

June 23, 2011

U.S. Nuclear Regulatory Commission, Region III
Materials Licensing Branch
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

RE: Amendment Request

LICENSEE: Centerpoint Medical Center of Independence, LLC
(d/b/a Centerpoint Medical Center)
NRC License No. 24-18655-01

To Whom It May Concern,

We wish to amend NRC License No. 24-18655-01 in the following ways:

1. Add the following Authorized Users:

Authorized User	Uses
Robert G. Schwegler, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
John E. Scott, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
William M. Chase, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
Craig M. Bruner, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
Douglas W. Nemmers, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
Michael B. Parsa, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
Jeffrey R. Conaway, M.D.	10 CFR 35.100, 35.200 and 35.300
John F. Eurich, M.D.	10 CFR 35.100, 35.200 and 35.300
William Brooks, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
Kelly Hart, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
Rick Moritz, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
Thomas Zinn, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
Sarah L. Sherard, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
Donald J. Stallard, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
Bradley McInay, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
Vandana Halder, M.D.	10 CFR 35.100, 35.200 and 35.300
Leo J. Splitter, M.D.	10 CFR 35.100, 35.200 and 35.300
Craig B. McClure, M.D.	10 CFR 35.100 and 35.200
Robert A. Wood, Jr., M.D.	10 CFR 35.100, 35.200 and 35.300
Joseph Philip Koury, M.D.	10 CFR 35.100 and 35.200
Jason Eric Himmel, M.D.	10 CFR 35.100, 35.200 and 35.300 (limited to sodium iodide iodine-131 in quantities less than or equal to 33 millicuries)
Michael J. Brigg, M.D.	10 CFR 35.100, 35.200 and 35.300 (limited to the use of sodium iodide iodine-131)
Nathaniel R. Jewell, M.D.	10 CFR 35.100, 35.200 and 35.300 (limited to the use of sodium iodide iodine-131)

Imaging Services

RECEIVED JUL 06 2011

All of the above physicians are listed as authorized users on NRC Radioactive Materials License Number 24-24660-01. A copy is enclosed.

Authorized User	Uses
Susan Chow, M.D.	10 CFR 35.100, 35.200 and 35.300
Michael B. Robertson, M.D.	10 CFR 35.100, 35.200 and 35.300 (limited to the use of sodium iodide iodine-131)

The two physicians above are listed as authorized users on The State of Kansas Radioactive Materials License number 19-B703-01. A copy is enclosed.

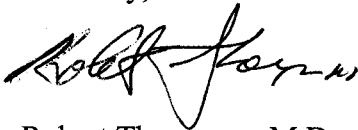
We also wish to add Aaron Lewis, M.D. as an authorized user for 10 CFR 35.100, 35.200 and 35.300 (for iodine-131, limited to the oral administration of sodium iodide iodine - 131 in quantities less than, equal to or greater than 33 millicuries). A copy of Dr. Lewis' Authorized User Training and Experience and Preceptor Attestation is enclosed.

2. Remove the following Authorized Users as of July 1, 2011:

Stephen R. Kunz, M.D.
Gwendolyn Ramsey Arnett, M.D.
Mark J. Lavin, M.D.
Kenneth M. Alfieri, M.D.
Matthew R. Caterine, M.D.
Dipak Shah, M.D.
Ramesh Avva, M.D.
Ira Cox, M.D.

We appreciate the help of the NRC in this matter.

Sincerely,



Robert Thompson, M.D.
Radiation Safety Officer

Enclosures

U.S. NUCLEAR REGULATORY COMMISSION

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 style="text-align: center;">Licensee</p> <p>1. Midwest Division - LSH, LLC (d/b/a Lee's Summit Hospital)</p> <p>2. 2100 S.E. Blue Parkway Lee's Summit, MO 64063</p>	<p>In accordance with the letter dated December 17, 2010,</p> <p>3. License number 24-24660-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date October 31, 2011</p> <hr/> <p>5. Docket No. 030-29074 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 31.11</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Prepackaged Kits</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 one curie of iodine-131)</p> <p>D. 2 millicuries</p>
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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. In vitro studies.

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 2100 S.E. Blue Parkway, Lee's Summit, Missouri.
- 11. The Radiation Safety Officer for this license is John E. Scott, M.D.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
24-24660-01

Docket or Reference Number
030-29074

Amendment No. 25

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 the materials and uses indicated:

Authorized Users

Material and Use

Robert G. Schwegler, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
John E. Scott, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
William M. Chase, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
Craig M. Bruner, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
Douglas W. Nemmers, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
Michael B. Parsa, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
Jeffrey R. Conaway, M.D.	10 CFR 35.100, 35.200 and 35.300.
John F. Eurich, M.D.	10 CFR 35.100, 35.200 and 35.300.
William Brooks, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
Ira Cox, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
Kelly Hart, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
Rick Moritz, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
Thomas Zinn, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
William B. Davis, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
Sarah L. Sherard, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
Donald J. Stallard, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
Daniel H. Dunker, M.D.	10 CFR 35.200.
James E. Sear, M.D.	10 CFR 35.200.
Michael Brian Robertson, M.D.	10 CFR 31.11.
Bradley McInay, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
Vandana Halder, M.D.	10 CFR 35.100, 35.200 and 35.300.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
24-24660-01

Docket or Reference Number
030-29074

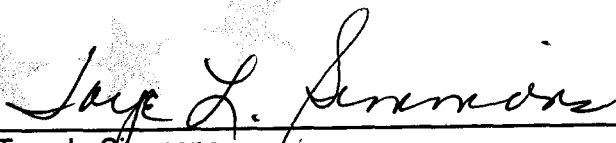
Amendment No. 25

Leo J. Splitter, M.D.	10 CFR 35.100, 35.200 and 35.300.
Craig B. McClure, M.D.	10 CFR 35.100 and 35.200.
Robert A. Wood, Jr., M.D.	10 CFR 35.100, 35.200 and 35.300.
Joseph Philip Koury, M.D.	10 CFR 35.100 and 35.200.
Wendall Doronio, M.D.	10 CFR 35.100, 35.200 and 35.300 (limited to sodium iodide iodine-131 in quantities less than or equal to 33 millicuries).
Jason Eric Himmel, M.D.	10 CFR 35.100, 35.200 and 35.300 (limited to sodium iodide iodine-131 in quantities less than or equal to 33 millicuries).
Michael J. Brigg, M.D.	10 CFR 35.100, 35.200 and 35.300 (limited to the use of sodium iodide iodine-131).
Nathaniel R. Jewell, M.D.	10 CFR 35.100, 35.200 and 35.300 (limited to the use of sodium iodide iodine-131).

13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
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. 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 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 April 6, 2001 (with attachments); and
- B. Letters dated March 26, 2003, April 15, 2003 (with enclosure), November 18, 2008, and February 17, 2009 (with enclosed close-out survey).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

By


Toye L. Simmons
Materials Licensing Branch
Region III

Date FEB 03 2011

State of Kansas

Radioactive Materials License

Pursuant to the Nuclear Development and Radiation Control Act (L. 1963, Ch. 290) and Kansas Annotated Regulations numbers 28-35-133 et. seq., and in reliance on statements and representations made to this agency by the licensee designated below, a license is hereby issued authorizing the licensee to transfer, receive, possess, and use the radioactive material or materials listed below; and to use such materials at the place or places listed below; and to use the material for the purpose or purposes listed below. This license is subject to all applicable rules, regulations, and orders now in effect or placed in effect by the Department of Health and Environment and any conditions specified below.

Amendment No. 27

<p style="text-align: center;">Licensee</p> <p>1. Name MIDWEST DIVISION - MMC, LLC d.b.a MENORAH MEDICAL CENTER</p> <p>2. Address 5721 W 119TH ST OVERLAND PARK, KS 66209</p>	<p>3. License Number 19-B703-01</p> <p>4. Expiration Date December 31, 2015</p> <p>5. Reference Number</p>
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6. Radioactive Material (Element and Mass Number)	7. Chemical and/or Physical Form	8. Maximum Quantity Licensee May Possess at One Time
A. Any radioactive material permitted by 10 CFR 35.100 as adopted by reference in K.A.R. 28-35-264	A. Unsealed: Any radioactive material prepared for medical use permitted by 10 CFR 35.100 as adopted by reference in K.A.R. 28-35-264	A. As necessary for uses authorized in subitem 9(A).
B. Any radioactive material permitted by 10 CFR 35.200 as adopted by reference in K.A.R. 28-35-264	B. Unsealed: Any radioactive material prepared for medical use permitted by 10 CFR 35.200 as adopted by reference in K.A.R. 28-35-264	B. As necessary for uses authorized in subitem 9(B).
C. Any radioactive material permitted by 10 CFR 35.300 as adopted by reference in K.A.R. 28-35-264	C. Unsealed: Any radioactive material prepared for medical use permitted by 10 CFR 35.300 as adopted by reference in K.A.R. 28-35-264	C. As necessary for uses authorized in subitem 9(C). 750 millicuries of each radioactive material authorized in Subitem 6.C.
D. Any radioactive material permitted by 10 CFR 35.400 as adopted by reference in K.A.R. 28-35-264	D. Sealed source(s): Any brachytherapy source permitted by 10 CFR 35.400 as adopted by reference in K.A.R. 28-35-264	D. As necessary for uses authorized in subitem 9(D). 1000 millicuries of gold-198, iodine-125, iridium-192, strontium-90 and palladium-103
E. Iridium-192	E. Sealed source(s): (Varian VS2000)	E. 20 Curie(s) total. No single source to exceed 13 Curie(s).

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Radioactive Materials License

Supplementary Sheet

License Number: 19-B703-01 Amendment No. 27

F. Any radioactive material	F. Sealed source(s): Any sealed source authorized by 10 CFR 35.65 or equivalent agreement state regulation.	F. 50 millicurie(s) total. No single source to exceed 30 millicurie(s). Limited to 50 millicuries of each radionuclide.
G. Gadolinium-153	G. Sealed source(s): (DuPont Models NES-8424; Isotope Products Model 301B)	G. 1000 millicurie(s) total. no single source to exceed 400 millicuries
H. Yttrium-90	H. Sealed source(s): Sirtex SIR-Spheres resin microspheres	H. 250 millicurie(s) total.
I. Iodine-131	I. Radiopharmaceutical: Sodium Iodide	I. 500 millicurie(s) total.
J. Yttrium-90	J. Radiopharmaceutical: Yttrium chloride	J. 200 millicurie(s) total.
K. Strontium-89	K. Radiopharmaceutical: Strontium chloride	K. 15 millicurie(s) total.
L. Samarium-153	L. Radiopharmaceutical: Lexidronam pentasodium	L. 200 millicurie(s) total.
M. Fluorine-18	M. Radiopharmaceutical: Fluorodeoxyglucose (FDG)	M. 1 Curie(s) total.
N. Fluorine-18	N. Unsealed: Fluorodeoxyglucose (FDG)	N. 50 millicurie(s) total.
O. Carbon-11	O. Radiopharmaceutical: Choline	O. 1 Curie(s) total.

CONDITIONS

9. Authorized use.
- A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100 as adopted by reference in K.A.R. 28-35-264.
 - B. Any imaging and localization study permitted by 10 CFR 35.200 as adopted by reference in K.A.R. 28-35-264.
 - C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300 as adopted by reference in K.A.R. 28-35-264.
 - D. Any manual brachytherapy procedure permitted by 10 CFR 35.400 as adopted by reference in K.A.R. 28-35-264.

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- E. To be used in a Varian Medical Systems VariSource High Dose Rate (HDR) remote afterloader for the treatment of cancer using a high dose rate. An authorized medical physicist and an authorized user shall be physically present during patient treatment.
- F. To be used for calibration, transmission, reference and quality control.
- G. To be used for bone mineral analysis
- H. To be used for the therapeutic treatment of unresectable metastatic liver tumors.
- I. To be used for the BEXXAR therapeutic regime involving the use of Tositumomab for the treatment of malignant human B lymphocytes.
- J. To be used as Zevalin (ibritumomab tiuxetan) for radioimmunotherapy of non-Hodgkin's lymphoma.
- K. To be used as Metastron for bone pain palliation.
- L. To be used as Quadramet for bone pain palliation.
- M. Diagnostic studies involving imaging or tumor localizations.**
- N. To be used for calibration, transmission, reference and quality control.**
- O. Diagnostic studies involving imaging or tumor localizations.**
10. Radioactive materials shall only be used at the following location(s):
MIDWEST DIVISION - MMC, LLC, 5721 W 119TH ST
OVERLAND PARK, KS 66209
11. The following shall be responsible for the licensee's radiation protection program
Scott Sorensen M.S. Radiation Safety Officer
William M. Chase M.D. Assistant Radiation Safety Officer
12. Radioactive material listed in Item 6 above is authorized for use by individuals for the materials and uses described as follows:
Radioactive material shall be used by or under the supervision of an individual listed below:
- | | |
|---------------------------|---|
| William Brooks M.D. | Subitem(s) A, B, C, F |
| Craig M. Bruner M.D. | Subitem(s) A, B, C, F |
| Matthew D. Callister M.D. | Subitem(s) D |
| William M. Chase M.D. | Subitem(s) A (except xenon-133), B, C, F, G |
| Susan Chow M.D. | Subitem(s) A, B, C, F |
| Jeffrey R. Conaway M.D. | Subitem(s) A, B, C, F, G |
| John Eurich M.D. | Subitem(s) A, B, C, F, G |
| Shalina Gupta-Burt M.D. | Subitem(s) I, J, K, L |
| Vandana Halder M.D. | Subitem(s) A, B, C, F, G |
| Kelly Hart M.D. | Subitem(s) A, B, C, F |

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Robyn M. Hart M.D.	Subitem(s) C, D, E
Jason E. Himmel M.D.	Subitem(s) A, B, C (iodine-131 only for which patient can be released pursuant to 10CFR35.75), F
Michael A. Hughes M.D.	Subitem(s) D, E
Nathaniel Jewell M.D.	Subitem(s) A, B, C (iodine-131 only)
Brad H. Koffman M.D.	Subitem(s) D, E, H
Bradley J. McIlany M.D.	Subitem(s) A, B, C, F
Rick Moritz M.D.	Subitem(s) A, B, C, F
Richard Morrison M.D.	Subitem(s) D
Douglas W. Nemmers M.D.	Subitem(s) A, B, C (except phosphours-32), F
Jorge C. Paradelo M.D.	Subitem(s) D, E
Michael B. Robertson M.D.	Subitem(s) A, B, C (iodine-131 only), F
Alan M. Schneider M.D.	Subitem(s) A, B, C (for which the patient can be released pursuant to 10 CFR 35.75), F, G
Robert G. Schwegler M.D.	Subitem(s) A (except xenon-133), B, C, F, G
John E. Scott M.D.	Subitem(s) A (except xenon-133), B, C, F, G
Sarah L. Sherard M.D.	Subitem(s) A, B, C, F
Michael S. Sokol M.D.	Subitem(s) C
Leo J. Spittler M.D.	Subitem(s) A, B, C, F
Donald Stallard M.D.	Subitem(s) A, B, C (for which the patient can be released pursuant to 10 CFR 35.75), F
Tom Zinn M.D.	Subitem(s) A, B, C, F

The individuals listed below may use radioactive materials in the capacity of an authorized medical physicist:

Marc Edwards M.S.	Subitem(s) A, B, C, D, E, F, G
Scott A. Sorensen M.S.	Subitem(s) A, B, C, D, E, F, G

13. The licensee shall perform testing for leakage or contamination of sealed sources in accordance with K.A.R. 28-35-216a.
14. The use of radioactive material in or on humans shall be by a physician.
15. Sealed sources containing radioactive material shall not be opened.
16. The licensee shall conduct a physical inventory every three (3) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for two years from the date of the inventory for inspection by the Radiation Control Program, Bureau of Environmental Health, Kansas Department of Health and Environment, and shall include the quantities and kinds of radioactive material, location of sealed sources and the date of the inventory.

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17. A. Radiopharmaceuticals dispensed and/or distributed for human use shall be either:
- (1) Repackaged from prepared radiopharmaceuticals that are the subject of an FDA-approved "New Drug Application" (NDA) or for which FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or
 - (2) Prepared from generators and reagent kits that are the subject of an FDA-approved NDA or for which FDA has accepted an IND.
- B. Prepared radiopharmaceuticals for which FDA has accepted an IND and radiopharmaceuticals prepared from generators or reagent kits for which FDA has accepted an IND shall be dispensed and/or distributed:
- (1) In accordance with the directions provided by the sponsor of the IND, and
 - (2) Only to physicians who have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug.
- The licensee shall inform, in writing, each physician who participates in an IND evaluation, that the physician is responsible to the sponsor of the IND for use of the drug in accordance with protocols established by the sponsor and for reporting to the sponsor the clinical information obtained through use of the drug.
18. Patients containing temporary interstitial or brachytherapy implants shall remain hospitalized until surveys made with an appropriate radiation detection instrument indicate all implants have been removed. The results of these surveys shall be recorded and maintained for inspection by the Radiation Control Program, Bureau of Environmental Health, Kansas Department of Health and Environment.
19. The licensee is not authorized to use weighting equations for the purpose of modifying the effective dose equivalent for whole body exposure to radiation or radioactive material under this license.
20. The licensee may transport radioactive material or deliver radioactive material to a carrier for transport, in accordance with the provisions of K.A.R. 28-35-196a, "Preparation of Radioactive Material for Transport".
21. The licensee shall comply with the provisions of Kansas Radiation Protection Regulations, Part 4, "Standards for Protection Against Radiation" and Part 10, "Notices, Instructions and Reports to Workers; Inspections."
22. The licensee shall possess and use radioactive material described in Items 6, 7 and 8 of this license according to the most restrictive of; the Kansas Radiation Protection Regulations, this license or statements, representations, and procedures contained in the following documents.
- a. The application dated May 26, 2010, signed by Steven D. Wilkinson, with attachments.

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- b. The letter dated October 4, 2010, signed by Scott A. Sorensen, with attachments.
- c. The letter dated November 11, 2010, signed by Scott A. Sorensen, with attachments.

FOR THE STATE DEPARTMENT OF HEALTH AND ENVIRONMENT

Date January 6, 2011

By: _____



Thomas A. Conley, CHP
Radiation Control Program

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.190, 35.290, and 35.590]

APPROVED BY OMB: NO. 3190-0120
EXPIRES: 08/15/2012

Name of Proposed Authorized User: Aaron Lewis, MD State or Territory Where Licensed: Missouri

Requested Authorization(s) (check all that apply)

- 35.100 Uptake, dilution, and excretion studies
- 35.200 Imaging and localization studies
- 35.500 Sealed sources for diagnosis (specify device _____)

PART I - TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

- 1. Board Certification**
 - a. Provide a copy of the board certification.
 - b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.
- 2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization**
 - a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.
 - b. Supervised Work Experience.
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			

Total Hours of Experience:

Supervising Individual: _____ License/Permit Number listing supervising individual as an authorized user: _____

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

- 35.290
- 35.390 + generator experience in 32.290(c)(1)(ii)(G)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use (not required for 35.500)			
Radiation biology			
Total Hours of Training:			

**b. Supervised Work Experience (completion of this table is not required for 35.500).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)**

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience. (continued)

Description of Experience Must include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Supervising individual:

License/Permit Number listing supervising individual as an authorized user

Supervisor meets the requirements below, or equivalent Agreement State requirements (check one).

- 35.190 35.290 35.390 35.390 + generator experience in 35.290(c)(1)(II)(G)

c. For 35.500 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, stop to and complete Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 36.590)

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each use requested:

For 35.180

Board Certification

I attest that Aaron M. Lewis has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

I attest that Aaron M. Lewis has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section

Complete the following for preceptor attestation and signature:

I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

- 35.180 35.290 35.390 35.390 + generator experience

Name of Preceptor <u>S. Ted Treves, M.D.</u>	Signature <u>S. T. Treves</u>	Telephone Number <u>617-355-7935</u>	Date <u>4/29/11</u>
License/Permit Number/Facility Name <u>Children's Hospital (Preceptor) RAM 60 0157 permit # NUC 0006</u>			

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.300)
[10 CFR 35.390, 35.392, 35.394, and 35.396]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized User

State or Territory Where Licensed

Claron Lewis, M.D.

MISSOURI

Requested Authorization(s) (check all that apply):

35.300 Use of unsealed byproduct material for which a written directive is required

OR

35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

35.300 Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

35.300 Parenteral administration of any other radionuclide for which a written directive is required

PART I - TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

1. Board Certification

a. Provide a copy of the board certification.

b. For 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.

c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.

d. Skip to and complete Part II Preceptor Attestation.

2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization

a. Authorized User on Materials License _____ under the requirements below or equivalent Agreement State requirements (check all that apply):

35.390 35.392 35.394 35.490 35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training 35.390 35.392 35.394 35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience 35.390 35.392 35.394 35.396

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	

NS-26.1

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Trained and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:	
<input type="checkbox"/> 35.390 <input type="checkbox"/> 35.392 <input type="checkbox"/> 35.394 <input type="checkbox"/> 35.396	With experience administering dosages of: <input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required <input type="checkbox"/> Parenteral administration of any other radionuclide requiring a written directive
** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.	

c. Supervised Clinical Case Experience

If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	5	Joint Program in Nuclear Medicine	7/1/2010 through 6/30/2011
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	6	Joint Program in Nuclear Medicine	7/1/2011 through 6/30/2011
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required	SM 155; 1056 2-9022222 3 cases	Joint Program in Nuclear Medicine	6/1/2011 through 7/1/2011 through 6/30/2011
Parenteral administration of any other radionuclide for which a written directive is required			
_____ (List radionuclides)			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Case Experience (continued)

Supervising Individual: <i>S. Ted Treves, M.D.</i>	License/Permit Number listing supervising individual as an authorized user: <i>Children's Hospital Boston NRC License # 37 Permit # NRC</i>
Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:	
<input checked="" type="checkbox"/> 35.390	With experience administering dosages of:
<input type="checkbox"/> 35.392	<input checked="" type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
<input type="checkbox"/> 35.394	<input checked="" type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
<input type="checkbox"/> 35.396	<input checked="" type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
	<input type="checkbox"/> Parenteral administration of any other radionuclide requiring a written directive
** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.	

d. Provide completed Part II Preceptor Attestation.

PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each requested authorization:

For 35.390:

Board Certification

I attest that *Aaron Lewis* has satisfactorily completed the training and experience requirements in 35.390(a)(1).
Name of Proposed Authorized User

OR

Training and Experience

I attest that _____ has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).
Name of Proposed Authorized User

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

For 35.394 (Identical Attestation Statement Regardless of Training and Experience Pathway):

I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).

Second Section

I attest that Alison Lewis has satisfactorily completed the required clinical case
Name of Proposed Authorized User

experience required in 35.390(b)(1)(ii)G listed below:

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 160 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

Third Section

I attest that Alison Lewis has satisfactorily achieved a level of competency to
Name of Proposed Authorized User

function independently as an authorized user for:

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 160 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

MSB

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.398:

Current 35.490 or 35.890 authorized user:

I attest that _____ is an authorized user under 10 CFR 35.490 or 35.890
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.398 (d)(1), and the supervised work and clinical case experience required by 35.398(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

- Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
- Parenteral administration of any other radionuclide for which a written directive is required

OR

Board Certification:

I attest that _____ has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 35.398(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.398 (d)(1) and the supervised work and clinical case experience required by 35.398(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

- Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
- Parenteral administration of any other radionuclide for which a written directive is required

Fifth Section

Complete the following for preceptor attestation and signature:

I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

- 35.390 35.392 35.394 35.398

I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor <i>S. Ted Treves, M.D.</i>	Signature <i>ST Treves</i>	Telephone Number <i>617 355 7935</i>	Date <i>4/29/10</i>
License/Permit Number/Facility Name <i>Children's Hospital Boston - P117106-0151 Permit # UUC-1066</i>			

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