PharmaLogic
Take The Lead

7/20/2016

Regional Administrator
US NRC, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532

RE: Amendment request for NRC RAM License 24-26241-01MD

Dear Sirs,

Please add Bynum Kimmons as an Authorized Nuclear Pharmacist to the above referenced RAM. Enclosed please find a copy of his MO Pharmacist license verification, number 2016025455. I have also enclosed the RAM license from IonSouth in Pensacola, FL listing Bynum as a ANP.

Should you need any additional information I may be reached at 678.333.5896, or email rvansant.pharmalogic.info.

Thank you,

Richard L. Van Sant, PharmD
Director of Regulatory Affairs

PharmaLogic Holdings Corp
1 South Ocean Blvd, Suite 206 • Boca Raton, FL 33432
Phone: 561-416-0085 • Website: www.pharmalogic.info

Richard Van Sant

From: Kimmons <bynumhelen@bellsouth.net>
Sent: Tuesday, July 19, 2016 10:23 PM
To: Richard Van Sant
Subject: Missouri license

General Inquiries

Board of Pharmacy
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573.751.0091 Telephone
573.526.3464 Fax
800.735.2966 TTY
800.735.2466 Voice Relay
MissouriBOP@pr.mo.gov
http://pr.mo.gov/pharmacists

Pharmacy Detail

Pharmacy Primary Source Verification

The licensee search function of this website provides data extracted from our database and constitutes a Primary Source Verification.

Licensee Name:	Kimmons, Bynum L
Profession Name:	Pharmacist
Licensee Number:	2016025455
Expiration Date:	10/31/2018
Original Issue Date:	7/15/2016
Address:	
Address Con't:	
City, State Zip:	Buford, GA 30519
County:	Unknown/Out of State
Practitioner DBA Name:	
Classification:	

Current Discipline Status:	None

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

RADIOACTIVE MATERIALS LICENSE

Pursuant to Chapter 404, Florida Statutes, and Chapter 64E-5, Florida Administrative Code (F.A.C.), and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to receive, acquire, possess and transfer the radioactive material(s) designated below and to use such radioactive material(s) for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the state of Florida, Department of Health now or hereafter in effect and to any conditions specified below.

Licensee	
1. Name: **IONSOUTH - PENSACOLA, LLC**	3. License Number: **4371-1** is hereby amended in its entirety with reference to correspondence dated April 25, 2013.
2. Address: **826 Creighton Road, Suite A-102 Pensacola, FL 32504**	4. Expiration Date: **4/30/2018** 5. Category: **3B**

6. Radioactive Material (element and mass number)	7. Chemical And/Or Physical Form	8. Maximum Quantity Licensee May Possess At Any One Time
A. Molybdenum 99	A. Any molybdenum/technetium 99m generator manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to section 64E-5.210, F.A.C., or a specific license issued to a manufacturer by the U.S. Nuclear Regulatory Commission (NRC) or an agreement state pursuant to equivalent regulations	A. 100 curies

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6. Radioactive Material (element and mass number)	7. Chemical And/Or Physical Form	8. Maximum Quantity Licensee May Possess At Any One Time
B. Xenon 133	B. Unit dose containers of gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by the Food and Drug Administration (FDA) or an active (i.e., not withdrawn, terminated or on "clinical hold") "Investigational New Drug Application" (IND) that has been accepted by the FDA	B. 200 millicuries
C. Technetium 99m	C. Any form described in sections 64E-5.626(1) and 64E-5.627(1), F.A.C.	C. 100 curies
D. Iodine 131	D. Any form described in section 64E-5.626(2), 64E-5.627(2) and 64E-5.630(1), (2), (3), F.A.C.	D. 1 curie
E. Any radioactive material except technetium 99m, described in section 64E-5.626(1), F.A.C.	E. Any form described in section 64E-5.626(1), F.A.C.	E. 100 millicuries
F. Any radioactive material except technetium 99m, described in section 64E-5.627(1), F.A.C.	F. Any form described in section 64E-5.627(1), F.A.C.	F. 1 curie
G. Fluorine 18	G. Any form described in section 64E-5.630(4), F.A.C.	G. 100 curies
H. Any radioactive material described in section 64E-5.630(4), F.A.C.	H. Any form described in section 64E-5.630(4), F.A.C.	H. 1 curie

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6. Radioactive Material (element and mass number)	7. Chemical And/Or Physical Form	8. Maximum Quantity Licensee May Possess At Any One Time
I. Any radioactive material listed in sections 64E-5 .206(7) and .206(8) F.A.C.	I. Prepackaged in vivo and in vitro diagnostic test kits	I. 50 millicuries total for in vivo kits and 50 millicuries total for in vitro kits
J. Depleted Uranium	J. Depleted metal	J. 2200 pounds
K. Any radioactive material authorized under section 64E-5.617, F.A.C.	K. Any sealed source listed in section 64E-5.617, F.A.C.	K. 250 millicuries, not to exceed 30 millicuries each
L. Strontium 82/85 Rubidium 82	L. Solid and liquid (Strontium/ Rubidium generator, model Cardiogen-82®)	L. 2 curies

9. AUTHORIZED USES

A. Production of technetium 99m pertechnetate. Redistribution of unused generators and associated depleted uranium shielding to authorized recipients in accordance with statements, representations and procedures contained in the application.

B. For dispensing, distributing or redistributing prepared radiopharmaceuticals to authorized recipients. For distribution as calibration or reference standard to authorized recipients.

C. For dispensing, distributing or redistributing prepared radiopharmaceuticals to authorized recipients. For distribution as calibration or reference standard to authorized recipients. For use of technetium 99m pertechnetate for processing with reagent kits in preparing radiopharmaceuticals.

D.– H. For dispensing, distributing or redistributing prepared radiopharmaceuticals to authorized recipients. For distribution as calibration or reference standard to authorized recipients.

I. Redistribution to general and specific licensees in accordance with statements, representations and procedures contained in the application.

J. To be used as shielding for molybdenum 99/technetium 99m generators.

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9. AUTHORIZED USES

K. To be used for instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to section 64E-5.210, F.A.C., the licensee is authorized to redistribute sources to persons licensed pursuant to section 64E-5.601, F.A.C., or under equivalent licenses of the NRC or an agreement state.

L. Redistribution of generators to authorized recipients in accordance with statements, representations and procedures contained in the application.

CONDITIONS

10. The authorized place of use is the licensee's facility located at the address in Item 2.

11. Failure to comply with the provisions of this license is a felony of the third degree pursuant to section 404.161, Florida Statutes. Also, violations may warrant an administrative fine of up to $1,000.00 per violation per day, pursuant to section 404.162, Florida Statutes.

12. A. Licensed material shall be used by, or under the supervision and in the physical presence of at least one of the below listed nuclear pharmacists. Licensed material may also be used by, or under the supervision and in the physical presence of a visiting nuclear pharmacist. A visiting nuclear pharmacist may work for up to 60 days each calendar year, provided the licensee's management approves, in writing, each visiting nuclear pharmacist; the licensee maintains a copy of that individual's licensure from the Florida Board of Pharmacy as a nuclear pharmacist; and the licensee maintains a record of each visitation. Copies of these records shall be maintained for 5 years after the visiting nuclear pharmacist's last visit.

Authorized Users	**Authorized Users**
Terry J. Scheidel, R.Ph. Bynum Kimmons, R.Ph.	Richard Van Sant, R.Ph. Dean Bryant, R.Ph.

B. The radiation safety officer is Terry J. Scheidel, R.Ph.

C. Licensed material may be used by, or under the supervision and in the physical presence of a visiting nuclear pharmacist. When visiting they may work for up to 60 days each calendar year, provided the licensee's management approves, in writing, each visit. The licensee is required to maintain a copy of that individual's licensure from the Florida Board of Pharmacy as a nuclear pharmacist and maintain a record of each visitation. Copies of these records shall be maintained for 5 years after their last visit.

13. Radioactive material transported on public thoroughfares shall be packaged, prepared for shipment, and transported in accordance with Title 49, Code of Federal Regulations and Chapter 64E-5, F.A.C.

14. Pursuant to section 64E-5.210, F.A.C., the licensee is authorized to distribute the radioactive material described in Items 6, and 7 of this license to persons licensed pursuant to section 64E-5.601, F.A.C., or under equivalent licenses of the NRC or an agreement state, for the uses indicated below:

    A. Unused molybdenum 99/technetium 99m and strontium 82/85/rubidium 82 generators and associated depleted uranium shielding may be redistributed to persons licensed pursuant to section 64E-5.627, F.A.C.

    B. Any form listed in each section, radioactive materials described in sections 64E-5.626, 64E-5.627, 64E-5.630 and 64E-5.632, F.A.C., may be redistributed to persons licensed pursuant to that section.

15. Sealed sources containing licensed material shall not be opened.

16. Radiopharmaceuticals shall be assayed in a dose calibrator to accurately measure the activity of the radiopharmaceutical before administration. Instruments utilized in the assay of pure alpha or beta-emitting radiopharmaceuticals shall be calibrated in accordance with the dose calibrator's or drug manufacturer's instructions. The licensee shall maintain copies of these procedures for inspection by the department.

17. The licensee shall assure that each sealed source is tested for leakage or contamination and follow the appropriate actions as required by section 64E-5.1303, F.A.C. Licensed material shall be tested at least every 6 months. The test sample (smear) shall be taken by the licensee using an approved leak test kit. Analysis of the test sample shall be performed by individuals who are licensed by the department, NRC, agreement state, or licensing state to provide these services. The licensee is required to retain leak test records containing the manufacturer's name, model and serial number of each sealed source tested, identity of each sealed source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries, the date of the test and signature of the radiation safety officer or designee. The records shall be maintained for 3 years for inspection by the department.

18. The licensee shall conduct a physical inventory and inspection at least every 6 months to account for all sealed sources received and possessed under this license as required by section 64E-5.1304, F.A.C. Inventory records shall be maintained for 3 years from the date of the inventory for inspection by the department, and shall include the manufacturer's name, model and serial numbers of each sealed source, the identity of each sealed source radionuclide and its estimated activity, the location of each sealed source, the date of the inventory and the signature of the radiation safety officer or designee.

19. The licensee shall notify the Bureau of Radiation Control within 48 hours of any medical event of licensed material that occurred as a result of activities conducted under the authority of this license. Records of these medical events shall be maintained indefinitely for inspection by the department.

20. 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; otherwise reagent kits must be prepared and compounded from a prescription in accordance with the regulations of the Florida Board of Pharmacy.

21. 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 as required by 64E-5.628, F.A.C.

22. The licensee is authorized to collect and dispose of radioactive waste in the form of contaminated syringes, needles, vials and unused doses, except for materials described in section 64E-5.632, F.A.C., from their customers only when these materials were originally supplied by the licensee. This condition does not authorize the receipt of any other forms of radioactive waste.

23. Individuals involved in operations which utilize, at any one time or over a 3 month period, radioiodine in an unsealed form that exceeds activities specified in table 1 shall have bioassays performed at the frequency specified in 64E-5.1320(1), F.A.C. Records of the bioassays shall be maintained for inspection by the department for 3 years.

24. 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), Abbreviated New Drug Application (ANDA) or an Investigational New Drug Application (IND); or

    (2) Prepared from generators and reagent kits that are subject of an FDA approved NDA, ANDA or IND.

24. B. Prepared radiopharmaceuticals for which the FDA has accepted an IND and radiopharmaceuticals prepared from generators or reagent kits for which the 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.

25. A. The licensee shall ensure their clients follow all of the U.S. Food and Drug Administration (FDA) requirements of the Cardiogen-82 Label and Assay Label as revised 2/2012 (FDA DARRTS Reference ID # 3084430).

B. The licensee shall ensure their clients follow all of the requirements in manufacturer's CardioGen-82 Infusion System User Manual Revision 17, its supportive documents and updates. The licensee shall ensure their clients maintain and follow updates to the manual provided by the manufacturer. Copies of this manual, its supportive documents and updates shall be available to each person using and persons having responsibility for the use of, the device and shall be available for inspection by the department.

C. The Certified Nuclear Medicine Technologists and authorized users who use the generator and the Radiation Safety Officer must receive device specific training by the manufacturer prior to initial use. The Certified Nuclear Medicine Technologists who use the generator and the Radiation Safety Officer must annually receive the manufacturer's refresher or recertification training for this device. Documentation of the initial, retraining, and refresher or recertification training shall be available for inspection by the department.

D. For each generator the licensee shall ensure that they and their clients maintain an on-going record of all eluate volumes, (washing, testing and dosing volumes), including a summary of the cumulative volume of eluate. The on-going daily records of volume usage shall be maintained by the licensee and their clients for three years and be available for inspection by the department.

E. The licensee shall ensure their clients measure and calculate the Strontium 82 (Sr-82)/Rubidium 82 (Rb-82) and Strontium 85 (Sr-85)/Rb-82 concentrations using a dose calibrator set on its most sensitive microcurie scale and record all values with at least one significant figure and at least two places to the right of the decimal place according the following schedule below. Records of these tests shall be kept by the licensee and their clients in accordance with 64E-5.628(2)(c), the manufacturer's user manuals and its supportive documentation.

1. Daily on days of use prior to administration; and

25. E. 2. a. Additional daily test at the midpoint of the day should the initial test concentrations of Sr-82 reach 0.002 microcuries per millicurie of Rb-82; or

b. Additional daily test at the midpoint of the day should the initial test concentrations of Sr-85 reach 0.02 microcuries per millicurie of Rb-82; or

c. Additional daily tests during the day when 14 liters of total eluate has passed through the generator at the time points determined by the day's elution volumes where tests are performed at every 750 milliliters eluate use for that day. (i.e., one additional test when 750 milliliters of eluate is used during the day, a second additional test when 1,500 milliliter of eluate is used during the day and an additional test for each 750 milliliters of eluate used during the day.)

F. The licensee shall ensure their clients immediately stop using the generator to treat patients at the expiration limits listed below and the client shall return the generator to the licensee and remove it from service:

1. 17 liters for the generator's cumulative eluate volume; or
2. 42 days post generator calibration date; or
3. An eluate concentration of Sr-82 of equal to or greater than 0.01 microcuries per millicurie of Rb-82; or
4. An eluate concentration of Sr-85 of equal to or greater than 0.10 microcuries per millicurie of Rb-82.

G. The licensee and their clients shall follow the manufacturer's annual preventative maintenance schedule for the Infusion Cart System and complete all of the recommended corrective actions. The licensee shall retain copies of all preventative maintenance checks, corrective actions taken and any manufacturer's quality review audits for inspection by the department.

H. The licensee shall ensure their clients immediately report to the department each occurrence when the eluate concentration of Sr-82 equals or exceeds 0.02 microcuries per millicurie of Rb-82 or the eluate concentration of Sr-85 equals or exceeds 0.20 microcuries per millicurie of Rb-82.

I. Prior to redistribution of the generator, the licensee shall review the use and eluate volume records. The licensee shall ensure entries are properly recorded, up to date and the use limits have not been exceeded.

26. The licensee shall notify the Bureau of Radiation Control within 48 hours of any medical event of licensed material that occurred as a result of activities conducted under the authority of this license. Records of these medical events shall be maintained indefinitely for inspection by the department.

27. A. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, 8 and 9 of this license in accordance with statements, representations and procedures contained in the licensee's application dated February 22, 2013, signed by David A. Cox, COO, and correspondence dated:

March 13, 2013 (facility diagrams/nuclear pharmacy license/Appendix P/LLEA letters/I-131 capsule compounding procedure/Mo-99 breakthrough procedure/multiple commitments), signed by Terry J. Scheidel, R.Ph.
April 25, 2013 (certifying official to Terry J. Scheidel, R.Ph.), signed by David A. Cox, COO.

B. The licensee shall comply with all applicable requirements of Chapter 64E-5, Florida Administrative Code, and these regulations shall supersede the licensee's statements in applications or correspondence, unless the statements are more restrictive than the regulations.

C. For the purpose of these rules "Total effective dose equivalent (TEDE)" means the sum of the effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures and when the external exposure for compliance with subsection 64E-5.308(3) is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the department.

For the Bureau of Radiation Control:

Issuance Date: JUN 19 2013

Lee Thomas
Environmental Specialist III
4052 Bald Cypress Way – Bin C21
Tallahassee, FL 32399-1741
(850) 245-4545

A party whose substantial interest is affected by this order may petition for an administrative hearing pursuant to sections 120.569 and 120.57, Florida Statutes. Such proceedings are governed by Rule 28-106, Florida Administrative Code. A petition for administrative hearing must be in writing and must be received by the Agency Clerk for the Department, within twenty-one (21) days from the receipt of this order. The address of the Agency Clerk is: Agency Clerk, 4052 Bald Cypress Way, BIN # A02, Tallahassee, Florida 32399-1703. The Agency Clerk's facsimile number is 850-410-1448. A copy of the petition should also be sent to: Bureau Chief, Bureau of Radiation Control, 4052 Bald Cypress Way, BIN # C21, Tallahassee, FL 32399-1741. The Bureau Chief's facsimile number is 850-487-0435. Mediation is not available as an alternative remedy. Your failure to submit a petition for hearing within 21 days from receipt of this order will constitute a waiver of your right to an administrative hearing, and this order shall become a "final order." Should this order become a final order, a party who is adversely affected by it is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings may be commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by the filing fees required by law, with the Court of Appeal in the appropriate District Court. The notice must be filed within 30 days of rendition of the final order.

ORIGIN ID:PHKA (561) 416-0085
RICHARD VAN SANT
PHC
1 SOUTH OCEAN BLVD
SUITE 206
BOCA RATON, FL 33432
UNITED STATES US

SHIP DATE: 20JUL16
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BILL SENDER

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U.S. NRC REGION III
2443 WARRENVILLE ROAD
SUITE 210
LISLE IL 60532

(800) 522-3025 REF: 337653782
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