

COPY

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Amendment No. 54

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 March 23, 2007
1. The Queen's Medical Center	3. License number 53-16533-02 is amended in its entirety to read as follows:
2. 1301 Punchbowl Street Honolulu, Hawaii 96813	4. Expiration date December 31, 2014
	5. Docket No. 030-14522 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 permitted by 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As needed
C. Any byproduct material permitted by 10 CFR 35.300	Any	C. 1.0 curie
D Any byproduct material permitted by 10 CFR 35.400	D. Sealed sources (3M Health Physics Services Model 6D6C-CA, Amersham Model SA.20, North American Scientific, Inc. Models MED3631 and MED3633, Best Medical International, Inc. [formerly Best Industries] Model 81-01 Series, Medi-Physics, Inc. Models 6711 or 6733, Mills Biopharmaceuticals, Inc. Model I-125 SL, Implant Sciences Corporation Model 3500, Best Medical International, Inc. Model 2300 Series, IsoAid, LLC, Model IAI-125A, or IsoRay Model CS-1)	D. 5.15 curies

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No. 471471

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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
E. Iodine-125 permitted by 10 CFR 35.1000	E. Liquid as Proxima Therapeutics, Inc. Iotrex™	E. 5 curies
F. Iridium-192 permitted by 10 CFR 35.600	F. Sealed sources (Varian Medical Systems Haan GmBH Model GammaMed 232)	F. 25 curies total, one source not to exceed 10 curies at the time of treatment, and one source not to exceed 15 curies stored
G. Cesium-137	G. Sealed sources (Compagnie ORIS Industrie Model CSL-15)	G. 5610 curies
H. Hydrogen-3	H. Any	H. 20 millicuries
I. Carbon-14	I. Any	I. 10 millicuries
J. Phosphorus-32	J. Any	J. 10 millicuries
K. Phosphorus-33	K. Any	K. 10 millicuries
L. Sulfur-35	L. Any	L. 10 millicuries
M. Calcium-45	M. Any	M. 10 millicuries
N. Iodine-125	N. Any	N. 100 millicuries
O. Depleted uranium	O. Metal	O. 100 kilograms
P. Strontium-90 permitted by 10 CFR 35.400	P. Sealed source (Amersham Corporation Model SIA.20)	P. 90 millicuries

9. Authorized use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.

B. Any imaging and localization study permitted by 10 CFR 35.200.

C. Any study permitted by 10 CFR 35.300.

D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.

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E. For brachytherapy use in the Proxima Therapeutics' GliaSite® Radiotherapy system permitted by 10 CFR 35.1000.

F. One source for medical use permitted by 10 CFR 35.600, in a Varian Medical Systems, Inc., GammaMed plus or GammaMed plus 3/24 high dose rate remote afterloading brachytherapy unit. The source activity may not exceed 10 curies at the time of treatment. One source may be stored in its shipping container as necessary, for the replacement of the source in the remote afterloading unit.

G. For use in a CIS-US, Inc. Model IBL-437C irradiator for the irradiation of blood.

H. through N. In vitro research.

O. Shielding to be used in technetium generators.

P. Strontium-90 for ophthalmic radiotherapy permitted by 10 CFR 35.400.

CONDITIONS

10. A. Licensed material identified in items 6.A. through 6.E., 6.H. 6.O. and 6.P., shall be used or stored only at the licensee's facilities located at 1301 Punchbowl Street, Honolulu, Hawaii.

B. Licensed material identified in items 6.C. and 6.G. shall be used or stored only at the license's facilities located in the Kamehameha wing of the A.E.A. building at 1301 Punchbowl Street, Honolulu, Hawaii.

C. Licensed material identified in items 6.A. through 6.E. and 6.O., shall be used or stored only at the licensee's facilities located at 550 South Beretania Street, Honolulu, Hawaii.

D Licensed material identified in items 6.H. through 6.N., shall be used or stored only at the licensee's facilities located at University Towers, Suites 802, 803, 804, 805, 806, and 815, 1356 Lusitana Street, Honolulu, Hawaii.

11. The Radiation Safety Officer for this license is Brian Oyadomari.

12. Licensed material is only authorized for use by, or under the supervision of:

A. Individuals permitted to work as an authorized user, authorized nuclear pharmacist, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

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B. The following individuals are authorized users for medical use:

Authorized Users	Material and Use
Koshrow Behjati, M.D.	35.100; 35.200; 35.300; depleted uranium
Marc Coel, M.D.	35.100; 35.200; 35.300; depleted uranium
Sandi Kwee, M.D.	35.100; 35.200; 35.300; depleted uranium
Jehoon Ko, M.D.	35.100; 35.200; 35.300; depleted uranium
Richard L. Littenberg, M.D.	35.100; 35.200; 35.300; depleted uranium
Werner Schroffner, M.D.	35.100; oral administration of sodium iodide I-131
Mark Kanemori, M.D.	35.400; 35.600; 35.1000 only Iodine-125 Gliasite RTS system
Scott Moon, M.D.	35.400; 35.600; 35.1000 only Iodine-125 Gliasite RTS system
Vincent Brown, M.D.	35.400; 35.600; 35.1000 only Iodine-125 Gliasite RTS system; Strontium 90 for ophthalmic radiotherapy
Paul DeMare, M.D.	35.400; 35.600; 35.1000 only Iodine-125 Gliasite RTS system; Strontium 90 for ophthalmic radiotherapy
Thanh Huynh, M.D.	35.400; 35.600; 35.1000 only Iodine-125 Gliasite RTS system; Strontium 90 for ophthalmic radiotherapy
John Lederer, M.D.	35.400; 35.600; 35.1000 only Iodine-125 Gliasite RTS system; Strontium 90 for ophthalmic radiotherapy
Christina Liu, M.D.	35.400; 35.600; 35.1000 only Iodine-125 Gliasite RTS system; Strontium 90 for ophthalmic radiotherapy
Laeton Pang, M.D.	35.400; 35.600; 35.1000 only Iodine-125 Gliasite RTS system; Strontium 90 for ophthalmic radiotherapy
Charles Yamashiro, M.D.	35.400; 35.600; 35.1000 only Iodine-125 Gliasite RTS system; Strontium 90 for ophthalmic radiotherapy

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C. Licensed material for use in in vitro research and for the irradiation of blood shall be used by, or under the supervision of, Brian Oyadomari, or other individuals designated by the Radiation Safety Committee. The licensee shall maintain records of individuals designated as users.

D. The following individuals are authorized medical physicists:

Authorized Medical Physicists	Material and Use
Alan Cassady, M.S. Harold Palmer, M.C.E. Ed Price, Ph.D. Emily Robinson, M.S.	Iridium-192 in a High Dose Rate Remote Afterloader Unit for calibration, spot-checks, and training; Strontium-90 in an ophthalmic applicator for activity calculation; Iodine-125 Iotrex™ for activity calculation in association with the Proxima Therapeutics' GliaSite® system
Rebecca C. Middleton, Ph.D.	Iridium-192 in a High Dose Rate Remote Afterloader Unit for calibration, spot-checks, and training

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. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:

A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. 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 U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of 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 test results received.

D. 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.

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E. Sealed sources need not be leak tested if they 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.

F. 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 76011-4005, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.

G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

15 The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license.

16. The licensee is authorized to hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity provided that it:

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 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.

B. A record of each disposal permitted under this License Condition shall be retained for 3 years. The record must include the date of 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 survey.

17. The licensee shall not repair, remove, replace, or alter any of the following: electrical and mechanical systems that control source or shielding movement, the irradiator' s shielding or sealed source, safety interlocks, or any component that may affect safe operation of the irradiator. These activities shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.

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18 Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from the U. S. Nuclear Regulatory Commission 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 32.210 or by an Agreement State.

19 Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

20. 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."

21. The licensee will comply with the requirements for "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern" (IC) (ADAMS Accession No. ML053130364) published in the Federal Register on December 11, 2005 (70 FR 72128) as "Attachment B" to the "Orders Imposing Increased Controls" (Accession No. ML053130218). The licensee will complete implementation of the IC requirements by the first day that radionuclides specified in "Table 1: Radionuclides of Concern", (Accession No. ML053130250) of the IC are possessed at or above the limits specified in the table. Notwithstanding any provisions of the Commission's regulations to the contrary, all measures implemented or actions taken in response to the IC requirements shall be maintained until the Commission orders otherwise or the Commission explicitly modifies its regulations to reflect increased controls, and states in modifying its regulations that the revisions are to supercede these Order EA-05-090. The licensee shall notify the Director, Office of Federal and State Materials and Environmental Management Programs, U.S. NRC, Washington, DC, 20555, in writing, within 25 days after it has completed the requirements of this condition. In addition, licensee responses applicable to this license condition shall be marked as "Withhold From Public Disclosure Under 10 CFR 2.390."

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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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. 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 August 30, 2004 (ML042660300)
B. Letter dated November 1, 2004 (ML043380272)
C. Letter dated November 30, 2004 (ML043380272)
D Letter dated January 26, 2005 (ML050460260)
E. Letter dated April 28, 2005 (ML051400325)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: April 17, 2007

By:

Roberto J. Torres, Senior Health Physicist
Nuclear Materials Licensing Branch
Region IV
Arlington, Texas 76011

AUG 29 2007

DATE

This is to acknowledge the receipt of your letter/application dated 8/13/07, 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** 4711421.
When calling to inquire about this action, please refer to this mail control number.
You may call me at 817-860-8103.

Sincerely,

Colleen Marrachia

Licensing Assistant

NRC FORM 532 (RIV)
(10-2006)

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02120
Status Code: O
Fee Category: 7C
Exp. Date: 20150531
Fee Comments: _____
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: STRAUB CLINIC & HOSPITAL
   Received Date: 20070816
   Docket No: 3014529
   Control No.: 471471
   License No.: 53-18126-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: /
   Check No.: /

3. COMMENTS

Signed Colleen Murachan
Date 8-23-07

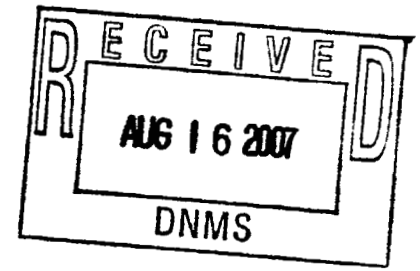
B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:
   Amendment _____
   Renewal _____
   License _____

3. OTHER _____
   _____

Signed _____
Date _____



888 South King Street, MS 30/9110 ♦ Honolulu, HI ♦ 96813

Straub
CLINIC & HOSPITAL

From: Art Gladstone – Chief Operating Officer

To

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

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