

December 29, 2009

U.S. Nuclear Regulatory
Material Licensing Branch
2343 Warrenville Road
Suite 210
Lisle, IL 60532-4652

RE:
Amendment Request
License # 24-24660-01

Dear Sirs,

We wish to add the following physician to our license.

- 1.) Craig B. McClure M.D. for CFR 35.100, 35.200, 35.300. Enclosed is a copy of his American Board of Radiology and a Kansas Radioactive material License # 19-B296-01.
- 2.) Robert A. Wood Jr. M.D. for CFR 35.100, 35.200, 35.300. Enclosed is a copy of his American Board of Radiology and a Kansas Radioactive material License # 19-B 296-01.

If you have any questions concerning this, please do not hesitate to contact the Nuclear Medicine department 816-282-5624.

Sincerely,



Tracy Thellman
Director of Imaging Services

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The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology, the Association of
University Radiologists, and American Association of Physicists in Medicine
Hereby certifies that

Robert Armacost Wood, Jr., M.D.

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

On this eleventh day of June, 1997
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Diagnostic Radiology



Lars E. Sanderson, MD President
Robert R. Hooten, MD Secretary-Treasurer
M. Paul Capp, M.D. Executive Director

The American Board of Radiology

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the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology,
and the Association of University Radiologists*

Hereby certifies that

Craig B. McClure, M.D.

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

The American Board of Radiology

On this twenty-sixth day of May, 1988

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

Diagnostic Radiology

M. Paul Capp, M.D.

President

John H. R. Ziehlendyckel

Secretary



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.

| | | | |
|------------|--------------------------------------|---------------------|------------------|
| Licensee | | Amendment No. 39 | |
| 1. Name | OLATHE MEDICAL CENTER | 3. License Number | 19-B296-01 |
| 2. Address | 20333 W 151ST ST OLATHE, KS 66061 | 4. Expiration Date | October 31, 2013 |
| | | 5. Reference Number | |

| 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. Radiopharmaceutical: Any radiopharmaceutical 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. Radiopharmaceutical: Any radiopharmaceutical 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. Radiopharmaceutical: Any radiopharmaceutical 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). 350 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 each radioactive material authorized in Subitem 6.D. |
| E. Any radioactive material | E. Sealed source(s): Any sealed source authorized by 10 CFR 35.65 or equivalent agreement state regulation. | E. No single source to exceed 30 millicurie(s). Limited to 50 millicuries of each radionuclide. |

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- F. Samarium-153 F. Sealed source(s): Samarium chloride (DuPont NES-8153) F. 10 source(s). No single source to exceed 250 millicurie(s).
- G. Fluorine-18 G. Radiopharmaceutical: Fluorodeoxyglucose (FDG) G. 2 Curie(s) total.
- H. Strontium-90 H. Sealed source(s): (Bebig Sr0.S03; AEA Technology SICW series) H. 800 millicurie(s) total. No single source to exceed 5 millicurie(s).

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.
 - E. To be used for calibration, transmission, reference and quality control.
 - F. To be used for calibration, transmission, reference and quality control.
 - G. To be used for diagnostic studies involving imaging and tumor localizations.
 - H. To be used in the Novoste Model A1000 series transfer device for intravascular brachytherapy.
- 10. Radioactive materials shall only be used at the following location(s):
 - OLATHE MEDICAL CENTER, 20333 W 151ST ST
OLATHE, KS 66061
 - OLATHE MEDICAL PAVILION, 21120 W 152ND ST
OLATHE, KS 66061
 - Xenon-133 will not be used at this location.
- 11. The following shall be responsible for the licensee's radiation protection program
 - Michael Robertson M.D. Radiation Safety Officer
 - Patrick Santiago M.D. Assistant Radiation Safety Officer
 - Ronald Galloway CNMT Assistant Radiation Safety Officer

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12. Radioactive material listed in Item 6 above is authorized for use by individuals for the materials and uses described as follows:

Radioactive materials shall be used by or under the supervision of an individual listed below:

| | |
|----------------------------|---|
| Michael J. Brigg M.D. | Subitem(s) A, B, C (iodine-131 only), F, G |
| William Brooks M.D. | Subitem(s) A, B, C, F, G |
| Craig M. Bruner M.D. | Subitem(s) A, B, C, F, G |
| Susan Chow M.D. | Subitem(s) A, B, C, F, G |
| Ira Cox M.D. | Subitem(s) A, B, C, F, G |
| Scott C. Cozad M.D. | Subitem(s) C, D, H |
| W. B. Davis M.D. | Subitem(s) A, B, C (iodine-131 only for which the patient can be released pursuant to 10 CFR 35.75), F, G |
| Dion Depalois M.D. | Subitem(s) A, B, F, G |
| Wendall Doronio M.D. | Subitem(s) A, B, C (iodine-131 only for which the patient can be released pursuant to 10 CFR 35.75), F, G |
| Vandana Halder M.D. | Subitem(s) A, B, C (iodine-131 only for which the patient can be released pursuant to 10 CFR 35.75), F, G |
| Kelly Hart M.D. | Subitem(s) A, B, C, F, G |
| Nathaniel R. Jewell M.D. | Subitem(s) A, B, C (iodine-131 only), F, G |
| Bradley H. Koffman M.D. | Subitem(s) C, D, H |
| Vickie L. Massey M.D. | Subitem(s) C, D, H |
| Craig McClure M.D. | Subitem(s) A, B, F, G |
| Bradley McIlroy M.D. | Subitem(s) A, B, C, F, G |
| Gayle P. Miller M.D. | Subitem(s) C, D, H |
| Rick Moritz M.D. | Subitem(s) A, B, C (iodine-131 only for which the patient can be released pursuant to 10 CFR 35.75), F, G |
| Jay Murphy M.D. | Subitem(s) A, B, F, G |
| Douglas W. Nemmers M.D. | Subitem(s) A, B, C (except phosphorus-32), F, G |
| Stephen S. Nigh M.D. | Subitem(s) C, D, H |
| Steven D. Obermueller M.D. | Subitem(s) A, B, F, G |
| Michael B. Parsa M.D. | Subitem(s) A, B, C, F, G |
| Michael Robertson M.D. | Subitem(s) A, B, C, F, G |
| Jay Robinow M.D. | Subitem(s) C, D, H |
| Patrick Santiago M.D. | Subitem(s) A, B, F, G |
| Sarah L. Sherard M.D. | Subitem(s) A, B, C, F, G |
| Steven Smalley M.D. | Subitem(s) D, H |

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|---------------------------|--|
| Donald Stallard M.D. | Subitem(s) A, B, C (iodine-131 only), F, G |
| Steve S. Whitfield M.D. | Subitem(s) A, B, F, G |
| Robert Armacost Wood M.D. | Subitem(s) A, B, C, F, G |
| Thomas Zinn M.D. | Subitem(s) A, B, C, 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 Air and Radiation, 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.

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, or

(3) PET radiopharmaceuticals for which an NDA or IND is not required and shall fully comply with all USP standards and monographs pertaining to PET drugs.

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.

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- 18 A. The licensee shall perform a test to detect and quantify the activity of Molybdenum-99 contamination in each elution of Technetium-99m from a Molybdenum-99/Technetium-99m generator and in each extraction or separation of Technetium-99m from Molybdenum-99 not contained in a generator.
- B. The licensee shall not distribute for human use Technetium-99m that, at the expiration date and time shown on the package label, contains more than 0.15 microcuries of Molybdenum-99 per millicurie of Technetium-99m or more than five (5) microcurie of Molybdenum-99 per dose of Technetium-99m. The expiration date and time shown on the package label shall be such that the limits above are not exceeded for any single patient dose. The limits for Molybdenum-99 contamination represent maximum values and Molybdenum-99 contamination should be kept as low as reasonably achievable below these limits.
- C. The licensee shall establish written procedures for personnel performing tests to detect and quantify Molybdenum-99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of Molybdenum-99 in excess of the limits specified in Subitem B above are detected.
- D. Personnel performing tests to detect and quantify Molybdenum-99 contamination shall be given specific training in performing these tests prior to conducting such tests.
- E. (1) The licensee shall maintain for inspection by the Radiation Control Program, Bureau of Air and Radiation, Kansas Department of Health and Environment records of the results of each test performed to detect and quantify Molybdenum-99 contamination and records of training given to personnel performing these tests.
- (2) Records described in E(1) above shall be maintained for three (3) years following the performance of the tests and training of personnel.
- 19 The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.
- 20 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 Air and Radiation, Kansas Department of Health and Environment.
- 21 Specific requirements for the Novoste Intravascular Brachytherapy System:
- A. Prior to each use of the Novoste System on a human patient, a catheter integrity evaluation (a dummy run) shall be conducted outside of the patients' body to allow the clinician to simulate a clinical procedure with non-radioactive sources. For delivery catheter designs which do not accommodate a dummy run external to the patient, perform a catheter integrity evaluation according

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to manufacturer instructions.

B. Each intravascular brachytherapy device shall be inspected and serviced at intervals established by the manufacturer. Maintenance and repair shall be performed only by the manufacturer or persons specifically authorized by the Nuclear Regulatory Commission or an Agreement State to perform such services.

22. 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.
23. 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".
24. The licensee shall comply with the provisions of Kansas Radiation Protection Regulations, Part 4, "Standards for Protection Against Radiation", Part 6, "Use of Radioactive Materials in the Healing
25. 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 letter dated February 9, 2004, signed by Ron Galloway, with attachment.
 - b. The letter dated August 4, 2004, signed by Ron Galloway, with attachment.
 - c. The electronic mail dated September 7, 2004, from Ron Galloway.
 - d. The fax dated September 30, 2005, from Dr. Paul Chesis.
 - e. The letter dated September 27, 2005, signed by Lucretia Craig.
 - f. The letters dated February 6, 2007 and May 11, 2007, signed by Ron Galloway, with attachments.
 - g. The electronic mail dated May 30, 2007, from Ron Galloway.
 - h. The letter dated July 2, 2007, signed by Ron Galloway, with attachment. And electronic mail dated July 31, 2007, from Ron Galloway.
 - i. The facsimile dated October 24, 2007, from Jeanette L. Schutte, with attachment(s).
 - j. The letter dated April 7, 2008, signed by Ron Galloway, with attachment(s).
 - k. The letter dated May 2, 2008, signed by Ron Galloway, with attachment(s).
 - l. The letter dated June 8, 2009, signed by Michael Robertson, M.D., with attachment(s).
 - m. The letter dated August 18, 2009, signed by Michael Robertson, M.D., with attachment(s).

Oct. 30. 2009 8:42AM

2009-10-29 10:28

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KCC

No. 9545 P. 9/9

P 9/9

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FOR THE STATE DEPARTMENT OF HEALTH AND ENVIRONMENT

Date September 9, 2009

By: _____



Thomas A. Cowley, CHP
Radiation Control Program

Received Time Oct. 30. 8:50AM

LSMC
2100 S.E. Blue Parkway
Lees Summit MO 64073
(Nuclear Medicine Dept)

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