BALA MEDICAL CENTER

Wayne V. Arnold, D.O., F.A.C.O.I.

CARDIOLOGY - PERIPHERAL VASCULAR DISEASES

15 NORTH PRESIDENTIAL BLVD. SUITE 100 BALA CYNWYD, PA 19004

(610) 667-2746 (610) 667-2749 Fax# (610) 667-9420

21 August 2006

U.S Nuclear Regulatory Commission, Region 1 Licensing Assistance Team 475 Allendale Road King of Prussia, PA 19409-1415 Br. 2

Dear Sir or Madam:

Please accept the following as an amendment request to our Medical Use Materials License, No. 37-28333-01: 03030949

- 1. Add the following physicians as an authorized users for 10 CFR 35.200:
 - a. Edgar Massabni, M.D.
 - b. Alan D. Askenase, M.D.
 - c. Douglas Jacoby, M.D.

Please find attached documentation of training and experience for these physicians.

If you have any questions or concerns regarding this amendment, please do not hesitate to contact me at 610-667-2746, or our Nuclear Operations Manager, Terry Day, RT, at 856-786-4700.

Sincerely,

Wayne Arnold, D.O. Radiation Safety Officer

Enclosures

m/ MIS 29 PM 1: 0

CABINET FOR HEALTH SERVICES COMMONWEALTH OF KENTUCKY RADIOACTIVE MATERIAL LICENSE

PAGE 1

LICENSEE AND 2. ADDRESS 1.

> BIG SANDY CARDIOLOGY, PSC 255 CHURCH STREET PIKEVILLE. KY 41501

ATTENTION:

CHARLES A. GIOMOSO, M.S.

TELEPHONE:

606-432-3524

PURSUANT TO KRS 211.842 ET SEQ., THE KENTUCKY CABINET FOR HUMAN RESOURCES REGULATIONS, 902 KAR 100, AND IN RELIANCE ON STATEMENTS AND REPRESENTATIONS HERETOFORE MADE BY THE LICENSEE, A LICENSE IS HEREBY ISSUED TO RECEIVE, ACQUIRE, OWN, POSSESS AND TRANSFER RADIOACTIVE MATERIAL LISTED BELOW; AND TO USE SUCH RADIOACTIVE MATERIAL FOR THE PURPOSE(S) AND AT THE PLACE(S) DESIGNATED BELOW. THIS LICENSE IS SUBJECT TO ALL APPLICABLE RULES, REGULATIONS, AND ORDERS OF THE CABINET FOR HEALTH SERVICES, NOW OR HEREINAFTER IN EFFECT AND TO ANY CONDITIONS SPECIFIED BELOW.

3. LICENSE NUMBER: 202-296-24 AMENDMENT NO. 5

4. EXPIRATION DATE: JANUARY 31, 2007

5. REVIEWER:

12

6. LICENSED MATERIAL 7. FORM

8. POSSESSION LIMIT

A. TECHNETIUM 99M A. ANY FORM

A. AS NECESSARY FOR USES AUTHORIZED IN SUBITEM 9.A. AND B. AT LOCATION SPECIFIED IN CONDITION 11

B. THALLIUM 201 B. THALLIUS

CHLORIDE

B. AS NECESSARY FOR USES AUTHORIZED IN SUBITEM 9.A. AND B. AT

LOCATION SPECIFIED IN CONDITION 11

CABINET FOR HEALTH SERVICES COMMONWEALTH OF KENTUCKY RADIOACTIVE MATERIAL LICENSE

LICENSE NUMBER: 202-296-24 AMENDMENT 5

C. COBALT 57

MODEL 8400

C. SEALED SOURCE C. NO SINGLE SOURCE TO EXCEED 30 MILLI-CURIES

9. AUTHORIZED USE

- A. AND B. CARDIOLOGY STUDIES ONLY.
- C. USED FOR INSTRUMENTATION QUALITY CONTROL.

CONDITIONS:

- 10. THE LICENSEE SHALL COMPLY WITH THE PROVISIONS OF THE KENTUCKY CABINET FOR HEALTH SERVICES ADMINISTRATIVE RADIATION REGULATIONS, 902 KAR 100.
- 11. RADIOACTIVE MATERIAL SHALL BE USED ONLY AT THE LICENSEE'S FACILITIES LOCATED AT:

255 CHURCH STREET, PIKEVILLE, KENTUCKY 41501

RADIOACTIVE MATERIAL SHALL BE USED BY: 12.

> EDGAR MASSABNI, M.D. ANTHONY VILLAROSA, M.D.

- NOTWITHSTANDING THE REQUIREMENTS OF 902 KAR 100:073, SECTION 7, THE LICENSEE IS NOT REQUIRED TO ESTABLISH A RADIATION SAFETY COMMITTEE.
- THE RADIATION SAFETY OFFICER FOR THE ACTIVITIES AUTHORIZED BY THIS LICENSE IS EDGAR MASSABNI, M.D. .
- 15. SEALED SOURCES CONTAINING RADIOACTIVE MATERIAL SHALL NOT BE OPENED.
- EXCEPT AS OTHERWISE SPECIFIED BY LICENSE CONDITION, RECORDS MAINTAINED PURSUANT TO KENTUCKY ADMINISTRATIVE REGULATIONS 902 KAR 100 MAY BE DISPOSED OF AFTER A PERIOD OF FIVE YEARS OF THE RECORDED EVENT EXCEPT RECORDS OF RECEIPT, TRANSFER AND DISPOSAL OF RADIOACTIVE MATERIAL SHALL BE MAINTAINED IN ACCORDANCE WITH 902 KAR 100:040, SECTION 15 AND 902 KAR 100:073, SECTION 28. RECORDS OF PERSONNEL MONITORING SHALL BE MAINTAINED UNTIL DIS-POSAL IS AUTHORIZED BY THE CABINET.

CABINET FOR HEALTH SERVICES COMMONWEALTH OF KENTUCKY RADIOACTIVE MATERIAL LICENSE

LICENSE NUMBER: 202-296-24

AMENDMENT 5

PAGE

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- EXCEPT AS SPECIFICALLY PROVIDED OTHERWISE IN THIS LICENSE, THE LICENSEE SHALL CONDUCT ITS PROGRAM IN ACCORDANCE WITH THE STATEMENTS, REPRESENTATIONS, AND PROCEDURES CONTAINED IN THE DOCUMENTS, INCLUDING ANY ENCLOSURES, LISTED BELOW. THE CABINET FOR HEALTH SERVICES REGULATIONS, 902 KAR 100, SHALL GOVERN UNLESS STATEMENTS, REPRESENTATIONS, AND PROCEDURES IN THE LICENSEE'S APPLICATION AND CORRESPONDENCE ARE MORE RESTRICTIVE THAN THE REGULATION.
 - A. APPLICATION DATED NOVEMBER 22, 2002, SIGNED BY EDGAR J. MASSABNI, M.D.
 - B. LETTERS DATED:

 - DECEMBER 20, 2002, SIGNED BY EDGAR J. MASSABNI, M.D. JANUARY 21, 2003, SIGNED BY EDGAR J. MASSABNI, M.D.
 - FEBRUARY 10, 2004, SIGNED BY EDGAR MASSABNI, M.D.
 - 4. JUNE 14, 2004, SIGNED BY EDGAR MASSABNI, M.D.
 - 5. SEPTEMBER 24, 2004, SIGNED BY EDGAR MASSABNI, M.D.
 - 6. DECEMBER 29, 2004, SIGNED BY EDGAR MASSABNI, M.D.

MARCH 9, 2005, SIGNED BY EDGAR MASSABNI, M.D.

MANAGER

RADIATION HEALTH BRANCH

JAMES W. HOLSINGER, JR., M.D.

SECRETARY

CABINET FOR HEALTH AND FAMILY SERVICES

DATE ISSUED DECEMBER 22, 2005

Incorporated 1996

CERTIFICATION BOARD OF NUCLEAR CARDIOLOGY

CERTIFIES THAT

Edgar Jöseph Massabnī, m.d.

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD FOR PHYSICIANS RESIDING IN THE UNITED STATES AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION, IS HEREBY DESIGNATED

A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

NUCLEAR CARDIOLOGY

FOR THE PERIOD 2000 THROUGH 2010

CERTIFICATE #1773



OCTOBER 29, 2000

USNRC R1 LAS

610 337 53**93**

P.02

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 of 2 PAGES Amendment No. 03

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 163 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 hereafts: in effect and to any conditions specified below.

L	CO	nse	е
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- 1. The Heart Institute of Southern New Jersey
- 1400 E. Route 70 Cherry Hill, New Jersey 08034

In accordance with the application dated August 15, 2005

- 3. License No. 29-30202-02
- is amended in its entirety to read as follows:
- 4. Expiration Date: August 31, 2013
- 5. Docket No. 030-:4700

- Byproduct, source, and/or special/ nuclear material
- A. Any byproduct material, permitted by 10 CFR 35:200
- B. Any byproduct materials; permitted by 10 CFR 35.500
- Chemical and/or physical form
- 8 Maximum amount that licensee may make sees at any one time under this license
- A. As needed
- B. Sealed source (Notific Mode)
 American Scientific Mode)
- B. O'écurie per source and fécurie total

9. Authorized use:

- A. Any imaging and localization study permitted by 10 CFR 35.200.
- B. Diagnostic medical use of sealed sources permitted by 10 CFR 35.5(10 in compatible devices registered pursuant to 10 CFR 30.32 (g).

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 1400 E. Route 70, Cherry Hill, New Jersey.
- 11. The Radiation Safety Officer (RSO) for this license is Alan D. Askenase, M.D.
- 12. Licensed material is only authorized for use by, or under the supervision of:
 - A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
 - B. The following individuals are authorized users for medical use as indicated;

P.03

NOV-18-2005 11:47

USNRC R1 LAS

610 337 5393

NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

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License No.
29-30202-02

Docket No.
030-34700

Amendment No.
03

Authorized User

Material and Use

Alan D. Askenase, M.D.

35.200, 35.500

Douglas Jacoby, M.D.

35.200

- 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. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packageing and Transportation of Radioactive Material."
- 15. Except as specifically provided otherwise in this license, the license 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 projection 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 correst ondence are more restrictive than the regulations.

Βv

A. Application dated April 18, 2003

B. Letter dated July 23, 2003 ...

For the U. S. Nuclear Regulatory Commission

Date October 3, 2005

Original signed by Bryan A. Parker

Bryan A. Parker
Commercial and R&D Branch
Division of Nuclear Viaterials Safety
Region I
King of Prussia, Pennsylvania 19406



Environmental Health & Radiation Safety

August 10, 2005

To whom it may concern,

Dr. Douglas Jacoby is an Authorized User under the University of Pernsylvania's NRC license no: 37-00118-07 and PA State license no: PA-0131. He is licensed under 10CFR35.290 for Nuclear Cardiology imaging and localization studies not requiring a written directive.

If you have any questions please contact me.

Robert D. Forrest, CHP

Assoc. Dir/Radiation Safety Officer

Environmental Health and Radiation Safety

University of Pennsylvania

215-898-2109

rforrest@ehrs.upenn.edu

05-01039 AM-dp



Luis I. Araujo, MD Director, Nuclear Cardiology Associate Professor of Radiology and Medicine

Department of Radiology

August 4, 2005

Nuclear Regulatory Commission Department of Environmental Protection Division of Radiation Safety

Re: Douglas Jacoby, M.D.

To Whom It May Concern:

Dr. Douglas Jacoby is a third year Cardiovascular Fellow at the Hospital of the University of Pennsylvania. His training began July 1, 2002 through June 30, 2005. Under my supervision as an authorized user under 10CFR35.290 he has more than 700 hours of experience in the medical use of byproduct material for imaging and localization studies involving ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring, and safely preparing patient or human research subject dosages; using administrative controls to prevent a medical event involving the use of unsealed byproduct material; using procedures to safely contain spilled radioactive material and using proper decontamination procedures; administering dosages of radioactive drugs to patients or human research subjects; and eluting generator systems appropriate for preparation of radioactive drugs for imagin; and localization studies, measuring and testing the cluate for radionuclidic purity, and processing the cluate with reagent kits to prepare labeled radioactive drugs. In addition he has completed more than 80 hours of classroom and laboratory training in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, the chemistry of byproduct material for medical use and radiation biology.

Dr Jacoby has satisfactorily completed the requirements in paragraph 10CFR290(c)(1) during his 12 month rotation during the period from July 1, 2002 through June 30, 2005 in the nuclear cardiology laboratory of the Division of Nuclear Medicine at the Hospital of the University of Pennsylvania and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10CFR35.200.

Sincerely

Luis Anaujo, MD

Director, Nuclear Cardiology

LIA:akd

This is to acknowledg	e the receipt of your letter/application dated
	ative review has been performed.
technical reviewer.	ninistrative omissions. Your application was assigned to a Please note that the technical review may identify additional ire additional information.
Please provide to	this office within 30 days of your receipt of this card
A copy of your action	has been forwarded to our License Fee & Accounts Receivable
Branch, who will cont	act you separately if there is a fee issue involved.
When calling to inqui	assigned Mail Control Number 139336. re about this action, please refer to this control number. 610) 337-5398, or 337-5260.
NRC FORM 532 (RI) (6-96)	Sincerely, Licensing Assistance Team Leader