

# Research Medical Center<sup>SM</sup>

Your HCA Midwest Hospital

2 February 2010

U. S. Nuclear Regulatory Commission  
Region III  
Materials Licensing Section  
2443 Warrensville Road, Suite 210  
Lisle, Illinois 60532-4352

Re: Change in authorized users.

Research Medical Center would like to make the following changes in authorized users under license number 24-18625-01.

1. Deletion of James E. Sear, M. D.

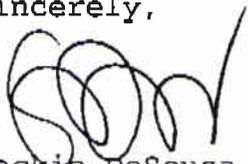
Please delete James E. Sear, M. D., from our list of authorized users. He has permanently ceased to practice at this hospital.

2. Addition of 10 CFR 35.300 uses for Kevin L. Litwin, M. D.

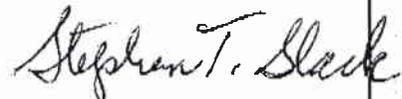
Please add 10 CFR 35.300 uses to those approved for Kevin L. Litwin, M. D. Dr. Litwin is already listed on our license for 35.100 and 35.200 uses. He is currently listed on the license of St. Luke's Hospital of Kansas City, a broad scope medical license, license number 24-00889-01, for use of 35.100, 35.200 and 35.300 at St. Luke's East. A copy of their license with an attachment for users at St. Luke's East is included.

Should you need further information, please feel free to contact us at (816) 276-4449.

Sincerely,



Jackie DeSouza,  
Chief Executive Officer



Stephen T. Slack, Ph. D.  
Radiation Safety Officer

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**U.S. NUCLEAR REGULATORY COMMISSION**

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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 1. St. Luke's Hospital of Kansas City 2. 4401 Wornall Road Kansas City, MO 64111		In accordance with letters dated July 22, 2009, and August 10, 2009, 3. License number 24-00889-01 is amended in its entirety to read as follows: 4. Expiration date July 31, 2012 5. Docket No. 030-02286/030-34167/030-83080 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	
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. As needed not to exceed one curie of iodine-131	
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed sources	D. Not to exceed two curies of cesium-137; two curies of iridium-192; and two curies of iodine-125	
E. Any byproduct material permitted by 10 CFR 35.500	E. Sealed sources (North American Scientific, Inc. Model MED 36Q1 or DuPont Merck Pharmaceutical Company Model NES-8412 or Isotope Products Lab, Inc. Model A3410)	E. Five curies	
F. Cesium-137	F. Sealed source (International CIS Model No. CEA-ORIS-LAPIB Model 437C)	F. 5,100 curies total (3 sources not to exceed 1,700 curies each)	
G. Any byproduct material with Atomic Numbers between 1 through 83, inclusive	G. Any	G. Not to exceed 3 curies per isotope, 6 curies total	

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6. Byproduct, source, and/or special nuclear material

**H. Iridium-192 as permitted by 10 CFR 35.600**

7. Chemical and/or physical form

**H. Sealed sources (Varian Medical Systems Model VS2000)**

8. Maximum amount that licensee may possess at any one time under this license

**H. Two sources not to exceed 21 curies total**

9. Authorized Use:

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

B. Any imaging and localization procedure approved in 10 CFR 35.200.

C. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300.

D. Any manual brachytherapy procedure approved in 10 CFR 35.400.

E. Medical use of sealed sources included in 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).

F. For use in an International CIS Model IBL-437C irradiator for the irradiation of blood, blood products, cells, tissues and research samples, excluding explosives or highly flammable materials.

G. Medical use as defined in 10 CFR 30.4 and 35.2 and research and development as defined in 10 CFR 30.4, excluding animal studies.

H. One source for medical use permitted by 10 CFR 35.600 in a Varian - TEM Ltd. Model VariSource HDR Remote afterloader unit. Physics calibrations and quality assurance testing are also permitted. The source activity may not exceed 11 curies at the time of installation. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.

CONDITIONS

10. A. Licensed material listed in Subitems A. through H. shall be used at St. Luke's Hospital of Kansas City, 4401 Wornall Road, Kansas City, Missouri.

B. Licensed material listed in Subitems 6.A., 6.B. and 6.C. may be used at Medical Plaza III Building, 4321 Washington Street, Kansas City, Missouri; St. Luke's Northland Hospital, Barry Road Campus, 5830 N.W. Barry Road, Kansas City, Missouri; and at Saint Luke's East - Lee's Summit, 100 N.E. Saint Luke's Boulevard, Lee's Summit, Missouri.

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- C. Licensed material listed in Subitem No. 6.B. may be received, possessed, used and stored at temporary job sites, anywhere the U.S. Nuclear Regulatory Commission maintains jurisdiction, in the licensee's mobile van, in accordance with the letter dated March 26, 2009.
11. A. Individuals designated to work as authorized users as defined in 10 CFR 35.2, shall meet the training, experience, and recentness of training criteria established in 10 CFR Part 35, and shall be designated, in writing, by the licensee's Radiation Safety Committee.
- B. The Radiation Safety Officer for this license is Gregory D. Sackett, M.S.
- C. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.
- D. Physicians, dentists, or podiatrists designated to use licensed material in or on humans shall meet the training criteria established in 10 CFR 35 and shall be designated by the licensee's Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.
- E. Individuals designated to work as medical physicists for high dose rate (HDR) brachytherapy shall meet the training and experience criteria established in 10 CFR 35.51 or be named on a current U.S. Nuclear Regulatory Commission or Agreement State license or a permit issued under a broad scope license as a medical physicist for HDR brachytherapy and shall be designated, in writing, by the Radiation Safety Committee. In addition, the physicist must meet the recentness of training requirement in 10 CFR 35.59 and have recent device-specific training and experience for each make and model of HDR brachytherapy device used by the licensee.
12. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
- A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.
- B. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- C. Sealed sources need not be leak tested if:
- (i) they contain only hydrogen-3; or
  - (ii) they contain only a radioactive gas; or
  - (iii) the half-life of the isotope is 30 days or less; or
  - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

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- (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or 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 or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- D. 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 for inspection by the Commission. Records may be disposed of following Commission inspection.
- E. 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.
13. 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.
14. The procedures contained in the International CIS instruction manual for the Model IBL-437C device shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.
15. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed pursuant.
16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
17. 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 ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate meter 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.
- B. A record of each 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.

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18. 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.
19. In addition to the possession limits in Item 8, 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.
20. Notwithstanding the requirements of License Condition 22, the licensee is authorized to make program changes and changes to procedures specifically identified in applications dated November 14, 1994, July 17, 1998, and January 29, 2002; and letters dated June 13, 1996, June 14, 1996, July 18, 1996, July 31, 1996, January 2, 1997, January 27, 1997, August 19, 1997, October 6, 1997, December 16, 1998, December 21, 1998, August 26, 1999 and January 24, 2000 (with attachment), 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 the implementation.
  - D. The licensee's audit program evaluates the effectiveness of the change and its implementation.
21. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive 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. 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).

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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 2.390."

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 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. Applications dated November 14, 1994, July 17, 1998, January 29, 2002, December 1, 2004 (excluding requests to add Roy Sions as Assistant RSO; delete locations of use at Dickson-Diveley Laboratory, 4312 J.C. Nichols Parkway, Kansas City, Missouri and Medical Plaza I Building, 4320 Womall Road, Kansas City, Missouri; all references to "Site-specific Radiation Safety Committees" including, but not limited to, the naming of authorized users by site-specific Radiation Safety Committees; restriction to not permit iodine-131 treatment of thyroid carcinoma at St. Luke's Northland Hospital; and references to incorporate letters dated May 15, 2001, and November 11, 2003, into this license) and March 2, 2005; and,

B. Letters dated June 13, 1996, June 14, 1996, July 18, 1996, July 31, 1996, January 2, 1997, January 27, 1997, August 19, 1997, October 6, 1997, December 16, 1998, December 21, 1998, August 26, 1999, January 24, 2000 (with attachment), October 21, 2003, December 1, 2004, March 3, 2005, April 8, 2005, May 16, 2005, August 17, 2005, April 5, 2006, and March 26, 2009; and,

C. Facsimiles dated June 30, 2005, and September 7, 2005.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

OCT 23 2009

Date \_\_\_\_\_

By

*Colleen Carol Casey*

Colleen Carol Casey  
Materials Licensing Branch  
Region III

**Attachment 2:  
Saint Luke's East Authorized User List  
NRC License #24-00889-01**

Date of Review: 3/1/2008

AUTHORIZED USER	AUTHORIZED USE											
	10 CFR 35 Part 100	10 CFR 35 Part 200	10 CFR 35 Part 300	10 CFR 35 Part 400	10 CFR 35 Part 500	10 CFR 35 Part 600	10 CFR 35 Part 1000	Medical Physicist	Blood Irradiator	Research Laboratory	Human Research	RSO
Delgado, Pablo M.D.	[Pending]	[Pending]	[Pending]									
Gubin, Berry M.D.	Yes <sup>1</sup>	Yes <sup>1</sup>	Yes <sup>1</sup>									
Kunkin, Jeffrey M.D.	[Inactive]	[Inactive]	[Inactive]									
Litwin, Kevin M.D.	Yes <sup>1</sup>	Yes <sup>1</sup>	Yes <sup>1</sup>									

- 1 Approved by Saint Luke's Hospital RSC
- 2 For Cardiovascular Clinical Procedures
- 3 Approved by NRC Region III prior to Broad Scope License
- 4 For Intravascular Brachytherapy Procedures
- 5 For GliaSite Procedures
- 6 For HDR
- 7 For 35.398 Y-90 SirSpheres Only
- 8 Gadolinium-153 in VANTAGE device
- 9 For 35.394 I-131 > 33mCi
- 10 For Sentinel Node Only

# Midwest Gamma Knife Center

## Research Medical Center

### FAX Cover Sheet

**TO: U. S. Nuclear Regulatory Commission  
Materials Licensing Section**

**From: Stephen T. Slack, Radiation Safety Officer, Research Medical Center**

**Return FAX number: (816) 276-3478**

**Date: 4 February 2010**

**Message: Please file this license amendment request.**

**We have not received acknowledgements of our last two license amendment requests. Please acknowledge with attention: Stephen Slack.**