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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
SAM NUNN ATLANTA FEDERAL CENTER
61 FORSYTH STREET SW SUITE 23T85
ATLANTA, GEORGIA 30303-8931

FEB 2 4 2003

National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
ATTN: E. Lynn McGuire
Director, National Health Physics Program
2200 Fort Roots Drive
North Little Rock, Arkansas 72114

SUBJECT: LICENSE AMENDMENT APPLICATION

Dear Mr. McGuire:

We are sending you the enclosed transmittal letter and license amendment to be forwarded to the Veterans Affairs Medical Center in Memphis, Tennessee.

In accordance with 10 CFR 2.790 of NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

Any correspondence regarding your application should reference the control number and license number specified below.

Thank you for your cooperation.

Sincerely,

David J. Collins

David J. Collins
Health Physicist
Division of Nuclear Materials Safety

License No. 41-00119-08
Docket No. 030-03253
Control No. 260532

Enclosure: Transmittal Letter and License Amendment

6/33

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
SAM NUNN ATLANTA FEDERAL CENTER
61 FORSYTH STREET SW SUITE 23T85
ATLANTA, GEORGIA 30303-8931

FEB 2 4 2003

Veterans Affairs Medical Center
ATTN: K. L. Mulholland, Jr.
Medical Center Director
1030 Jefferson Avenue
Memphis, Tennessee 38104

SUBJECT: TRANSMITTAL AND EXPLANATION OF AMENDMENT TO LICENSE NO. 41-00119-08 (REFERENCE: MAIL CONTROL NO. 260532; DOCKET NO. 030-03253)

Dear Mr. Mulholland:

Enclosed please find Amendment No. 79 to your NRC materials license. Changes to the license are printed in **BOLD** typeface. We have added the use of the Galileo Interventional Brachytherapy (IVB) device, added Dr. Tai as Medical Physicist for IVB only, and added Dr. Sheikh for use of unsealed byproduct material for which a written directive is required (10 CFR 35.300).

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify this office (ATTN: Ms. Janice Kirby at 404-562-4719) so that we can provide appropriate corrections and answers.

In accordance with 10 CFR 2.790 of NRC's "Rules of Practice," a copy of this letter and Enclosure 1 will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

Thank you for your cooperation.

Sincerely,

David J. Collins

David J. Collins, Health Physicist
Division of Nuclear Materials Safety

Enclosures: 1. Amendment No. 79
License No. 41-00119-08
2. NRC Form 313

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 79

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 the letter dated **January 7, 2003**
1. Veterans Affairs Medical Center	3. License No. 41-00119-08 is amended in its entirety to read as follows:
2. 1030 Jefferson Avenue Memphis, Tennessee 38104	4. Expiration Date: November 30, 2011
	5. Docket No. 030-03253

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 in 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material permitted in 10 CFR 35.200	B. Any	B. As needed
C. Iodine 131	C. Any unsealed form for preparation and administration as specified in §35.300	C. 55.5 gigabecquerels (GBq) (1.5 curies)
D. Any byproduct material permitted in 10 CFR 35.300, except iodine 131	D. Any	D. As needed
E. Any byproduct material permitted in 10 CFR 35.400	E. Any brachytherapy sources identified in 10 CFR 35.400	E. As needed
F. Strontium 90	**F. Sealed sources (Guidant Models GDT-P32-1 and GHT-P32-2)**	**F 44.4 GBq (1200 millicuries (mCi)), no single source to exceed 22.2 GBq (600 mCi)**
G. Any byproduct material permitted in 10 CFR 31.11	G. Any prepackaged kits	G. As needed
H. Cesium 137	H. Sealed source registered pursuant to 10 CFR 32.210 contained in a compatible registered device specified in Item 9.G.	H. 148 terabecquerels (TBq) (4000 curies) total
I. Uranium (depleted in uranium 235)	I. Cadmium plated metal shielding components	I. 182 kilograms

MATERIALS LICENSE
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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
J. Strontium 90	J. Sealed source (Nuclear Enterprises Model No. 2503)	J. 370 megabecquerels (MBq) (10 millicuries)
K. Any byproduct material with atomic numbers 1 through 83, inclusive	K. Any form except sealed sources	K. 111 MBq (3 millicuries) per radionuclide and 3.7 GBq (100 millicuries) total, except as follows: (1) carbon 14: 29.6 GBq (800 millicuries) (2) phosphorus 32 and/or phosphorus 33: 37 GBq (1000 millicuries) total (3) sulfur 35: 7.4 GBq (200 millicuries) (4) hydrogen 3: 55.5 GBq (1500 millicuries) (5) iodine 125: 29.6 GBq (800 millicuries) (6) chromium 51: 3.7 GBq (100 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. and D. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300.
E. Any manual brachtherapy procedure permitted by 10 CFR 35.400.
F. For use in Guidant Corporation VI Model GALILEO intravascular brachytherapy high does rate afterloader devices for intravascular brachytherapy
G. *In vitro* studies.
H. For possession and use in J.L. Shepherd Model 25-1 irradiator for irradiation of laboratory animals, plant cells, and chemical compounds.
I. For possession and use as shielding in a linear accelerator.
J. For possession and use in a Nuclear Enterprises dosimeter calibrator for calibration of dosimetry systems.
K. For possession and use in laboratory research including *in vitro* studies and tracer studies in laboratory animals.

MATERIALS LICENSE
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CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 1030 Jefferson Avenue, Memphis, Tennessee.

11. A. The Radiation Safety Officer for this licensee is Michael Kaiser.

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.

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

Authorized Users	Material and Use
James D. Massie, M.D.	35.100, 35.200, 35.300
Jorge E. Salazar, M.D.	35.100, 35.200
Randall Lee Scott, M.D.	35.100, 35.200
Donna Swain, M.D.	35.100, 35.200, 35.300
John R. Ware, M.D.	35.100, 35.200, 35.300
Alan H. Appelbaum, M.D.	35.100, 35.200
Muhammad Sheikh, M.D.	**35.100, 35.200, 35.300**
Joan A. (Jacobson) Kaufman, M.D.	35.400, phosphrorous 32 contained in Guidant Corporation Model Galileo high dose rate intravascular brachytherapy device

C. The following individual(s) are authorized medical physicists are indicated:

Authorized Medical Physicist	**Material and Use**
Douglas Tai, Ph.D.	**Strontium-90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot-checks, and training**

D. The following individuals are authorized users for non-medical uses as indicated:

	Material and Use
Solomon S. Solomon, M.D.	*In vitro* studies
John M. Stuart, M.D.	Cesium-137 for irradiation of samples
Michael Kaiser	Strontium-90 for calibration

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12. **E. Intravascular brachytherapy procedures shall be conducted under the supervision of the authorized user, who will consult with the interventional cardiologist/physician and authorized medical physicist prior to initiating treatment. The procedures shall be conducted in the physical presence of the authorized user or the authorized medical physicist.**

F. Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.

13. **Source stepping or pullback procedures are authorized in accordance with the FDA (U.S. Food and Drug Administration) approval of these procedures with the Guidant Corporation Model Galileo high dose rate intravascular afterloading device.**

14. **The intravascular brachytherapy afterloader device shall be inspected and serviced at intervals recommended by the manufacturer and maintenance and repair shall be performed by the manufacturer or persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.**

15. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material as follows:

    A. For unsealed sources to quantities less than 10^5 times the applicable limits in Appendix B, 10 CFR Part 30 as specified in 10 CFR 30.35(d) and

    B. For sealed sources, to quantities less than 10^{10} times the applicable limits in Appendix B, 10 CFR Part 30 as specified in 10 CFR 30.35(d).

16. The provisions of this condition are applicable to the licensee's possession and use of the J.L. Shepherd Mark I Series Model 25-1 irradiator.

    A. The licensee shall follow the device manufacturer's instruction manual and shall make copies available to each person using or having responsibility for use of the irradiator.

    B. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.

    C. The licensee shall assure that the irradiator is tested for proper operation of the "on-off" mechanism and indicator, if any, at intervals not to exceed six months.

    D. The licensee shall install a room (area) radiation monitor in proximity to the irradiator for the purposes of alerting the operator of unexpected radiation levels. The device shall as a minimum meet the specifications recommended by the irradiator manufacturer.

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16. E. The irradiator shall be used by, or under the supervision of John M. Stuart, M.D., or individuals designated by the Radiation Safety Committee.

F. The licensee shall not irradiate explosive, flammable, or corrosive materials, or any other material which might impair the containment integrity of the sealed sources and/or the irradiator shielding and safety mechanisms.

G. The licensee is not authorized to irradiate food or food products for human consumption.

17. The licensee is authorized to hold non-medical radioactive material with a physical half-life of less than 90 days for decay-in-storage before disposal in ordinary trash provided:

A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

18. Pursuant to 10 CFR 20.2001(b), 20.2002, and 20.2004(a), the licensee is authorized to dispose of carbon 14 and hydrogen 3 by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR Part 20. Ash residues may be disposed of as ordinary waste provided appropriate surveys pursuant to 10 CFR 20.1501(a) are made to determine that concentrations of licensed material appearing in the ash residues do not exceed the concentrations (in terms of microcuries per gram) specified for water in Appendix B, Table II, 10 CFR Part 20.

19. Sealed sources containing licensed material shall not be opened, and when installed in an exposure device (irradiator, calibrator, etc.) shall not be removed from said device by the licensee.

20. A. (1) The sealed source(s) specified in Item 7, shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 3.7 megabecquerels (MBq) (100 microcuries) or less of beta and/or gamma emitting material or 0.37 MBq (10 microcuries) or less of alpha emitting material.

B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer. **Except for those sources authorized by 10 CFR Part 35, no source shall remain in storage exceeding 10 years unless it has been tested.**

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20. C. The test shall be capable of detecting the presence of 185 becquerels (Bq) (0.005 microcurie) of radioactive material on the test sample. If the test reveals the presence of 185 Bq 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.

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

21. A. Individuals involved in operations which utilize, at any one time, more than 3.7 GBq (100 millicuries) of hydrogen 3 in a non-contained form, other than metallic foil, shall have bioassays performed within one week following a single operation and at weekly intervals for continuing operations.

B. When implementing the bioassay program at the level indicated in paragraph A, these actions shall also be taken:

(1) Hydrogen 3 shall not be used in such a manner as to cause any individual to receive a radiation exposure such that urinary excretion rates exceed 1.036 MBq (28 microcuries) per liter when averaged over a calendar quarter.

(2) Urinalysis shall be performed at weekly intervals on all individuals who work in the restricted areas of facilities in which hydrogen 3 is used. If the average concentration of hydrogen 3 in urine for any single individual during a calendar quarter is less than 0.37 MBq (10 microcuries) per liter, urinalysis may be performed on that individual at monthly intervals for the following quarter and may continue at monthly intervals so long as the average concentration in the calendar quarter remains below 0.37 MBq (10 microcuries) per liter. The urine specimen shall be collected on the same day of the week insofar as possible.

(3) A report of an average concentration in excess of the limit specified in B.(1) above for any individual shall be filed, in writing, within thirty days of the end of the quarter with the U. S. Nuclear Regulatory Commission, Region II, Division of Nuclear Materials Safety, 61 Forsyth Street SW, Suite 23T85, Atlanta, GA 30303-8931. The report shall contain the results of all urinalyses for the individual during the quarter, the causes of excessive concentration, and corrective steps taken or planned to prevent a recurrence.

B. (4) Any single urinalysis which discloses a concentration of greater than 1.85 MBq (50 microcuries) per liter shall be reported, in writing, within seven days of the licensee's receipt of the report, to the address stated in paragraph B.(3) above.

C. Personnel working in Research and Nuclear Medicine with iodine 125 and iodine 131 in liquid form in an amount of 37 MBq (1 millicurie) and 370 MBq (10 millicuries) or greater respectively, and with iodine 131 in encapsulated form in an amount of 1.11 GBq (30 millicuries) or greater, shall be required to undergo a thyroid count in Nuclear Medicine within approximately 24 hours after cessation of work.

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22. Experimental animals administered licensed material or their products shall not be used for human consumption.

23. The licensee shall conduct 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.

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

25. 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 May 17, 1990 and revised application submitted with letter dated October 30, 1991

B. Letters (or facsimiles) dated (or received) (as noted):

1) April 11, 1991
2) July 2, 1993 [excepting: Authorized users for medical uses identified in 10 CFR 35.100, 35.200 and 35.300 are listed in Amend. #76; 35.400 deletions: Drs. Kun, Paig, Shah; 31.11 deleteions: Drs. Brooks and Martinez-Hernandez]
3) September 29, 1993 [excepting: see note for July 2, 1993]
4) June 6, 1994 [excepting: RSO and alternative RSO same as in Amend #76; See note for July 2, 1993]
5) October 2, 1996 [excepting: see note for July 2, 1993]
6) October 23, 1996 [fax re: therapy qualifications for Dr. Swain]
7) February 3, 1997 [excepting: see July 2, 1993 note]
8) December 5, 1997 [excepting: see note for July 2, 1993]
9) February 19, 1999 [excepting: see note for June 6, 1994 and July 2, 1993]
10) March 11, 1999 [added information for Dr. Tai, including telephone conversation with State of Tennessee radiation control]
11) December 6, 1999 [change Nuclear Medicine Area from Building #1, A Wing, first floor to new addition, first floor]
12) January 27, 2000 [change RSO to M. Kaiser, delete C. Brannon]
13) July 31, 2000 [remove Radiation Safety Office's bi-monthly survey requirement]
14) September 26, 2000 [add new location of use for cardiac imaging]
15) April 4, 2001 [delete instrument calibrator, add Dr. Appelbaum for 35.100 and 35.200]

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25. B. 16) May 1, 2001 [leak test certificate for calibrator]
17) July 23, 2001 [renewal as is]
18) October 29, 2001 [restatement of tiedown letters and exceptions]
19) September 16, 2002 [add Dr. Sheikh for 35.100 and 35.200, Including intravascular brachytherapy information excluding medical physicist]
20) January 7, 2003 [add IVB]
21) February 19, 2003 [additional information on Dr. Sheikh for 35.300 uses]

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DATE FEB 2 4 2003

BY David J. Collins

David J. Collins, Health Physicist
Region II, Division of Nuclear Materials Safety
61 Forsyth Street, SW, Suite 23T85
Atlanta, GA 30303-8931

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NRC FORM 313 (10-2002) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2005

Estimated burden per response to comply with this mandatory collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

SAM NUNN ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
61 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-8931

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- ☐ A. NEW LICENSE
- ☐ B. AMENDMENT TO LICENSE NUMBER _____
- ☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

TELEPHONE NUMBER

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY | AMOUNT ENCLOSED $

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

PRINTED ON RECYCLED PAPER

DEPARTMENT OF VETERANS AFFAIRS

Memorandum

Date: MAR 3 0 2003

From: Director, VHA National Health Physics Program (115HP/NLR)

Subj: VHA Permit Number 41-00119-08

To: Director (614/00), VA Medical Center, Memphis, Tennessee

1. We are forwarding the attached VHA Permit Number 41-00119-08, Amendment No. 81. This amendment is being issued as your initial permit in VHA format.

2. Please review the permit amendment carefully to ensure you understand the permit approvals, authorizations, and conditions. This permit is issued as a program code 2120/3610 for limited-scope medical and broad-scope research uses. In addition, the permit has authorization for an irradiator and intravascular brachytherapy.

3. You should note future amendment requests can be submitted as VHA correspondence or electronic mail. Electronic mail is preferred to help expedite responses. The e-mail address is vheonhrp@med.va.gov.

4. If you have any questions, please contact Gary E. Williams, VHA National Health Physics Program, at (501) 257-1572.

E. Lynn McGuire

E. Lynn McGuire

Attachment

Department of Veterans Affairs

MATERIALS PERMIT

Amendment No. **81**

In accordance with VHA Directive and Handbook 1105.1, and in reliance on statements made by the applicant, permission is hereby granted to receive, possess, transfer, and store radioactive materials listed below, and to use this material for the purpose and at the places listed below.

Permittee	
1. VA Medical Center 2. 1030 Jefferson Avenue Memphis, Tennessee 38104	3. In accordance with your request of January 7, 2003, Permit No. 41-00119-08 is amended to read as follows: 4. Expiration date: November 30, 2011 5. Docket or Reference No.: 030-03253

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount permittee may possess at any one time under this permit
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	C. Any	C. 55.5 gigabecquerels (GBq) (1.5 curies)
D. Any byproduct material permitted by 10 CFR 35.400	D. Any brachytherapy sources identified in 10 CFR 35.400	D. As needed
E. Phosphorus 32	E. Sealed sources (Guidant Models GDT-P32-1 and GDT-P32-2)	E. 44.4 GBq (1200 millicuries (mCi)), no single source to exceed 22.2 GBq (600 mCi)
F. Any byproduct material permitted by 10 CFR 31.11	F. Prepackaged kits	F. As needed
G. Cesium 137	G. Sealed source registered pursuant to 10 CFR 32.210 contained in a compatible registered device specified in Item 9G	G. 148 terabecquerels (TBq) (4000 curies) total
H. Uranium (depleted in Uranium 235)	H. Cadmium plated metal shielding components	H. 182 kilograms
I. Strontium 90	I. Sealed source (Nuclear Enterprises Model No. 2503)	I. 370 megabecquerels (MBq) (10 millicuries)

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount permittee may possess at any one time under this permit
J. Any byproduct material with atomic numbers 1-83, inclusive	J. Any form except sealed sources	J. 111 MBq (3 millicuries) per radionuclide and 3.7 GBq (100 millicuries) total, except as follows: (1) Carbon 14: 29.6 GBq (800 millicuries) (2) Phosphorus 32 and/or Phosphorus 33: 37 GBq (1 curie) total (3) Sulfur 35: 7.4 GBq (200 millicuries) (4) Hydrogen 3: 55.5 GBq (1.5 curies) (5) Iodine 125: 29.6 GBq (800 millicuries) (6) Chromium 51: 3.7 GBq (100 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 diagnostic study or therapy procedure permitted by 10 CFR 35.300

D. Any manual brachytherapy procedure permitted by 10 CFR 35.400

E. For use in Guidant Corporation VI Model GALILEO intravascular brachytherapy high dose rate afterloader devices for intravascular brachytherapy

F. *In vitro* studies permitted by 10 CFR 31.11

G. For possession and use in J. L. Shepherd Model 25-1 irradiator for irradiation of laboratory animals, plant cells, and chemical compounds

H. For possession and use as shielding in a linear accelerator

I. For possession and use in a Nuclear Enterprises dosimeter calibrator for calibration of dosimetry systems

J. Research and development as defined in 10 CFR 30.4, animal studies, instrument calibration, and teaching and training of students

CONDITIONS

10. Permitted material may be used or stored only at the permittee's facilities located at 1030 Jefferson Avenue, Memphis, Tennessee.

11. The Radiation Safety Officer for this permit is Michael Kaiser.

12. Permitted 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.

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

Authorized Users	Material and Use
James D. Massie, M.D.	35.100, 35.200, and 35.300
Jorge E. Salazar, M.D.	35.100 and 35.200
Randall Lee Scott, M.D.	35.100 and 35.200
Donna Swain, M.D.	35.100, 35.200, and 35.300
John R. Ware, M.D.	35.100, 35.200, and 35.300
Alan H. Appelbaum, M.D.	35.100 and 35.200
Muhammad Sheikh, M.D.	35.100, 35.200, and 35.300
Joan A. (Jacobson) Kaufman, M.D.	35.400, Phosphorus 32 contained in Guidant Corporation Model Galileo high dose rate intravascular brachytherapy device

    C. The following individual is an authorized medical physicist:

Authorized Medical Physicist	Material and Use
Douglas Tai, Ph.D.	Phosphorus 32 in an intravascular brachytherapy afterloader device for calibrations, spot-checks, and training

    D. The following individuals are authorized users for non-medical uses:

Authorized Users	Material and Use
Solomon S. Solomon, M.D.	31.11
John M. Stuart, M.D.	Cesium 137 for irradiation of samples
Michael Kaiser	Strontium 90 for calibration

    E. Permitted material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.

13. Intravascular brachytherapy procedures shall be conducted under the supervision of the authorized user, who will consult with the interventional cardiologist/physician and authorized medical physicist prior to initiating treatment. The procedures shall be conducted in the physical presence of the authorized user or the authorized medical physicist.

14. Source stepping or pullback procedures are authorized in accordance with the Food and Drug Administration approval of these procedures with the Guidant Corporation Model Galileo high dose rate intravascular afterloading device.

15. The intravascular brachytherapy afterloader device shall be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair shall be performed by the manufacturer or persons specifically licensed by the Nuclear Regulatory Commission or an Agreement State to perform such services.

16. The provisions of this condition are applicable to the permittee's possession and use of the J. L. Shepherd Mark I Series Model 25-1 irradiator.

    A. The permittee shall follow the device manufacturer's instruction manual and shall make copies available to each person using or having responsibility for use of the irradiator.

    B. The permittee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the permitted material. A person specifically licensed by the Nuclear Regulatory Commission or an Agreement State to perform such services shall perform removal, replacement, and disposal of sealed sources in the irradiator.

    C. The permittee shall ensure the irradiator is tested for proper operation of the "on-off" mechanism and indicator, if any, at intervals not to exceed six months.

    D. The permittee shall install a room (area) radiation monitor in proximity to the irradiator for the purposes of alerting the operator of unexpected radiation levels. The device shall as a minimum meet the specifications recommended by the irradiator manufacturer.

    E. The irradiator shall be used by, or under the supervision of John M. Stuart, M.D., or individuals designated by the Radiation Safety Committee.

    F. The permittee shall not irradiate explosive, flammable, or corrosive materials, or any other material that might impair the containment integrity of the sealed sources and/or the irradiator shielding and safety mechanisms.

    G. The permittee is not authorized to irradiate food or food products for human consumption.

17. A. Individuals involved in operations which utilize, at any one time, more than 3.7 GBq (100 millicuries) of hydrogen 3 in a non-contained form, other than metallic foil, shall have bioassays performed within one week following a single operation and at weekly intervals for continuing operations.

    B. When implementing the bioassay program at the level indicated in Paragraph A, these actions shall also be taken:

        (1) Hydrogen 3 shall not be used in such a manner as to cause any individual to receive a radiation exposure such that urinary excretion rates exceed 1.036 MBq (28 microcuries) per liter when averaged over a calendar quarter.

        (2) Urinalysis shall be performed at weekly intervals on individuals who work in the restricted areas of facilities in which hydrogen 3 is used. If the average concentration of hydrogen 3 in urine for any single individual during a calendar quarter is less than 0.37 MBq (10 microcuries) per liter, urinalysis may be performed on that individual at monthly intervals for the following quarter and may continue at monthly intervals so long as the average concentration in the calendar quarter remains below 0.37 MGq (10 microcuries) per liter. The urine specimen shall be collected on the same day of the week insofar as possible.

        (3) A report of an average concentration in excess of the limit specified in Subparagraph B(1) above for any individual shall be filed, in writing, within 30 days of the end of the quarter with the National Health Physics Program (115HP/NLR), 2200 Fort Roots Drive, North Little Rock, AR 72114. The report shall contain the results of all urinalyses for the individual during the quarter, the causes of excessive concentration, and corrective steps taken or planned to prevent a recurrence.

(4) Any single urinalysis which discloses a concentration of greater than 1.85 MBq (50 microcuries) per liter shall be reported, in writing within seven days of the permittee's receipt of the report, to the address stated in Subparagraph B(3) above.

C. Personnel working in Research and Nuclear Medicine Services with iodine 125 and iodine 131 in liquid form in an amount of 37 MBq (1 millicurie) and 370 MBq (10 millicuries) or greater respectively, and with iodine 131 in encapsulated form in an amount of 1.11 GBq (30 millicuries) or greater, shall be required to undergo a thyroid count in nuclear medicine within approximately 24 hours after cessation of work.

18. The permittee shall not use permitted material in field applications where activity is released except as provided otherwise by specific condition of this permit.

19. Experimental animals, or the products from experimental animals, that have been administered permitted material shall not be used for human consumption.

20. This permit does not authorize commercial distribution of permitted material.

21. Sealed sources containing permitted material shall not be opened, and when installed in an exposure device (irradiator, calibrator, etc.) shall not be removed from said device by the permittee.

22. For sealed sources not associated with 10 CFR 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 by the certificate of registration issued by the Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.

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

C. Each sealed source fabricated by the permittee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

D. In the absence of a certificate from a transferor indicating a leak test has been made within the intervals specified in the certificate of registration issued by the Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

E. Sealed sources need not be 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.

F. Sealed sources need not be tested if they 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 shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

G. 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 National Health Physics Program 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 Nuclear Regulatory Commission regulations.

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

23. Sealed sources containing permitted material shall not be opened or sources removed from source holders by the permittee.

24. The permittee shall conduct a physical inventory every six months to account for all sources and/or devices received and possessed under this permit. Records of inventories shall be maintained for five years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

25. 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 temperature from exceeding that specified by the manufacturer and approved by Nuclear Regulatory Commission.

    B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

26. 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 Nuclear Regulatory Commission or an Agreement State to perform such services.

27. For radioactive material held for decay in storage other than that held in accordance with 10 CFR 35.92, the permittee is authorized to hold radioactive material with a physical half-life of less than 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 10 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 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 permit 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.

28. The permittee is authorized to transport permitted material in accordance with the provision of 10 CFR 71, "Packaging and Transportation of Radioactive Material."

29. In addition to the possession limits in Item 8, the permittee shall further restrict the possession of permitted material as follows:

    A. For unsealed sources to quantities less than 10^5 times the applicable limits in Appendix B, 10 CFR 30 as specified in 10 CFR 30.35(d) and

    B. For sealed sources, to quantities less than 10^{10} times the applicable limits in Appendix B, 10 CFR 30 as specified in 10 CFR 30.35(d).

30. Pursuant to 10 CFR 20.2001(3), 20.2002, and 20.2004(a), the permittee is authorized to dispose of carbon 14 and hydrogen 3 by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR 20. Ash residues may be disposed of as ordinary waste provided appropriate surveys pursuant to 10 CFR 20.1501(a) are made to determine that concentrations of permitted material appearing in the ash residues do not exceed the concentrations (in terms of microcuries per gram) specified for water in Appendix B, Table II, 10 CFR 20.

31. Except as specifically provided otherwise in this permit, the permittee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This permit condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this permit condition does not limit the permittee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The Nuclear Regulatory Commission regulations shall govern unless the statements, representations, and procedures in the permittee's application and correspondence are more restrictive than the regulations.

A.	Application dated May 17, 1990, and revised application submitted with letter dated October 30, 1991	
B.	Letter dated April 11, 1991	
C.	Letter dated July 2, 1993	[excepting Authorized users for medical uses identified in 10 CFR 35.100, 35.200, and 35.300 are listed in Amendment No. 76; 35.400 deletions: Drs. Kun, Paig, Shah; 31.11 deletions: Drs. Brooks and Martinez-Hernandez]
D.	Letter dated September 29, 1993	[excepting: see note for July 2, 1993]
E.	Letter dated June 6, 1994	[excepting: RSO and alternative RSO same as in Amend #76; See note for July 2, 1993]
F.	Letter dated October 2, 1996	[excepting: see note for July 2, 1993]
G.	Letter dated October 23, 1996	[fax re: therapy qualifications for Dr. Swain]
H.	Letter dated February 3, 1997	[excepting: see July 2, 1993, note]
I.	Letter dated December 5, 1997	[excepting: see note for July 2, 1993]
J.	Letter dated February 19, 1999	[excepting: see note for June 6, 1994, and July 2, 1993]
K.	Letter dated March 11, 1999	[added information for Dr. Tai, including telephone conversation with State of Tennessee radiation control]
L.	Letter dated December 6, 1999	[change Nuclear Medicine Area from Building #1, A Wing, first floor to new addition, first floor]
M.	Letter dated January 27, 2000	[change RSO to M. Kaiser, delete C. Brannon]
N.	Letter dated July 31, 2000	[remove Radiation Safety Office's bi-monthly survey requirement]
O.	Letter dated September 26, 2000	[add new location of use for cardiac imaging]
P.	Letter dated April 4, 2001	[delete instrument calibrator, add Dr. Appelbaum for 35.100 and 35.200]
Q.	Letter dated May 1, 2001	[leak test certificate for calibrator]
R.	Letter dated July 23, 2001	[renewal as is]
S.	Letter dated October 29, 2001	[restatement of tie-down letters and exceptions]
T.	Letter dated September 16, 2002	[add Dr. Sheikh for 35.100 and 35.200, including intravascular brachytherapy information, excluding medical physicist]
U.	Letter dated January 7, 2003	[add IVB]
V.	Letter dated February 19, 2003	[additional information on Dr. Sheikh for 35.300 uses]

FOR THE DEPARTMENT OF VETERANS AFFAIRS

Date MAR 30 2003

By E. Lynn McGuire
E. Lynn McGuire
Director, National Health Physics Program
North Little Rock, AR