

### ST. JOHN'S

ST. JOHN'S HOSPITAL

1235 EAST CHEROKEE STREET ■ SPRINGFIELD, MISSOURI 65804-2263 417-820-2000 ph.

08/23/2011

Materials Licensing
US NRC Region III
2443 Warrenville Road Suite 210
Lisle, IL 60532-4352

**ATTN Toye Simmons:** 

This letter is a request for the following amendments to license # 24-00866-02. I am requesting that this be combined with a pending amendment with the control number 575334.

We are needing to purchase new Cs-137 sources for our manual brachytherapy program. Specifically we are planning on purchasing the Ezip model 067-6520 and 067-6525 sources. I would also like to have the following Ezip models placed on our license to allow us the ability to purchase these models in the future. 067-6510, 067-6515, 067-6530, 067-6535 and 067-6540.

Also we have a license renewal pending which requests the addition of Dr Steven Braun as an authorized user for 35-300 and 35.400 use. I would like to have Dr Braun added to our license on this amendment since the renewal may take a few more months to complete. He was previously listed on Kansas license number 19-B081-01 for 35-300 and 35-400 and I have provided a copy of that license for your review.

Since this amendment will apply to our old license and the license renewal request was sent to the NRC prior to the date(s) of this amendment (control number 575334), I would like to request that the details of this amendment be applied to the license renewal request as well. I do not want amendments made to our license after our renewal submission to be omitted from the renewal application.

If you have any questions regarding this request or if you require additional information please contact me at (417) 820-7704.

Sincerely,

Nick Lannutti, MS

Radiation Safety Officer

Department of Nuclear Medicine

Nie Les

St Johns Hospital-Springfield

cc:

Linda Earnest, Administration Alan Burns, Radiation Oncology

Dennis Frieda, Ph.D., Radiation Oncology

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# 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.

				Amend	men	t No. 56
Licensee				3. License Number		
I.Name PROMISE REGIONAL MEDICAL CENTER				19-B081-01		
2.Address 1701 E 23RD ST HUTCHINSON, KS 67502			4. Expiration Date			
			November 30, 2013			
				5. Reference Number		
	lioactive Material ement and Mass Number)	7.	Chemical and/or Physica	al Form	8.	Maximum Quantity Licensee May Possess at One Time
per as:	y radioactive material rmitted by 10 CFR 35,100 adopted by reference in A.R. 28-35-264	A.	Unsealed: Any radioac material prepared for medical use permitted CFR 35.100 as adopted reference in K.A.R. 28	by 10 d by		As necessary for uses authorized in subitem 9(A).
per as ;	y radioactive material mitted by 10 CFR 35.200 adopted by reference in A.R. 28-35-264	В.	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 except generators		<b>B.</b>	As necessary for uses authorized in subitem 9(B).
per as a	y radioactive material mitted by 10 CFR 35.300 adopted by reference in 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			As necessary for uses authorized in subitem 9(C). Limited to 300 millicuries of each radioactive material
per as a	y radioactive material mitted by 10 CFR 35.400 adopted by reference in A.R. 28-35-264	D.	Sealed source(s): Any brachytherapy source permitted by 10 CFR 2 as adopted by reference K.A.R. 28-35-264		D.	As necessary for uses authorized in subitem 9(D). Limited to 600 millicuries of each radioactive material
E. An	y radioactive material	E.	Sealed source(s): Any source authorized by 1 35.65 or equivalent agreement state regular	0 CFR	E.	No single source to exceed 20 millicurie(s). Limited to 50 millicuries of each radioactive material

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Supplementary Sheet

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F. Gadolinium-153

F. Sealed source(s): (Isotope Products NES-8412 or equivalent source approved by the NRC or an agreement state) F. 1000 millicurie(s) total. No single source to exceed 600 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.
- 10. Radioactive materials shall only be used at the following location(s):

  PROMISE REGIONAL MEDICAL CENTER, 1701 E 23RD ST
  HUTCHINSON, KS 67502
- The following shall be responsible for the licensee's radiation protection program
  Ragu Tirukonda M.S.
  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 materials shall be used by or under the supervision of an individual listed below:

Steven Braun M.D.

Subitem(s) C, D

Rona K. Gazaway M.D.

Subitem(s) A, B, E, F

Edward (Ted) A. Hobart M.D.

Subitem(s) A, B, E, F

T. Krishna Reddy M.D.

Subitem(s) A (cardiovascular procedures only), B

(cardiovascular procedures only), E, F

- The licensee shall perform testing for leakage or contamination of sealed sources in accordance with K.A.R. 28-35-216a.
- The use of radioactive material in or on humans shall be by a physician.
- 15 Sealed sources containing radioactive material shall not be opened.

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- 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.
- 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.

- 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.
- 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.
- 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".
- 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

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Healing Arts" 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 letter dated September 22, 2003, signed by Duke Eldridge and Bill Giersch, with attachment(s).
  - b. The letter dated November 10, 2003, signed by Mark Norrell, with attachment(s).
  - c. The letter dated June 22, 2004, signed by Radu TiruKonda, M.S. DABR, with attachment(s).
  - d. The electronic mail dated July 13, 2004, from Radu TiruKonda, M.S. DABR, with attachment(s).
  - e. The letter received November 9, 2005, signed by Radu TiruKonda, with attachment(s).
  - f. The letter received March 30, 2010, signed by Radu TiruKonda.

FOR THE STATE DEPARTMENT OF HEALTH AND ENVIRONMENT

Date April 5, 2010

y: \_\_\_\_\_\_ Thomas A. Conley, CHP

Thomas A. Conley, CHP
Radiation Control Program

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