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Health System

Office of the President
601 Children's Lane
Norfolk, VA 23507
757.668.7044
757.668.9450 Fax

July 12, 2005

K-3

Ms. Michelle Simmons
U.S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
Region I
475 Allendale Road
King of Prussia, PA 19406

2005 JUL 14 AM 10:23

RECEIVED
REGION I

03020229

Reference: Radioactive Materials License No. 45-23063-01

Dear Ms. Simmons:

The following is notification of our Radiation Safety Committee action taken today to:

- Add Lori Gay, CNMT, as temporary Radiation Safety Officer according to 10 CFR 35.24(c) until NRC action on license amendment request dated June 7, 2005, requesting that she be added as permanent Radiation Safety Officer.
- Add David C. Kushner, M.D. as an authorized user on our license for medical uses identified in 10 CFR 35.100, and 35.200. Please find attached his qualifications for authorized user under 10 CFR 35.13(b)(4)(i).

In response to your question about Stephanie E. Spottswood, M.D., her duties and privileges end as of July 12, 2005. Please remove her as authorized user from our license as of this date.

Thank you for your assistance with this matter. Should other information be required, please contact our consulting health physicist, Mr. Roy F. Heltzel, Jr. at 757-410-9051.

Sincerely,

Jim Dahling
President and Chief Executive Officer

Enclosure

137212
NRC/REGION I MATERIALS-002

Radiation Safety Officer

Radiation Safety Officer: Thomas Fearon, Ph.D.

NRC License Number: 09-03309-01 and 08-03309-04

Training and Experience: RSO at Children's National Medical Center for 23 years (1980-present), NRC from 313A and Curriculum Vitae attached (Attachment 7.3).

Delegation of Authority attached (Attachment 7.4).

We will adopt the Model RSO Duties and Responsibilities as published in NUREG 1556 Vol. 9, Appendix I.

Authorized Users for Medical Use

Primary Nuclear Medicine Physicians

**Massoud Majd, M.D.
Eglal Shalaby-Rana, M.D.**

Secondary Physicians

**Anna Blask, M.D.
Wendy Thomas Brown, M.D.
Dorothy Bulas, M.D.
David Kushner, M.D.
Melanie Levin, M.D.
Bruce Markle, M.D.**

NRC Form 313A, Certification and *curriculum vitae* Attachments 7.5-7.12

8. Training for Individuals Working in or Frequenting Restricted Areas (Instruction of Workers)

The Model Training Program provided in NUREG-1556 vol. 9 Appendix J will be implemented.

9. Facilities and Equipment

The Nuclear Medicine Department (room 2432, Attachment 9.I), where the major portion of the byproduct material is used, is located on the second floor quadrant of the hospital. It is out of the mainstream of patient and visitor traffic.

Enclosure

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.

<p>Licensee</p> <p>1. Children's National Medical Center</p> <p>2. 111 Michigan Avenue, N.W. Washington, D.C. 20010</p>	<p>In accordance with the letter with letter dated July 21, 2004,</p> <p>3. License number 08-03309-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date <u>May 31, 2014</u></p> <hr/> <p>5. Docket No. <u>03001323</u> Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with atomic numbers 3 through 83 and a half-life of less than or equal to 120 days</p> <p>B. Hydrogen 3</p> <p>C. Carbon 14</p> <p>D. Iodine 125</p> <p>E. Technetium 99m</p> <p>F. Americium 241</p> <p>G. Americium 241</p>	<p>7. Chemical and/or physical form</p> <p>A. Any, except sealed sources</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> <p>F. Sealed source (Amersham Model No. AMC.24)</p> <p>G. Sealed source (Amersham Model No. AMC.24)</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 100 millicuries of each radionuclide and 2 curies total</p> <p>B. 400 millicuries</p> <p>C. 60 millicuries</p> <p>D. 500 millicuries</p> <p>E. 2 curies</p> <p>F. 15 millicuries</p> <p>G. 14 millicuries</p>
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9. Authorized use:

A. through E. Medical diagnosis, therapy and research in humans in accordance with any applicable Food and Drug Administration (FDA) requirements. Research and development as defined in 10 CFR 30.4; including instrument calibration and student instruction.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
08-03309-01Docket or Reference Number
030-01323

Amendment No. 45

- F. For use in a Siemens Gammasonics, Inc. Model 035-42300C dual isotope motion correction point source holder.
- G. For use in a Siemens Gammasonics, Inc. Model SS-10244 anatomical marker.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 111 Michigan Avenue, N.W., Washington, District of Columbia.
11. A. Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.
- B. The use of licensed material in or on humans shall be by an authorized user as defined in 10 CFR 35.2.
- C. Individuals designated to work as authorized users, authorized nuclear pharmacists, or authorized medical physicists, as defined in 10 CFR 35.2 shall meet the training, experience, and recency of training criteria established in 10 CFR 35 and shall be designated, in writing, by the licensee's Radiation Safety Committee.
- D. The Radiation Safety Officer for this license is Thomas C. Fearon, Ph.D.
12. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
13. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
14. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
- A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. 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.

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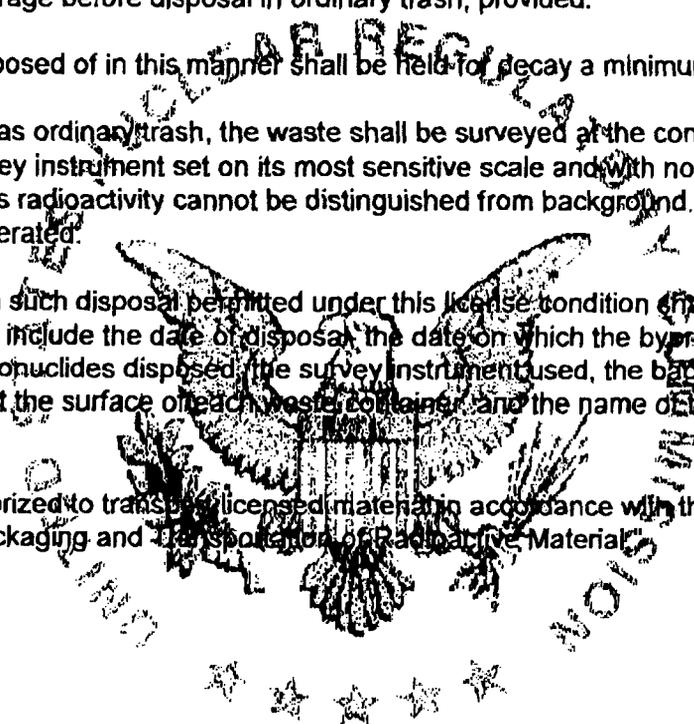
Amendment No. 45

- D. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source 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 transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source 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 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.
- H. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 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.
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.

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- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
18. For radioactive material held for decay-in-storage other than that held in accordance with 10 CFR 35.92, 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 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 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 3 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.
19. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."



**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

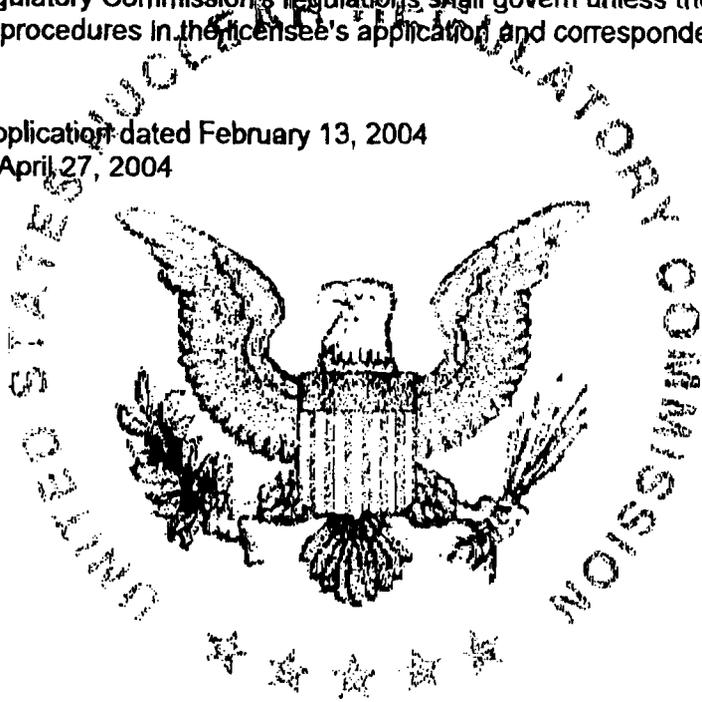
License Number
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20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. 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. The letter with application dated February 13, 2004
- B. The letter dated April 27, 2004



For the U.S. Nuclear Regulatory Commission

Date August 30, 2004

By *Fara L. Weidner*

Fara L. Weidner
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety
Region
King of Prussia, Pennsylvania 19406

82258738

NRC FORM 313A (10-2002)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY _____ EXPIRES: 10/31/2005
TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT		

PART I - TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations.

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

David Kushner MD

2. For Physicians, Podiatrists, Dentists, Pharmacists - State or Territory Where Licensed

DC Md Va

3. CERTIFICATION

Specialty Board	Category	Month and Year Certified
ABR	Diagnostic	6/15/79

Stop here when using Board Certification to meet 10 CFR Part 35 training and experience requirements.

4. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation			
Radiation Protection			
Mathematics Pertaining to the Use and Measurement of Radioactivity			
Radiation Biology			
Chemistry of Byproduct Material for Medical Use			
OTHER			

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

5a. WORK EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and Clock Hours of Experience

5b. SUPERVISED CLINICAL CASE EXPERIENCE

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and Clock Hours of Experience

The American Board of Radiology

Organized through the cooperation of the American College of Radiology, the American Roentgen Ray Society, the American Radium Society, the Radiological Society of North America, the Section on Radiology of the American Medical Association and the American Society of Thoracic Radiologists
Sincerely certifies that

David Whaim Kuschner, M.D.

Has pursued an accepted course of graduate study and clinical work, has met certain standards and qualifications and has passed the examinations conducted under the authority of

The American Board of Radiology

On this fifteenth day of June, 1979

Thereby demonstrating to the satisfaction of the Board that he is qualified to practice the specialty of

Diagnostic Radiology

E. Richard King

C. Allen Good
President

