

MATERIALS LICENSE

Amendment No. 40

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

1. Veterans Administration Medical Center
Radiation Safety Office

2. 50 Irving Street, N.W.
Washington, DC 20422

In accordance with the letter dated
January 17, 1997,
3. License Number 08-00942-05 is amended in
its entirety to read as follows:

4. Expiration Date June 30, 2005

5. Docket or
Reference No. 030-01314

6. Byproduct, Source, and/or
Special Nuclear Material7. Chemical and/or Physical
Form8. Maximum Amount that Licensee
May Possess at Any One Time
Under This License

A. Any byproduct material
included in 10 CFR
35.100

B. Any byproduct material
included in 10 CFR
35.200

C. Any byproduct material
included in 10 CFR
35.300

D. Any byproduct material
identified in 10 CFR
31.11

E. Hydrogen 3

F. Carbon 14

G. Phosphorus 32

H. Sulfur 35

I. Chromium 51

J. Strontium 85

K. Iodine 125

L. Cerium 141

M. Manganese 54

N. Cobalt 60

O. Barium 133

P. Cadmium 109

Q. Iodine 129

R. Cesium 137

S. Nickel 63

T. Cesium 137

A. Any radiopharmaceutical
included in 10 CFR
35.100

B. Any radiopharmaceutical
included in 10 CFR
35.200(except generators
and gas)

C. Any radiopharmaceutical
included in 10 CFR
35.300

D. Prepackaged Kits

E. Any

F. Any

G. Any

H. Any

I. Any

J. Any

K. Any

L. Any

M. Sealed source

N. Sealed source

O. Sealed source

P. Sealed source

Q. Sealed source

R. Sealed source

S. Sealed source

T. Sealed source

(Nuclear Associates Inc.
Model No. 64-715)

U. Sealed source
(Radiochemical Center
Model No. AMC-25)

A. As needed

B. As needed

C. 215 millicuries

D. As needed

E. 300 millicuries

F. 500 millicuries

G. 50 millicuries

H. 50 millicuries

I. 50 millicuries

J. 50 millicuries

K. 50 millicuries

L. 50 millicuries

M. 10 microcuries

N. 1 millicurie

O. 1 millicurie

P. 20 microcuries

Q. 2 microcuries

R. 10 millicuries

S. 5 millicuries

T. 10 millicuries

U. 45 millicuries

9706160152 970210
PDR ADOCK 03001314
C PDR

U. Americium 241

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V. Gadolinium 153

V. Sealed sources (North
American Scientific Model
MED 3601)V. Not to exceed 300
millicuries per source
and 800 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. through R. Research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; and in-vitro studies.
- S. through U. For storage incident to disposal.
- V. For use in an ADAC Laboratories Model Vantage device for patient attenuation correction during S.P.E.C.T. imaging.

CONDITIONS

- 10. Licensed material may be used only at the licensee's facilities at 50 Irving Street, N.W., Washington, DC.
- 11. A. Licensed material in Items 6.E through 6.U. shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee, Steven Lunzar, M.D., Chairperson.
- B. Licensed material listed in Item 6.A through 6.D. 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

H. Richard Bates, M.D.

35.100; 35.200; 35.300;
In vitro studies
Gadolinium 153 for patient attenuation
correction during S.P.E.C.T. imaging

Daniel J. Fernicola, M.D.

35.100 and 35.200 for cardiovascular clinical
procedures; Gadolinium 153 for patient
attenuation correction during S.P.E.C.T.
imaging

- C. The Radiation Safety Officer for this license is Michael D. Funkhouser, M.S.

- 12. 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

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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.

- 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.
13. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
14. 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.
15. 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.

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16. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.
17.
 - 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 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.
18. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
19. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
20. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 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.
21. 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 December 7, 1995.
22. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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23. 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 March 4, 1994
- B. Letter dated April 25, 1994
- C. Letter dated November 10, 1994
- D. Letter dated May 5, 1995
- E. Letter dated May 19, 1995
- F. Letter dated June 9, 1995
- G. Letter dated December 7, 1995
- H. Letter dated October 18, 1996

FEB 10 1997

Date _____

For the U.S. Nuclear Regulatory Commission

Original Signed By

Tara Weidner

By

Nuclear Materials Safety Branch
Region I

King of Prussia, Pennsylvania 19406

FEB 10 1997

Sanford M. Garfunkel
Medical Center Director
Department of Veterans Affairs Medical Center
50 Irving Street NW
Washington, DC 20422

Dear Mr. Garfunkel:

This refers to your license amendment request. Enclosed with this letter is the amended 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
Tara Weidner

Tara Weidner
Division of Nuclear Materials Safety

License No. 08-00942-05
Docket No. 030-01314
Control No. 124203

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\L0800942.05

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	<input checked="" type="checkbox"/> N	DNMS/RI	<input checked="" type="checkbox"/> N			
NAME	Beardsley <i>MB</i>		Weidner <i>for</i>				
DATE	02/05/97		02/6/97		02/ /97		02/ /97

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DEPARTMENT OF VETERANS AFFAIRS

Medical Center
50 Irving Street NW
Washington DC 20427

In Reply Refer To:

January 17, 1997

Michelle Beardsley
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415

030-01314

The Washington D.C. VA Medical Center requests an emergency amendment of our specific U.S. Nuclear Regulatory Commission license number 08-00942-05. Please expedite as quickly as possible.

This Medical Center is currently without an Authorized User under 10 CFR 35.300, In vitro studies; and gadolinium-153 for patient attenuation correction during S.P.E.C.T. imaging. Please delete Bina Lakhanpal, M.D., S.K. Suneja, M.D., and Steven D. Johnson.


Under the requirements of 10 CFR 35.27, the Radiation Safety Committee has approved a recommendation designating H. Richard Bates, M.D. as an Authorized User under 10 CFR 35.100; 35.200; 35.300; In vitro studies; and gadolinium-153 for patient attenuation correction during S.P.E.C.T. imaging effective January 15, 1997.

Dr. H. Richard Bates was formally Chief of Nuclear Medicine at this facility from 1990 to 1993 under our then broad scope NRC license. Dr. Bates is currently a technical consultant to Imaging Service at this Medical Center. However, our current specific NRC license was never amended to designate Dr. Bates as an Authorized User. Previously, however, Dr. Bates was listed as an Authorized User at VA Medical Center, Wilmington, Delaware, on NRC license number 07-09495-01 from 1984-1988.

Dr. H. Richard Bates is recognized as Certified Specialist by the Conjoint Board of Nuclear Medicine with competence in all aspects of the diagnostic, therapeutic, and medical research use of radioactive material.

In addition, please designate Daniel J. Fernicola, M.D. as an Authorized User for gadolinium-153 for patient attenuation correction during S.P.E.C.T. imaging in accordance with our letter dated October 18, 1996.

Sincerely,


SANFORD M. GARFUNKEL
Medical Center Director

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FEB - 3 1997

Department of
Veterans Affairs

Memorandum

Date: January 16, 1997
From: Radiation Safety Office (115)
Subj: Actions by the Radiation Safety Committee
To: M. Goodrich/Administrative Assistant to the COS

1. The Radiation Safety Committee has approved Satinder Gill, M.D. as a Visiting Authorized User under NRC license number 47-00714-02 issued to the VA Medical Center, Martinsburg, West Virginia. Dr. Gill can authorized use of radiopharmaceuticals under 10 CFR 35.100; 35.200; 35.300; and In-vitro (31.11) studies at VA Medical Center, Washington, D.C. for the next 60-days, without requesting a NRC amendment to our current license in accordance with 10 CFR 35.27. Dr. Gill has been consulting with Imaging Service since Dr. Sidney Suneja departed. Dr. Gill has been extremely accommodating during these difficult times and has kindly agreed to this critical task as Visiting Authorized User.

2. This should allow NRC timely response to our request for amendment of our specific license, denoting H. Richard Bates as Authorized User. This action has been approved by the full membership of the Radiation Safety Committee. As indicated Dr. Bates was Chief of Nuclear Medicine from 1990-1993. Dr. Bates continues to visit weekly since 1993 as a Consultant to Imaging Services. He is eagerly looking forward to filling this essential, critical need on behalf of the Nuclear Medicine Department. The members of the Radiation Safety Committee, including Dr. Steven Lunzer and Dr. Raj Lakshman gratefully acknowledge Dr. Bates previous performance as Chief of Nuclear Medicine, and his expressed desire to continue his consultations in the capacity as Authorized User of radiopharmaceuticals.

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MICHAEL FUNKHOUSER, M.S.
Radiation Safety Officer

cc: Steven Lunzer, M.D., Chairman Radiation Safety Committee
David West, Acting Chief Imaging Service
Mitchell Wallin, M.D., Interim Director Occ. Health



DEPARTMENT OF VETERANS AFFAIRS
Medical Center
St Louis MO 63125

January 28, 1997

In Reply Refer To:

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

SUBJECT: NRC License No. 08-00942-05

The enclosed correspondence from the Washington, D.C. 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 Bakowsky

Francis K. Herbig
Health Physics Programs

(FOR LFMS USE)
INFORMATION FROM LTS

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: PROGRAM CODE: 02110  
: STATUS CODE: 0  
: FEE CATEGORY: EX 7B  
: EXP. DATE: 20050630  
: FEE COMMENTS:  
: DECOM FIN ASSUR REQD: Y
```

A. REGION

2. FEE ATTACHED

AMOUNT: _____
CHECK NO.: _____

- ### 3. COMMENTS

SIGNED M. A. Perkins
DATE 2/4/97

8. 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 _____