



June 11th, 2009

NRC License # 48-32697-01
Control Number 317975

Material Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352
ATTN: Colleen Casey

Attached please find the follow up letter for control number 317975 which will complete our original amendment request dated March 30, 2009.

Thank you for your kind attention. If any questions should arise, please feel free to contact me 608-839-9956.

Sincerely,

A handwritten signature in blue ink, appearing to read "Lisa Arington".

Lisa Arington, CEO
Northern Shared Medical Services

209 Limestone Pass
Cottage Grove, WI 53527
FAX 608 839-8950
Phone 608 839-9050

RECEIVED JUN 15 2009



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Material Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352
ATTN: Colleen Casey

Northern Shared Medical Services would like to add additional authorized users to our radioactive materials license. The authorized users are as follows:

Authorized Users:

James L. Littlefield, M.D.	NRC License# 24-00794-03 (Broad Scope)
Mark D. Wittry, M.D.	NRC License# 24-00794-03 (Broad Scope)

Please refer to Attachment A for the Radioactive Material User Permit and a copy of the above referenced NRC Licensure.

Authorized Users:

Medhat Osman, M.D.	NRC License# 24-00196-07 (Broad Scope)
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Please refer to Attachment B for the Radioactive Material User Permit and a copy of the above referenced NRC Licensure.

Authorized Users:

Jerold W. Wallis, M.D.	NRC License# 24-26243-01
Barry A. Siegel, M.D.	NRC License# 24-26243-01

Please refer to Attachment C for a copy of the above referenced NRC Licensure.

Attachment A

RADIOACTIVE MATERIAL USER PERMIT
(HUMAN USE)

A permit is hereby issued authorizing the individuals named herein to receive, acquire, and possess the radioactive materials listed below in the given quantities, and to use such radioactive materials for the purposes and at the places designated below. This permit is subject to all applicable rules and regulations of the Medical Center, and, in particular, to the provisions of Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standards for Protection Against Radiation". Radioactive materials specified herein shall be used only on the Medical Center premises and by, or under, the supervision of the named individuals.

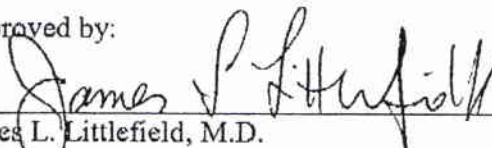
Radioactive material for use in humans shall be acquired from a supplier who certifies the pharmaceutical quality and assay of such material. If radioactive materials are prepared within the Medical Center for human use, the methods of establishing pharmaceutical quality shall be approved by a Subcommittee of the Radiation Safety Committee. All users requiring check, calibration and reference sources are authorized under 10 CFR 35.65 to possess same.

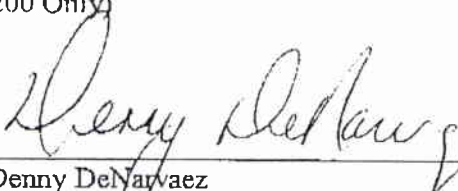
Authority for the issuance of this permit by the Medical Center is provided for in the U.S. Nuclear Regulatory Commission Materials License number 24-00794-03

INDIVIDUAL USERS:

- | | |
|--|---|
| <p>1. NAME: → James L. Littlefield, M.D.
→ Mark D. Wittry, M.D.
Christopher A. Swingle, D.O.
Delia Garcia, M.D. (35.200 only)
Michael Beat, M.D. (35.200 only)</p> | <p>2. DEPARTMENT OR LABORATORY:
Nuclear Medicine or 1000 Des Peres Rd, Suite 100</p> |
| <p>3. PERMIT NUMBER: 004-2</p> | <p>4. EXPIRATION DATE: January 31, 2010</p> |
| <p>5. RADIOACTIVE MATERIALS:
Any byproduct material identified in 10 CFR 35.200, 35.500 and State of Missouri registration RM-11</p> | <p>6. CHEMICAL AND/OR PHYSICAL FORM:
Any radiopharmaceutical identified in 10 CFR 35.200; sealed sources identified in 10 CFR 35.500</p> |
| <p>7. MAXIMUM POSSESSION AMOUNT AT ANY ONE TIME: As needed</p> | |
| <p>8. AUTHORIZED USE: Medical use as defined in 10 CFR 35.200 and 35.500 for imaging and localization, NP59 Adrenal and MIBG imaging.</p> | |
| <p>9. RESTRICTIONS: Must be ordered through Nuclear Pharmacy (any above) or 1000 Des Peres Rd, Suite 100 (35.200 Only)</p> | |

Approved by:


James L. Littlefield, M.D.
Chairman, Radiation Safety Committee


Denny DeNarvaez
President/CEO, St. John's Mercy Medical Center

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Amendment No. 67

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. St. John's Mercy Medical Center</p> <p>2. 615 S. New Ballas Road St. Louis, MO 63141</p>	<p>In accordance with the letter dated January 21, 2009,</p> <p>3. License number 24-00794-03 is amended in its entirety to read as follows:</p> <p>4. Expiration date May 31, 2012</p> <p>5. Docket No. 030-02283 / 030-36126 / 030-35039 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p> <p>D. Any byproduct material permitted by 10 CFR 35.400</p> <p>E. Any byproduct material permitted by 10 CFR 35.500</p> <p>F. Any byproduct material permitted by 10 CFR 31.11</p> <p>G. Depleted uranium</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any (Amersham Model Nos. CDCT1, S1A.3, S1A.6; 3M Model Nos. 6500, 6501, 6503, 6551R; Bara Model No. STM251; Oncura/Amersham Model No. 6711)</p> <p>E. Sealed sources (Isotope Products Model 3409)</p> <p>F. Prepackaged Kits</p> <p>G. Cadmium plated metal</p>	<p>8. Maximum amount that licensee may possess at any one time under this license.</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. As needed (not to exceed 5 curies of iodine-131)</p> <p>D. 2.5 curies</p> <p>E. 180 millicuries</p> <p>F. As needed</p> <p>G. As needed</p>
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H. Iodine-131	H. Any	H. 30 millicuries
I. Iodine-125	I. Any	I. 300 millicuries
J. Hydrogen-3	J. Any	J. 10 millicuries
K. Phosphorus-32	K. Any	K. 10 millicuries
L. Sulfur-35	L. Any	L. 10 millicuries
M. Cesium-137	M. Sealed source (Model No. Tech OPS 77032)	M. 165 millicuries
N. Cesium-137	N. Sealed Source (CEA-ORIS-LAPIB Model 437c)	N. 5,610 curies
O. Gadolinium-153	O. Sealed Sources (Isotope Products Laboratories Model 3409, HEGL-0022)	O. 2 sources, not to exceed 90 millicuries each
P. Technetium-99m	P. Any	P. As needed
Q. Iridium-192	Q. Sealed Sources (Nucletron Model No. 105.002, manufactured by Mallinckrodt Medical BV or AEA Technology, Inc.)	Q. 4 sources, two sources not to exceed 12 curies and two sources not to exceed 9 curies, total possession not to exceed 42 curies
R. Phosphorus-32	R. Sealed source wires (Guidant Corporation Model GDT P-32 Series)	R. Three source assemblies not to exceed 600 millicuries each.
S. Strontium-90, as permitted by 10 CFR 35.1000	S. Sealed sources (BEBIG Model Sr0.S03 or AEAT Model SICW.2)	S. No single source to exceed 5 millicuries; total possession not to exceed 800 millicuries

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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. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
- F. In-vitro studies.
- G. Shielding in a linear accelerator.
- H. In vitro studies.
- I. To be used for research and development as defined in 30.4, in vitro studies, instrument calibration and radioiodination of analytes.
- J. through L. In vitro studies.
- M. To be used in a Technical Operations Model 773 instrument calibrator for calibration of the licensee's survey instruments.
- N. To be used with Compagnie ORIS Industries Model IBL-437C irradiator for irradiation of biological materials.
- O. One source to be used in a Picker International PRISM 3000 Transmission Line Source Housing STEP device for medical radiography in humans. One source in its shipping container for replacement of the source.
- P. To be used in unsealed form in the fabrication of a sealed source as described in letter dated September 25, 1995, for use in a Picker International PRISM 3000 Transmission Line Source Housing STEP device for medical radiography in humans.
- Q. Two sources for medical use as permitted by 10 CFR 35.600, and physics calibrations and Quality Assurance Checks, in Nucletron Corporation MicroSelectron HDR Model 105.999 high dose rate remote afterloading brachytherapy devices. Two sources (not to exceed 12 curies while stored pending installation) in shipping containers for source replacement. The source activity may not exceed 10 curies at the time of installation.

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- R. One source assembly to be used in a Guidant Corporation VI Model GALILEO intravascular brachytherapy HDR device for intravascular brachytherapy; the source assemblies may also be used for physics calibrations and quality assurance testing; two source assemblies in shipping containers for replacement and disposal.
- S. For use in Novoste Model A1000-series devices for intravascular brachytherapy, physics calibrations and quality assurance testing, as permitted by 10 CFR 35.1000.

CONDITIONS

10. A. Licensed material shall be used at the licensee's facilities located at St. John's Mercy Medical Center, 615 S. New Ballas Road, St. Louis, Missouri.
- B. Licensed material listed in Subitem Nos. 6.A., 6.B., 6.C., and 6.F. shall be used at the licensee's facilities located at St. John's Mercy Hospital, 901 E. Fifth Street, Washington, Missouri.
- C. Licensed material listed in Subitem Nos. 6.A., 6.B., 6.C. (excluding iodine-131), 6.D. (limited to the strontium-90 sources identified in Subitem No. 7.D.) and 6.Q. shall be used at the licensee's facilities located at St. John's Mercy Cancer Center, 607 South New Ballas Road, St. Louis, Missouri.
- D. Licensed material listed in Subitem Nos. 6.A. and 6.B. shall be used at the licensee's facilities located at St. John's Mercy Diagnostic Services, 755 Dunn Road, Hazelwood, Missouri; St. John's Mercy Diagnostic Services, 12348 Old Tesson Road, St. Louis, Missouri; and 625 S. New Ballas Road, Suite 2030, St. Louis, Missouri.
- E. Licensed material listed in Subitem No. 6.B., limited to cardiac imaging, shall be used at the licensee's facilities located on the sixth floor of the Heart Hospital, 625 South New Ballas Road, St. Louis, Missouri.
- F. Licensed material listed in Subitem Nos. 6.B., 6.C., and 6.Q. may be received, possessed, used and stored at the licensee's facilities located at Ballas Cancer Center, d/b/a St. Louis Cancer and Breast Institute, 1000 Des Peres Road, Suite 100, Des Peres, Missouri.
11. A. Licensed material shall be used by, or under the supervision of, individuals who have been trained in accordance with application dated November 21, 2001, and who have been 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 recentness of training criteria established in 10 CFR 35, and shall be designated, in writing, by the licensee's Radiation Safety Committee.

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- D. Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.
- E. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.
- F. Licensed material listed in Subitem Nos. R. and S. of Items 6., 7., 8., and 9. shall be used by or under the supervision of an authorized user named in Condition No. 11., and in the physical presence of an authorized user named in Condition No. 11. or an Authorized Medical Physicist. The authorized user named in Condition No. 11. shall consult with an Authorized Medical Physicist and an interventional cardiologist prior to each treatment.
12. The Radiation Safety Officer for the activities authorized by this license is Robert F. Turco, Ph.D.
13. 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. 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.
- D. 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.
- E. 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.
- F. 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.

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- G. 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.
14. Sealed sources containing licensed material shall not be opened or removed from their respective source holders by the licensee.
15. 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. 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.
- B. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
- C. A record of each disposal permitted under this license 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.
16. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
17. In addition to the possession limits in Subitem Nos. 8.D. and 8.E., 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.
18. In lieu of 10 CFR 35.404(b) immediately after retracting the source from the patient into its shielded position in the Novoste Model A1000 Series System and/or the Guidant Galileo Radiotherapy System, a radiation survey shall be made of the patient and the Novoste Model A1000 Series System and/or the Guidant Galileo Radiotherapy System, with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(c).
19. In lieu of the source inventory required in 10 CFR 35.406, the licensee shall:
- A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each Novoste Model A1000 Series System and/or the Guidant Galileo Radiotherapy System treatment.
- B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.
- C. Make a record of the survey including the survey instrument used, dose rate expressed in mrem/hr (μ Sieverts/hr), time, date and name of the individual making the survey.

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- D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(c).
20. A. The licensee shall comply with the requirements for "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern" (IC) (Accession No. ML053130364) as Attachment B to the "Order Imposing Increased Controls" (ADAMS Accession No. ML053130218) published in the Federal Register on December 1, 2005 (70 FR 72128); and with the "Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Materials" (Fingerprinting Order) (ADAMS Accession No. ML073230831) published in the Federal Register on December 13, 2007 (72 FR 70901).
- B. The licensee shall complete implementation of the said requirements by the first day that radionuclides in quantities of concern are possessed at or above the limits specified in "Table 1: Radionuclides of Concern" contained within the Fingerprinting Order (ADAMS Accession No. ML080160582).
- C. Notwithstanding any provisions of the Commission's regulations to the contrary, all measures implemented or actions taken in response to these Orders shall be maintained until the Commission orders otherwise or until the Commission explicitly modifies its regulations to reflect the increased controls and fingerprinting requirements, and states in modifying its regulations that the revisions are to supersede these Orders.
- D. The licensee shall notify the Director, Office of Federal and State Materials and Environmental Management Programs, U.S. NRC, Washington, DC, 20555, in writing, within 25 days after it has completed the requirements of this condition. In addition, licensee responses applicable to this license condition shall be marked as "Security-Related Information - Withhold Under 10 CFR 2.390."

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21. 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 November 21, 2001; and

B. Letters dated March 2, 1992, May 14, 1992, February 24, 1994, June 21, 1994, May 31, 2002, June 19, 2002 (BCC), July 10, 2002 (BCC), September 30, 2002, June 27, 2003, November 6, 2003 (BCC), November 10, 2003, January 22, 2004 (BCC), March 26, 2004, June 25, 2004, September 29, 2004, December 7, 2005, January 12, 2007 (BCC), February 15, 2007 (BCC), and March 6, 2007 (BCC), October 8, 2007, December 19, 2007, May 16, 2008, and June 6, 2008, July 1, 2008, July 7, 2008, November 7, 2008, October 15, 2008, November 25, 2008, and January 21, 2009 (with facility diagram); and

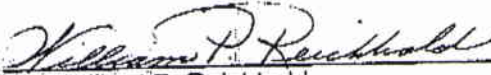
C. Facsimiles dated August 5, 2002 (excluding the Quality Management Program), December 5, 2002, August 7, 2003, August 28, 2003, August 29, 2003, October 30, 2008, and January 21, 2009.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

APR 01 2009

By


 William P. Reichhold
 Materials Licensing Branch
 Region III

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Attachment B



SAINT LOUIS UNIVERSITY NUCLEAR MEDICINE – HUMAN USE ONLY RADIOACTIVE MATERIALS PERMIT



Updated: December 2, 2008

This permit is hereby issued, authorizing the named individual(s) to receive, possess, and transfer the radioactive materials listed below. This permit is subject to all applicable rules and regulations of federal, state, and local governments including the Nuclear Regulatory Commission (NRC), the Occupational Safety & Health Administration (OSHA), the Environmental Protection Agency (EPA), the Department Of Transportation (DOT), the State of Missouri, and the City of St. Louis. Furthermore, the procurement, storage, use and disposal of the radioactive materials obtained under this permit must conform to the policies and procedures of the University, as defined by the Radiation Safety Committee in the Saint Louis University Radiation Safety Manual. Copies of the aforementioned documents are kept on file in the Radiation Safety Office. A copy of the Saint Louis University Radiation Safety Manual must be located in the Nuclear Medicine Department. This permit must be posted in the Nuclear Medicine Department.

APPROVED RADIONUCLIDES AND PROCEDURES	AUTHORIZED USERS (Pager Numbers)					
Authorized Radionuclides	Maximum Possession Limit					
1. Any byproduct material specified in:						
a. 10CFR35.100	As needed					
b. 10CFR35.200	As needed					
c. 10CFR35.300	As needed					
d. 10CFR35.500	As needed					
2. Any accelerator produced radionuclides to be used in radiopharmaceuticals or sealed sources, consistent with the purposes specified in 10CFR35.100, 10CFR35.200, 10CFR35.300, 10CFR35.500, provided that they are listed on the most recent Missouri Department of Health Registration of Radioactive Material, and do not exceed the possession limits specified thereon. Specifically excluded are Radium-226 and Uranium-238, both naturally occurring radionuclides listed on the state registration.						
3. Rhenium-186 labeled monoclonal antibodies	2 Ci					
4. Sealed sources for calibration or quality control						
a. Cs-137	2 mCi					
b. Ba-133	2 mCi					
c. Co-57	25 mCi					
FULL APPROVAL for All Nuclear Medicine & PET Imaging Procedures <i>(see all radionuclides and procedure list above & below)</i>	✓	✓	✓	✓	✓	✓
Nuclear Cardiology Studies under 10CFR35.200						
Category A Procedures – (see below)						
1. Ventilation/Perfusion Lung Scans	✓	✓	✓			✓
2. Tagged RBC scans for localization of Gastrointestinal bleeding	✓	✓	✓			✓
3. Hepatobiliary imaging for assessment of biliary obstruction, acute cholecystitis and biliary leakage	✓	✓	✓			✓
4. Spot and whole body bone scans for determination of metastatic disease or assessment of fractures	✓	✓	✓			✓
Category B Procedures – (see below)						
1. Renograms without pharmacologic intervention for the assessment of renal perfusion and function	✓	✓	✓			
2. Renograms with diuretic intervention for the assessment of urinary obstruction	✓	✓	✓			
3. 3-phase bone scans for the determination of osteomyelitis, toxic synovitis, reflex sympathetic dystrophy and acute fracture	✓	✓	✓			
4. Infection localization with In-111 labeled WBCs.	✓	✓	✓			
5. Cerebral perfusion studies for the diagnosis of 'brain death'	✓	✓	✓			
6. Localization of a Meckel's diverticulum	✓	✓	✓			
7. Renal transplant assessment with 99m-Tc sulphur colloid and 99m-Tc MAG3	✓	✓	✓			
8. Pancreas transplant evaluation with 99m-Tc MAG3	✓	✓	✓			
9. Liver spleen scan for organomegaly and metastatic disease	✓	✓	✓			
Category C Procedures – (see below)						
1. SPECT Cerebral perfusion studies for localization of seizure foci	✓	✓	✓			
2. In-111 Pentatriotide tumor localization studies	✓	✓	✓			
3. SPECT bone scans	✓	✓	✓			
4. Testicular scans	✓	✓	✓			
5. Gastric emptying studies	✓	✓	✓			
6. Gastroesophageal reflux studies	✓	✓	✓			
7. Nuclear Cystograms	✓	✓	✓			
8. Static planar renal scans for scar localization	✓	✓	✓			
9. MIBG tumor imaging studies	✓	✓	✓			
10. I-131 whole body thyroid malignancy scans	✓	✓	✓			
11. Thyroid Uptakes	✓	✓	✓			
12. Thyroid scans	✓	✓	✓			
13. RBC blood volume determinations	✓	✓	✓			
14. Schilling's Tests	✓	✓	✓			
15. Gallium tumor or infection imaging	✓	✓	✓			
16. Nuclear Cisternograms	✓	✓	✓			
17. Lymphoscintigraphies	✓	✓	✓			
18. Parathyroid imaging	✓	✓	✓			
19. Renograms with enalaprilat intervention for diagnosis of renal artery stenosis	✓	✓	✓			
20. Hepatobiliary imaging studies with cholecystokinin intervention for diagnosis of biliary dyskinesia	✓	✓	✓			
21. Hemangioma localization	✓	✓	✓			

Paul M. Lawrence

(Radiation Safety Committee Chairman)

December 2, 2008

(RSC Approval Date)

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> <ol style="list-style-type: none"> Saint Louis University Radiation Safety Office 1402 South Grand Blvd. St. Louis, MO 63104 	<p>In accordance with the letter dated July 9, 2008,</p> <ol style="list-style-type: none"> License number 24-00196-07 is amended in its entirety to read as follows: Expiration date June 30, 2013 Docket No. 030-11789 Reference No.
--	---

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material identified in 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any	C. As needed
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source permitted by 10 CFR 35.400	D. As needed
E. Any byproduct material identified in 10 CFR 35.500	E. Any sealed source permitted by 10 CFR 35.500	E. As needed
F. Any byproduct material identified in 10 CFR 31.11	F. Prepackaged	F. As needed

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G. Any byproduct material with atomic number 1-83, inclusive, with a half life of 120 days or less

G. Any

G. 3 curies each, with a total of 30 curies except as noted below:

- Chromium-51 5 curies
- Iodine-125 5 curies
- Iodine-131 5 curies
- Phosphorus-31 5 curies
- Sulfur-35 5 curies

H. Any byproduct material with atomic number 1-83, inclusive, with a half life of 120 days or less

H. Any

H. Not to exceed $10^5 \times 10$ CFR Part 30 Appendix B limits for each radionuclide. Total possession not to exceed $R/10^5$, where $R/10^5$ is less than or equal to 1, and R is the sum of the ratios of the quantity of each radionuclide to the applicable value in 10 CFR Part 30 Appendix B.

I. Any byproduct material with atomic number 1-83, inclusive

I. Sealed sources (registered pursuant to Section 32.210 of CFR Part 32 or an Agreement with State)

No single source to exceed 2 curies. Total possession not to exceed 20 curies.

J. Hydrogen-3

J. Any

40 curies

K. Carbon-14

K. Any

K. 10 curies

L. Americium-241

L. Sealed source

L. 1 millicurie

M. Polonium-210

M. Sealed source

M. 10 millicuries

N. Iridium-192 permitted by 10 CFR 35.600

N. Sealed source (BYK Mallinckrodt Model CI L BV)

N. No single source to exceed 12 curies. Total possession not to exceed 24 curies.

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O. Cesium-137

O. Sealed source (ORIS/CBI Model CSL-15)

O. Total possession not to exceed 5,610 curies

P. Iridium-192 permitted by 10 CFR 35.600

P. Sealed sources (Nucletron Model No. 096.001, manufactured by Mallinckrodt Medical BV or AEA Technology, Inc., or Alpha-Omega Services, Inc. Model No. CSN0010-192)

P. 2 sources, 1 source not to exceed 12 curies, and 1 source not to exceed 10 curies.

9. Authorized Use:

A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100.

B. Any imaging and localization study permitted in 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. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(c).

F. In vitro studies

G. through M. Medical diagnosis, therapy and research in humans in accordance with any applicable U.S. Food and Drug Administration (FDA) requirements. Research and development as defined in Section 30.4 of 10 CFR Part 30, including animal studies, instrument calibration, student instruction and in vitro studies.

N. and B. One source to be used in for interstitial, intracavitary, or bronchial therapy. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

O. To be used in a C.I.S.-U.S. Model IBL-437C irradiator for the irradiation of blood, blood products, and other biological and non-biological materials (excluding flammable materials and explosives).

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CONDITIONS

10. A. Licensed material shall be used at the licensee's facilities bounded by Olive Boulevard on the north, Shaw Avenue on the south, Compton Avenue on the east, and 39th Street on the west, St. Louis, Missouri.
- B. Licensed material may be used at Reis Biological Station, HC87, Box 7525, Steelville, Missouri.
- C. Licensed material listed in Subitems 6.A. through 6.C. and 6.E. may also be used at 3635 Vista Avenue, 2nd Floor South, Nuclear Medicine, St. Louis, Missouri.
- D. Licensed material listed in Subitems 6.G. and 6.H. may also be used at St. Mary's Health Center-West Pavilion, 1027 Bellevue Avenue, St. Louis, Missouri.
- E. Licensed material listed in Subitems 6.A, 6.B. (excluding generators), 6.C., 6.E., 6.G., and 6.H. may be used at University Club Tower, 1034 South Brentwood Blvd., Suite 1120, St. Louis, Missouri.
11. A. The use of licensed material in or on humans shall be by an authorized user as defined in 10 CFR 35.2.
- B. 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 Part 35, and shall be designated, in writing, by the licensee's Radiation Safety Committee.
- C. Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.
12. 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.
- 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

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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.

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.
- 13. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
- 14. Experimental animals administered licensed materials or their products shall not be used for human consumption.
- 15. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
- 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.
- 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 that prevents the foil temperature from exceeding that specified in the certificate of registration issued by NRC pursuant to 10 CFR 32.210 or the equivalent regulations from an Agreement State.
 - B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

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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."
20. 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.
21. In addition to the possession limits in item 1, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.
22. A. The licensee shall comply with the requirements for "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern" (IC) (Accession No. ML05313036) as Attachment B to the "Order Imposing Increased Controls" (ADAMS Accession No. ML053130218) published in the Federal Register on December 1, 2005 (70 FR 72128); and with the "Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Materials" (Fingerprinting Order) (ADAMS Accession No. ML073230831) published in the Federal Register on December 13, 2007 (72 FR 70901).
- B. The licensee shall complete implementation of the said requirements by the first day that radionuclides in quantities of concern are possessed at or above the limits specified in "Table 1: Radionuclides of Concern" contained within the Fingerprinting Order (ADAMS Accession No. ML080160582).

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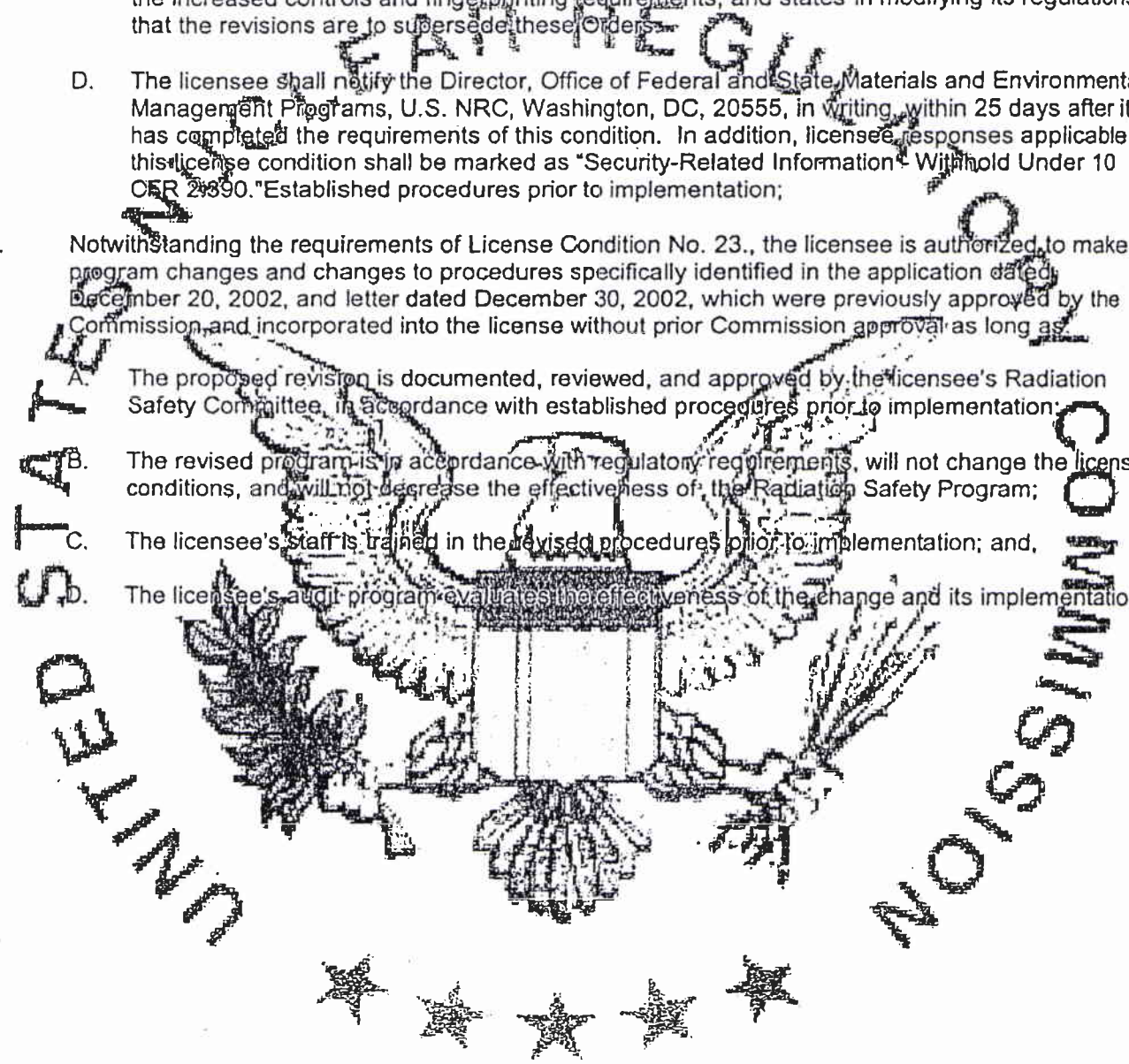
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- C. Notwithstanding any provisions of the Commission's regulations to the contrary, all measures implemented or actions taken in response to these Orders shall be maintained until the Commission orders otherwise or until the Commission explicitly modifies its regulations to reflect the increased controls and fingerprinting requirements, and states in modifying its regulations that the revisions are to supersede these Orders.
 - D. The licensee shall notify the Director, Office of Federal and State Materials and Environmental Management Programs, U.S. NRC, Washington, DC, 20555, in writing, within 25 days after it has completed the requirements of this condition. In addition, licensee responses applicable to this license condition shall be marked as "Security-Related Information - Withhold Under 10 CFR 23.90." Established procedures prior to implementation;
23. Notwithstanding the requirements of License Condition No. 23., the licensee is authorized to make program changes and changes to procedures specifically identified in the application dated December 20, 2002, and letter dated December 30, 2002, which were previously approved by the Commission and incorporated into the license without prior Commission approval as long as:
- A. The proposed revision is documented, reviewed, and approved by the licensee's Radiation Safety Committee, in accordance with established procedures prior to implementation;
 - B. The revised program is in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program;
 - C. The licensee's staff is trained in the revised procedures prior to implementation; and,
 - D. The licensee's audit program evaluates the effectiveness of the change and its implementation.



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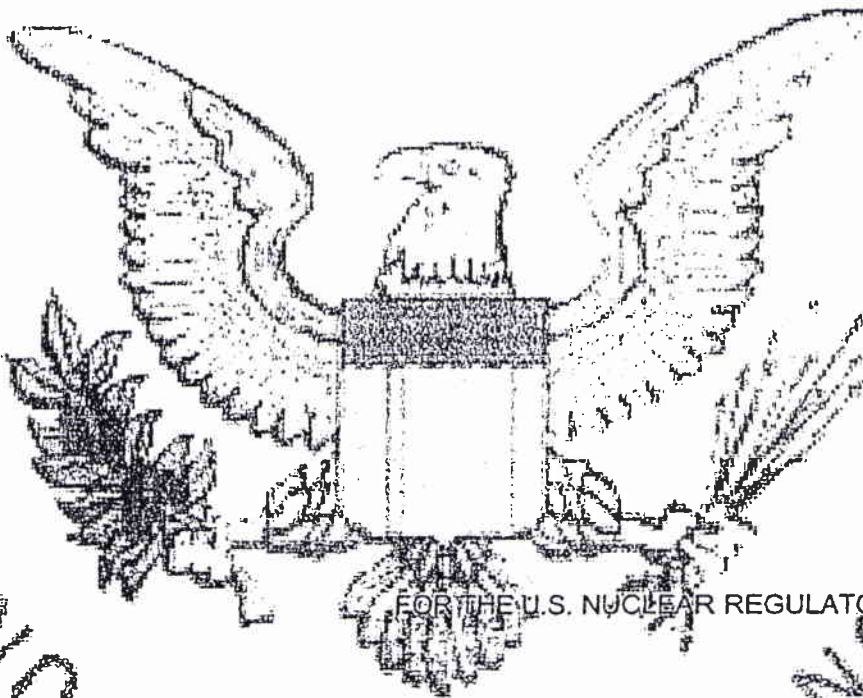
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22. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies 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 December 20, 2002; and

B. Letters dated December 30, 2002, June 17, 2003, October 31, 2005, January 13, 2006, and letter dated July 9, 2008

UNITED STATES



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date SEP 26 2008

BY

George M. McCann

George M. McCann
Decommissioning Branch
Region III

Attachment C

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Amendment No. 09

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.

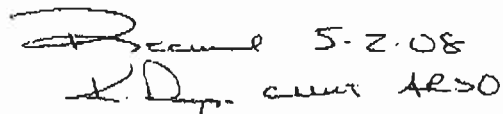
Licensee 1. Barnes-Jewish West County Hospital 2. 12634 Olive Blvd St. Louis, MO 63141	In accordance with letter dated February 25, 2008, and facsimile dated April 23, 2008, 3. License number 24-26243-01 is amended in its entirety to read as follows: 4. Expiration date May 31, 2011 5. Docket No. 030-31901 Reference No.
---	---

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 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

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.

CONDITIONS

- 10. Location of Use: 12634 Olive Blvd., St. Louis, Missouri.
- 11. Radiation Safety Officer: John J. Chorzel, M.S.
- 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. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:


 Received 5-2-08
 K. Dep. cum ALSO

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Authorized UsersMaterial and Use

Robert Gordon Levitt, M.D.	10 CFR 35.100 and 35.200.
William B. Dawson, M.D.	10 CFR 35.100 and 35.200.
Mary Middleton, M.D.	10 CFR 35.100 and 35.200.
Victor Davila-Roman, M.D.	10 CFR 35.200.
Farrokh Dehdashti, M.D.	10 CFR 35.100, 35.200.
Keith C. Fischer, M.D.	10 CFR 35.100 and 35.200.
Robert J. Gropler, M.D.	10 CFR 35.200.
Mark A. Mintun, M.D.	10 CFR 35.100 and 35.200.
Henry D. Royal, M.D.	10 CFR 35.100 and 35.200.
→ Barry A. Siegel, M.D.	10 CFR 35.100 and 35.200.
Wade L. Thorstad, M.D.	10 CFR 35.100 and 35.200.
→ Jerold W. Wallis, M.D.	10 CFR 35.100 and 35.200.
Delphine Chen, M.D.	10 CFR 35.100 and 35.200.
Bennett Greenspan, M.D.	10 CFR 35.100 and 35.200.
Akash Sharma, M.D.	10 CFR 35.100 and 35.200.
William James, M.D.	10 CFR 35.100 and 35.200.

13. The licensee shall limit the use of xenon-133 to the nuclear medicine procedure room number 2243.
14. 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.
15. 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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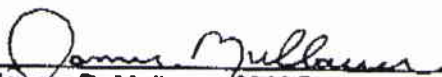
16. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are 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 received November 30, 2000; and
- B. Facsimile dated May 7, 2001.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

APR 30 2008

By


James R. Mullauer, M.H.S.
Materials Licensing Branch
Region III

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