

MATERIALS LICENSE

Amendment No. 58

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.

OFFICIAL RECORD COPY

Licensee		In accordance with the letter dated August 30, 1996,
1. Department of Veterans Affairs Medical Center		3. License Number 37-01230-03 is amended in its entirety to read as follows
2. University Drive C Pittsburgh, Pennsylvania 15240		4. Expiration Date September 30, 2004
		5. Docket or Reference No. 030-02978
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 identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed
D. Any byproduct material identified in 10 CFR 31.11	D. Prepackaged Kits	D. As needed
E. Hydrogen 3	E. Tritiated Oleate and Tritiated Glucose	E. 25 millicuries
F. Hydrogen 3	F. Any	F. 2 curies
G. Carbon 14	G. Any	G. 500 millicuries
H. Phosphorus 32	H. Any	H. 150 millicuries
I. Phosphorus 33	I. Any	I. 100 millicuries
J. Sulfur 35	J. Any	J. 500 millicuries
K. Chromium 51	K. Any	K. 100 millicuries
L. Iodine 125	L. Any	L. 100 millicuries
M. Calcium 45	M. Any	M. 100 millicuries
N. Cesium 137	N. Sealed sources	N. Not to exceed 170 millicuries per source, 300 millicuries total

9. Authorized use

- A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100.
B. Any imaging and localization procedure approved in 10 CFR 35.200.
C. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300.
D. In vitro studies.
E. For use in human research to study the effect of visceral obesity on muscle FFA utilization.

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N. For instrument calibration using Tech Ops Model 773 or Nuclear Associates Model 64-764.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at the Department of Veterans Affairs Medical Center, University Drive C, Pittsburgh, Pennsylvania.
11. The Radiation Safety Officer for this license is Yingchieh Hsu, Ph.D.
12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized UsersMaterial and Use

Manuel L. Brown, M.D.	35.100, 35.200 and 35.300; <u>In vitro</u> studies
Herbert Klein, M.D., Ph.D.	35.100, 35.200 and 35.300; <u>In vitro</u> studies
Mark A. Mintun, M.D.	35.100, 35.200 and 35.300; <u>In vitro</u> studies
Ajit Shah, M.D.	35.100, 35.200 and 35.300; <u>In vitro</u> studies
Martin Charron, M.D.	35.100, 35.200 and 35.300; <u>In vitro</u> studies
Janet A. Amico, M.D.	Phosphorus 32, Sulfur 35, Iodine 125
Byron T. Ballou, Ph.D.	Hydrogen 3, Carbon 14, Phosphorus 32, Phosphorus 33, Sulfur 35, Iodine 125, Iodine 131
Patricia A. Craven, Ph.D.	Hydrogen 3, Carbon 14, Phosphorus 32, Sulfur 35, Chromium 51, Iodine 125
James H. Dauber, M.D.	Hydrogen 3
Jau-Shyong Deng, M.D.	Hydrogen 3, Phosphorus 32, Sulfur 35, Chromium 51
Patricia K. Eagon, Ph.D.	Hydrogen 3, Carbon 14, Iodine 125
Howard D. J. Edington, M.D.	Hydrogen 3, Chromium 51
Christopher Evans, Ph.D.	Hydrogen 3, Sulfur 35, Iodine 125
Gene G. Finley, M.D.	Hydrogen 3, Phosphorus 32, Sulfur 35, Iodine 125
Antonio Francavilla, M.D., Ph.D.	Hydrogen 3, Chromium 51, Iodine 125
Roy A. Frye, M.D., Ph.D.	Phosphorus 32, Phosphorus 33, Sulfur 35
Yingchieh Hsu, Ph.D.	Cesium 137 for instrument calibration

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Yisrael Isaacson, M.D., Ph.D. Hydrogen 3, Carbon 14

Mark L. Jordan, M.D. Hydrogen 3, Chromium 51

David E. Kelly, M.D. Tritiated Oleate and Tritiated Glucose for human research, Hydrogen 3, Carbon 14, Iodine 125

Richard Kim, M.D. Sulfur 35

Arnold Meisler, M.D. Hydrogen 3, Phosphorus 32, Sulfur 35, iodine 125

John W. Mellors, M.D. Hydrogen 3, Phosphorus 32, Sulfur 35

Harry E. Rubash, M.D. Hydrogen 3

Raoul R. Salup, M.D. Hydrogen 3, Phosphorus 32, Sulfur 35, Chromium 51

Gurmukh Singh, M.B.B.S., Ph.D. Hydrogen 3, Carbon 14, Phosphorus 32, Phosphorus 33, Sulfur 35, Iodine 125

David C. Whitcomb, M.D., Ph.D. Hydrogen 3, Sulfur 35, Phosphorus 32, Iodine 125

Chandrashekhar Gandhi, Ph.D. Hydrogen 3, Carbon 14, Phosphorus 32, Sulfur 35, Calcium 45, Iodine 125

13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
14. The licensee shall not use licensed material in or on human beings except as provided otherwise by specific condition of this license.
15. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
16. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
17. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.
B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months 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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- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources and detector cells 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 transfer 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 test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
18. The licensee shall conduct a physical inventory every three months to account for all sealed sources and devices containing licensed material received and possessed pursuant to 10 CFR 35.59, 35.400 and 35.500 and every six months for all other sealed sources and devices.
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 shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.
21. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control

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mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.

- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
22. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash, provided:
- A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.
- B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
- C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
23. Radioactive waste generated shall be stored in accordance with the statements, representations, and procedures included with the waste storage plan described in the licensee's letter dated August 17, 1994.
24. 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, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. 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 April 11, 1991
- B. Letter dated April 29, 1993
- C. Letter dated May 7, 1993
- D. Letter dated August 17, 1994
- E. Letter received September 7, 1994
- F. Letter dated September 21, 1994
- G. Letter dated September 22, 1994

For the U.S. Nuclear Regulatory Commission

Original Signed By:

By

Michelle Beardsley

Nuclear Materials Safety Branch
Region I

King of Prussia, Pennsylvania 19406

Date

SEP 27 1996

SEP 27 1996

Thomas A. Cappello
Medical Center Director
Department of Veterans Affairs
Medical Center
University Drive
Pittsburgh, PA 15240

Dear Mr. Cappello:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. Your new expiration date is stated in Item 4 of the license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

Original Signed By:
Michelle Beardsley

Michelle R. Beardsley
Division of Nuclear Materials Safety

License No. 37-01230-03
Docket No. 030-02978
Control No. 123690

Enclosure:
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cc: Francis K. Herbig
Health Physics Programs (115HP)
Department of Veterans Affairs
915 North Grand Blvd.
St. Louis, MO 63106

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DOCUMENT NAME: R:\WPS\MLTR\L3701230.03

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI				
NAME	Beardsley <i>MB</i>						
DATE	09/18/96	09/	/96	09/	/96	09/	/96



DEPARTMENT OF VETERANS AFFAIRS
Medical Center
University Drive
Pittsburgh PA 15240

August 30, 1996

In Reply Refer To:

Mr. David B. Everhart
U. S. Nuclear Regulatory Commission, Region I
Nuclear Materials Safety Branch
475 Allendale Road
King of Prussia, PA 19406

030-02978

Thru:
Department of Veterans Affairs
National Health Physics Program (115HP)
915 North Grand Boulevard
St. Louis, MO 63106

SUBJ: Amendment of License No. 37-01230⁰-03^{med}

We are submitting information in duplicate to amend our NRC License No. 37-01230-30⁰³ so that Chandrashekhar R. Gandhi, Ph.D. can be added as an authorized user of H-3, C-14, P-32, S-35, Ca-45 and I-125 for non-human uses. Currently, he is an authorized user of the same radionuclides at the University of Pittsburgh. Enclosed is a copy of his authorization from the University of Pittsburgh.

Please include Ca-45 with maximum possession limit of 100 mCi in our license.

FAR Thomas A. Cappello
Medical Center Director

enclosure: Documents from the University of Pittsburgh (8 pages)

123690

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SEP 16 1996



DEPARTMENT OF VETERANS AFFAIRS
Medical Center
St Louis MO 63125

September 10, 1996

In Reply Refer To:

U.S. Nuclear Regulatory Commission
Region I
Attn: David Everhart
475 Allendale Rd.
King of Prussia, PA 19406-1415

SUBJECT: NRC License No. 37-0123⁰~~7~~-03
nucl

The enclosed correspondence from the Pittsburgh, Pennsylvania (University Drive) VA Medical Center has been received and is forwarded to your office for processing. If there are questions, please contact the facility.

Please provide a copy of any correspondence relative to licensing actions for this Medical Center to:

Department of Veterans Affairs
Health Physics Programs (115HP)
915 North Grand Blvd.
St. Louis, MO 63106

Sincerely,

for *Cindy Oukowsky*

Francis K. Herbig
Health Physics Programs

C O V E R

S H E E T

FAX

To: Dr. Hsu

Fax #: 688-6899

Subject:

Date: 8-30-96

Pages: 8, including this cover sheet.

COMMENTS:

As per your request.

Mike Shultz

From the desk of...

University of Pittsburgh

Radiation Safety Office
130 DeSoto Street
Pittsburgh PA 15261

(412) 624-2728
Fax: (412) 624-3562



University of Pittsburgh

Radiation Safety Office

Room G-7 Parran Hall
Pittsburgh, Pennsylvania 15261
412-624-2728, 2729
Fax: 412-624-3562

MEMORANDUM

TO: Dr. C.R. Gandhi

FROM: Radiation Safety Executive Committee

DATE: January 25, 1995

SUBJECT: **RENEWED APPROVAL TO UTILIZE RADIONUCLIDES**

The Executive Committee of the University Radiation Safety Committee has renewed your Authorization for use of radionuclides. Attached please find a copy of your application with the signatures of the Executive Committee members. Take special note of any added conditions in Item 9. Your approval is valid for the period 17 January 1995 until 31 January 1997. It is strongly suggested that this notice and the contents of your application be reviewed with all laboratory personnel as a means of informing them of your specific approval conditions.

As with any radiation source use, extension of radionuclides use to an Authorized User and his/her associated laboratory workers implies that each radiation worker will abide by all applicable regulations set forth by the U.S. Nuclear Regulatory Commission, Pennsylvania Department of Environmental Resources and the University Radiation Safety Committee.

Enclosure

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RSO AU# 1375

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UNIVERSITY OF PITTSBURGH
"APPLICATION FOR AUTHORIZATION FOR NON-HUMAN USES OF
RADIONUCLIDES"
Form RSO - 313 2/94

☐ New Application ("Attachment A" (Training Summary) must be completed)

☒ Renewal

The form must be typed or printed plainly. Send one completed form to the Radiation Safety Office, G7 Parran Hall, University of Pittsburgh. If an amendment to a current authorization is being requested, use Form RSO-313A. Retain a copy for your records.

If radionuclides are to be administered to humans, Form RSO - 313M must be submitted to the Subcommittee on Human Use of Radioisotopes and Radioactive Drug Research.

1. APPLICANT IDENTIFICATION

Name: Chandrashekhar R. Gandhi Degree: Ph.D.
Department: Anesthesiology/CCM Title: Assistant Professor
Office Location: Room A-1017 Building: Scaife Hall
Office Phone: 648-9790 Home Phone: 922-4403
Lab Phone: 648-8162 Radioactive Materials
Delivery Location: A-1016 Scaife Hall

2. RADIATION WORKER IDENTIFICATION

List the names of all other individuals (faculty, staff, students, etc.) who will work with radionuclides in your laboratories. Identify a primary contact person(s), in addition to yourself, for radiation safety concerns in the laboratory (Note with * in front of name and list the phone number).

NAME	POSITION	RSO USE ONLY	
		TRAINING DATE	DOSIMETRY ASSIGNED
Lisa Sproat	Research Specialist III	August, 1993	NONE
Heidi Gabriel	Visiting Assistant Professor	September, 1994	✓
CR Gandhi	AN	11-6-92	✓ ↓

5. USES

For each radionuclide requested, describe how it will be used, listing the estimated quantity of radionuclides to be used per experiment. Note any unique hazards such as high volatility, chemical reactivity or infectiousness and how they will be controlled. (Attach an additional sheet if necessary.)

- a) Will radionuclides be administered to animals? ☐ yes ☒ no
If yes, please complete and attach Form RSO ANA-1 for each different study

No more than 20 uCi of a radionuclide will be used per experiment. Mostly, the cell cultures, cell suspensions or tissue homogenates will be used to study the uptake of the radioactive material. All radioactive material is in bound form and non-volatile.

6. RADIATION DETECTION & MEASUREMENT INSTRUMENTATION

Instrument Type	Manufacturer	Model Number	Serial Number	Detector Type *
Beta	Beckman	LS5000TD	7040657	
Gamma	TmAnalytic	1185		
Geiger Counter	B & R VICTOREEN	SK-1 490 THYAC III	217	PAN
Beta	Beckman	LS7500	7776134	

*PORTABLE INSTRUMENTS ONLY

List location(s) where radionuclides will be used or stored.

[illegible]

4. AUTHORIZED LIMITS FOR RADIOACTIVE MATERIALS

List each radionuclide for which authorization to use is requested. Indicate the quantity you desire to order by placing a check in the proper block. NOTE: Maximum Order Limit is the maximum quantity of the radionuclide per vial or kit which may be ordered. Maximum Possession Limit in use and storage in your laboratories at any time is limited to ten times the maximum order limit.

[illegible]

7. RADIONUCLIDE USE AND WASTE PROJECTION

Radionuclide	Projected Amount Used per Quarter (mCi)*	Historical Amount Used Per Quarter (RSO USE ONLY)	Percent of Radionuclide Disposed in Waste Forms				
			Solid	Liquid (Aqueous) Sink Disposal	Liquid Absorbed or Solidified	Scintillation Vials	Animal Carcasses/Tissues
^{125}T	0.5	0.5	None	40-60%	None	20-40%	None
^{32}P	2 mCi max.	—	None	40-60%	None	20-40%	None
^3H	1-2	2.5	None	40-60%	None	20-40%	None
^{45}Ca	1-2	—	None	40-60%	None	20-40%	None
^{14}C	0.5	—	None	40-60%	None	20-40%	None
^{35}S	0.1	—	None	40-60%	None	20-40%	None

* Amount Used per quarter - Average activity ordered per calendar quarter in millicuries. Historical is average of past 4 quarters.

Identify all wastes containing infectious agents, pathogenic agents, or hazardous chemicals. Indicate the quantity of each such waste that you may generate per quarter.

Most of the waste will be in the scintillation vials and liquid waste comprised of physiological buffer and other aqueous solutions. No infectious agents, pathogenic agents or hazardous chemicals will be used for any of the experiments.

8. PERSONNEL TRAINING

Title 10, Part 19, Section 19.12 of the Code of Federal Regulations requires that all personnel working with sources of ionizing radiation be trained in the procedures and precautions necessary to minimize radiation exposure.

The Radiation Safety Office provides a general lecture and demonstration session for training personnel in the safe use of radioisotopes. The University requires that individuals requesting authorization to use sources of ionizing radiation, as well as all persons who will work under this authorization, attend this session before approval can be granted.

The Authorized User is responsible for providing additional training and instruction in safe radiation practices, specific to the type of work being performed, to all personnel working under the authorization.

10. REVIEW AND APPROVAL

A representative of the Radiation Safety Office has met with the applicant to review this application and has discussed the radiation protection requirements necessary for use of the radionuclides listed under Item 5. As part of this evaluation, the Radiation Safety Office representative has made a physical inspection of all proposed radionuclide laboratories.

RSO Representative: Ken BehrmanDate: ~~12-4-95~~ 1-4-95

Review by Health Physicists:

<u>Howard Behrman</u>	<u>1-6-95</u>
<u>Steve Smith</u>	<u>1-9-95</u>

Review by the Executive Committee of the University's Radiation Safety Committee:

Signature

Date

Chairperson:

Met Webb18 Jan 95

Vice Chairperson:

David Guk1-14-95

Radiation Safety Officer:

J. CA1/11/95

This application, signed by the Executive Committee, is your authorization to possess and use radioactive materials as indicated.

Date of Approval 18 January 1995Date of Expiration 31 January 1997

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

: (FOR LFMS USE)
: INFORMATION FROM LTS
: -----
:
: PROGRAM CODE: 02120
: STATUS CODE: 0
: FEE CATEGORY: EX 7C
: EXP. DATE: 20040930
: FEE COMMENTS: V
: DECOM FIN ASSUR REQD: Y
:
:

LICENSE FEE TRANSMITTAL

A. REGION I
1. APPLICATION ATTACHED
APPLICANT/LICENSEE: V. A., DEPARTMENT OF
RECEIVED DATE: 960916
DOCKET NO: 3002978
CONTROL NO.: 123690
LICENSE NO.: 37-01230-03
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: -----
CHECK NO.: -----

3. COMMENTS

SIGNED M.A. Perkins
DATE 9/12/96

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 -----