Indiana University Health
Arnett Hospital

February 13, 2018

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

Dear Sir or Madam:

Indiana University Health Arnett Hospital would like to amend its Byproduct Materials License, Number 13-32535-02, to add Imran Kazem, M.D., as an authorized user of 35.100 and 35.200 materials. Dr. Kazem is currently listed on the Arizona Agreement State license of Banner Casa Grande Medical Center (License Number 11-011) for these materials uses. A copy of this license is enclosed.

If there are any questions concerning this license amendment, please contact our nuclear medicine physicist, Mr. Bryce A. Caudle, at 317-443-9035 or by email at bcaudle@mpcphysics.com.

Sincerely,

Douglas Jackson
Imaging Services Manager

PO Box 5545
Lafayette, Indiana
47903-5545

765-448-8000
800-899-8448 toll free
www.iuhealth.org

ARIZONA RADIATION REGULATORY AGENCY

RADIOACTIVE MATERIAL LICENSE

Pursuant to Chapter 4, Title 30, Arizona Revised Statutes, and Title 12, Chapter 1 of the Arizona Administrative Code, and in reliance on statements and representations made to the Agency by the licensee, a license is hereby issued authorizing the acquisition, reception, possession, use and transfer of the radioactive material listed in this license for the purposes and at the places specified. This license is subject to all applicable rules and Agency orders now or hereafter in effect and to the conditions specified. **In accordance with Letter dated January24, 2017, signed by Anjali Roy MD, License Number 11-011 is hereby amended in its entirety to read as follows: ALL CHANGES ARE IN BOLD**

LICENSEE

1. **NAME:** Banner Casa Grande Medical Center

2. **ADDRESS:** 1800 East Florence Boulevard
Casa Grande, Arizona 85122

3. a. **LICENSE NUMBER:** 11-011
b. **AMENDMENT NO.:** 73

4. **EXPIRATION DATE:** July 31, 2019

5. **CATEGORY:** B2 MEDICAL MATERIALS
CLASS A

6. Radioactive material (element and mass number)	7. Chemical or physical form	8. Maximum quantity licensee may possess at any time
A. Any radioactive material listed in Group 100 of Exhibit A, Arizona Administrative Code, Title 12, Chapter 1, Article 7	A. Any prepared FDA approved radiopharmaceutical authorized in Group 100 of Exhibit A, Arizona Administrative Code, Title 12, Chapter 1, Article 7. Not to include investigational new drugs (IND).	A. 37 GBq (1,000 millicuries)
B. Any radioactive material listed in Group 200 of Exhibit A, Arizona Administrative Code, Title 12, Chapter 1, Article 7	B. Any prepared FDA approved radiopharmaceutical authorized in Group 200 of Exhibit A, Arizona Administrative Code, Title 12, Chapter 1, Article 7. Not to include investigational new drugs (IND).	B. 37 GBq (1,000 millicuries)
C. Any radioactive material listed in Group 300 of Exhibit A, Arizona Administrative Code, Title 12, Chapter 1, Article 7	C. Any prepared FDA approved radiopharmaceutical authorized in Group 300 of Exhibit A, Arizona Administrative Code, Title 12, Chapter 1, Article 7. Not to include investigational new drugs (IND).	C. 37 GBq (1,000 millicuries)
D. Any radioactive material listed in Group 400 of Exhibit A, Arizona Administrative Code, Title 12, Chapter 1, Article 7	D. Any brachytherapy source for therapeutic medical use authorized in Group 400 of Exhibit A, Arizona Administrative Code, Title 12, Chapter 1, Article 7	D. 37 GBq (1,000 millicuries)

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E. Fluorine-18	E. Any FDA approved radiopharmaceutical not to include investigational new drugs (IND).	E. 37 GBq (1,000 millicuries)

9. Authorized Use:

A. For diagnostic studies involving measurements of uptake, dilution and excretion, not requiring a written directive, authorized in Group 100 of Exhibit A, Arizona Administrative Code, Title 12, Chapter 1, Article 7.

B. For diagnostic studies involving imaging and localizations, not requiring a written directive, authorized in Group 200 of Exhibit A, Arizona Administrative Code, Title 12, Chapter 1, Article 7.

C. For medical uses requiring a written directive, as authorized in Group 300 of Exhibit A, Arizona Administrative Code, Title 12, Chapter 1, Article 7.

D. For the use of brachytherapy source for therapeutic medical use as authorized in Group 400 of Exhibit A, Arizona Administrative Code, Title 12, Chapter 1, Article 7.

E. For diagnosis of human disease.

CONDITIONS

10. Radioactive material may be possessed and used only at the licensee's address listed in Item 2 above.

11. The licensee shall comply with the provisions of Title 12, Chapter 1, Arizona Administrative Code; Article 3, "Radioactive Material Licensing"; Article 4, "Standards for Protection Against Ionizing Radiation"; Article 7, "Medical Uses of Radioactive Material"; and Article 10, "Notices, Instructions and Reports to Ionizing Radiation Workers; Inspections".

12. A. Radioactive material listed under sub items A through C of Items 6, 7, and 8 of shall be used by, or under the supervision of:

Christian Ingui, M.D. Robert R. McCarver, M.D. Anjali Roy, M.D.

Richard M. Willey, D.O. Brian W. Zernich, D.O.

B. Radioactive material listed under sub items A and B of Items 6, 7, and 8 shall be used by, or under the supervision of:

Robert Dappen, M.D. John A. Eelkema, M.D. Ziad M. ElGhoul, M.D.

Robert Hamburg, M.D. Imran Kazem, M.D. Akil Loli, M.D.

Suntharo Ly, M.D. Ashok C. Solsi, M.D.

C. Radioactive material listed under sub items C and D of Items 6, 7, and 8 shall be used by or under the supervision of:

Ajay Bhatnagar, M.D.

D. Radioactive material listed under sub item C of Items 6, 7, and 8 shall be used by, or under the supervision of Veronica Y. Ruvo, D.O.

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E. Radioactive material listed under sub item E of items 6, 7 and 8 shall be used by or under the supervision of:

Christian Inqui, MD Anjali Roy, MD Richard Wiley, DO

F. The Radiation Safety Officer for this license is: Anjali Roy, M.D.

G. The Alternate Radiation Safety Officers are:

Robert R. McCarver, M.D. Richard Willey, D.O.

The Alternate Radiation Safety Officer shall administer the Radiation Safety Program under the policy and procedure guidance of the Radiation Safety Officer.

13. A. The licensee shall ensure, in accordance with A.A.C. R12-1-419 (C) and (D), that an individual participates in a radioiodine bioassay if the individual:

1. Is likely to receive an annual intake in excess 0.1 of the Annual Limits of Intake (ALI) specified in Table 1, Columns 1 and 2 of Appendix B in 12 A.A.C.1, Article 4;

2. Is a minor or declared pregnant woman likely to receive an annual committed effective dose equivalent in excess of 50 mRem, or

3. Has been involved in a spill, an incident, or other occurrence during which radioiodine may have been taken into the body either by inhalation, ingestion, or by absorption through the skin or a wound.

B. The licensee shall ensure that an Individual who is directly involved in a radioiodine therapy, the handling of radioiodine stock solutions, or is involved in iodination's, and meets, as a minimum, any one of the three criteria in Part A above, participates in a bioassay between 6 and 72 hours following the exposure to radioiodine. With Agency approval, the licensee may perform I-131 bioassays up to 4 weeks and I-125 bioassays up to 12 weeks following radioiodine exposure.

C. For any individual whose cumulative annual intake is likely to exceed 0.1 ALI, the licensee shall perform a dosimetric determination based on the results of the bioassay perform under Part B. To assist in determining the total dose equivalent for the individual, the licensee shall add the obtained dose information to the committed dose equivalent information for the exposed individual. For the exposed individual whose bioassay exceeds 0.25 ALI, the licensee shall restrict the exposed individual from further radioiodine exposure until a bioassay indicates the individual's exposure has dropped below 0.1 ALI.

D. For bioassays exceeding 0.1 ALI, the licensee shall investigate the circumstances surrounding the exposed individual's uptake. Records of the investigation and all bioassay measurements shall be maintained as part of the licensee's personnel dosimetry records and shall be available for inspection by the Agency.

14. The licensee is authorized to release a patient in accordance with R12-1-717, in addition to the following conditions:

A. A patient may be released from licensee control without concern, if the activity administered is no greater than the activity in Column 1 of Table (U)(1) of NUREG 1556, Volume 9, Rev 2, available on the NRC website. The licensee shall maintain a record of the release in accordance with R12-1-717.
A patient shall be given instruction as required in Part E below.

B. A patient may be released from licensee control if administered an activity amount greater than the

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activities in Part A above, provided the measured dose rate at 1 meter from the surface of the patient is no greater than the value in Column 2 of Table (U)(1), for the radionuclide administered to the patient. In addition to the record requirements in Part A above, the licensee shall survey the patient before release and record the reading, survey instrument used, and person performing the survey, as described in Section (U)(3)(1), NUREG 1556. A patient shall be given instructions, as required in Part E below.

C. If a licensee chooses to administer a radionuclide (i.e. Cs-131) not listed in Table (U)(1) and release the patient based on the measured dose rate, the licensee shall calculate the dose rate that corresponds to the 500 mRem dose limit, using the suggested method in Section (U)(1)(2) of NREG 1556. If the measured dose rate is no greater than the calculated dose rate the patient may be released in accordance with Part B above. A patient shall be given instructions, as required in Part E below.

D. In lieu of the surveys required by this license condition, a licensee may perform a dose calculation using patient specific parameters in accordance with section (U)(1)(3) of NUREG 1556.

E. As applicable, the licensee shall provide the patient instructions in accordance with Section (U)(2)(3)(1) or (U)(2)(3)(2), NUREG 1556.

15. A. Before the first medical use of a brachytherapy source, not to include low dose-rate remote afterloader sources, a licensee shall:

1. Determine the source output or activity using a dosimetry system that is calibrated using a system or source that is:

a. Traceable to the National Institute of Science and Technology (NIST), and protocols accepted by a nationally recognized body; or

b. The calibration may be performed by a currently recognized laboratory accredited by the American Association of Physicists in Medicine (AAPM); and

c. The calibration shall have been performed within the previous 2 years and after any servicing that may have affected system calibration, or the system shall have been calibrated within the last 4 years, with an intercomparison performed 18 to 30 months after the calibration, using another dosimetry system that was calibrated within the last 24 months by NIST or by a calibration laboratory accredited by the AAPM. The brachytherapy source shall not be used until a calibration has been completed as required above, if the intercomparison indicates that the original calibration factor has changed by more than 2%.

2. Determine the source positioning accuracy within applicators, using currently recognized protocols meeting the standards of this rule.

3. Mathematically correct the output or source activity for physical decay at intervals consistent with 1% physical decay.

B. Maintain records of each calibration for 3 years after the last use of each source.

16. Notwithstanding the sealed source inventory frequency in R12-1-712, the licensee may perform the required inventory on a 6 month basis in accordance with R12-1-450.

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17. A. The licensee shall not administer to a person; radioactive material in an unsealed form that has not had its radioactivity determined.

B. For unit dosages, the determination may be made by:

1. Direct reading of the radioactivity in a dose calibrator; maintained in accordance with 10CFR 35.50, published January 1, 2002; or

2. Decay correction based on the radioactivity or radioactivity concentration determined by a properly licensed:

a. Manufacturer, or

b. Nuclear pharmacy

C. For other than unit dosages, the determination shall be made by

1. Direct measurement of the radioactivity in a dose calibrator; maintained in accordance with subsection (B)(1);

2. Combination of subsection (B) (1) and mathematical calculations; or

3. Combination of volumetric measurement and mathematical calculation based on a radioactivity measurement determined by a supplier listed in subsection (B) (2) (a) or (B) (2) (b).

D. A dosage determination shall not be used unless it falls within the authorized user's prescribed dosage range.

E. The dosage determination in subsection (A) shall be made and recorded before medical use.

18. A. In lieu of weekly wipe surveys the licensee may perform daily contamination surveys in all radiation use areas using a survey instrument and probe that can easily detect contamination levels that are commonly observed when performing wipe survey in contaminated work areas.

B. To facilitate the contamination survey, the licensee shall establish a contamination survey action level appropriate for the chosen survey instrument and probe in Part (A).

C. The licensee shall perform a wipe survey following:

1. Any known incident involving spilled radioactive material that may result in contamination of work areas.

2. Contamination surveys that exceed the licensee's contamination survey action level established under Part (B).

19. A. The licensee shall not change or modify a PET facility, or operations involving radioactive material, authorized under this license so that individuals exposed to radiation in or around the facility are exposed to radiation in excess of the levels in A.A.C. 12-1-408 and A.A.C. 12-1-416.

B. The licensee shall be informed at all times of activities in areas surrounding the PET facility to ensure that personnel occupancy does not change, resulting in radiation exposure in excess of the levels in A.A.C. 12-1-408 and A.A.C. 12-1-416.

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C. As part of the annual ALARA review required under R12-1-407, the licensee shall review the PET patient workload to ensure that personnel in unrestricted areas are not exposed to radiation in excess of the limits in A.A.C. 12-1-408 and A.A.C. 12-1-416.

D. The licensee shall not image more than **20** PET patients in a five day work week.

20. For purposes of ending the principal activities authorized under this radioactive material license:

A. The license stays in effect beyond the license expiration date. Beyond the expiration date the licensee shall store radioactive material only, until the Agency authorizes its use by license amendment, or the Agency notifies the licensee in writing that the license is terminated.

B. The licensee shall ensure the timeliness of decommissioning of facilities where principal activities are conducted under this license in accordance with Agency requirements.

C. The licensee shall continue to control public access into restricted areas and pay the annual licensing fee until the license is terminated.

21. Except as specifically provided otherwise by this license, the licensee shall possess and use the radioactive material described in Items 6, 7, and 8 of this license in accordance with the statements, representations and procedures contained in:

1. Application dated July 25, 2014, signed by Jennifer Velez.
2. Letter (MOU) dated March 18, 2016, signed by Anthony Moncayo.
3. Letter, with attachments, dated April 6, 2016, signed by Paul Demopoulos.
4. Letter with attachments, dated April 6, 2016, signed by Anthony Moncayo.
5. Letter with attachments, dated October 27, 2016 signed by Cheryl Dodd
6. **Letter with attachments, dated January 24, 2017 signed by Anjali Roy, MD.**

The most recent statements, representations, and procedures shall govern if they conflict with previously submitted documents, unless otherwise specified by a license condition; and the Agency's rules shall govern the licensee's statements in applications or letters.

BRIAN D. GORETZKI, INTERIM DIRECTOR

DATE ISSUED: FEB 14 2017

DHK:BDG:mjk

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00100

FedEx Express Package US Airbill

FedEx Tracking Number 8109 7603 4710

0215 Recipient's Copy

1 From
Date
Sender's Name [illegible] Phone 765 838-6296
Company INDIANA UNIVERSITY HEALTH
Address 5165 MCCARTY LN
Dept./Floor/Suite/Room
City LAFAYETTE State IN ZIP 47905-8764

2 Your Internal Billing Reference

3 To
Recipient's Name [illegible] Phone
Company [illegible]
Address 2413 Waverly Road, Suite 216
We cannot deliver to P.O. boxes or P.O. ZIP codes.
Dept./Floor/Suite/Room
Address
Use this line for the HOLD location address or for continuation of your shipping address.
City Lisle State IL ZIP 60532-4852

0125108975

8109 7603 4710

4 Express Package Service
Packages up to 150 lbs.

Next Business Day
- FedEx First Overnight
- FedEx Priority Overnight
- FedEx Standard Overnight

2 or 3 Business Days
- FedEx 2Day A.M.
- FedEx 2Day
- FedEx Express Saver

5 Packaging
- FedEx Envelope*
- FedEx Pak*
- FedEx Box
- FedEx Tube
- Other

6 Special Handling and Delivery Signature Options
- Saturday Delivery
- No Signature Required
- Direct Signature
- Indirect Signature

Does this shipment contain dangerous goods?
- No
- Yes
- Dry Ice
- Cargo Aircraft Only

7 Payment Bill to:
- Sender
- Recipient
- Third Party
- Credit Card
- Cash/Check

Total Packages Total Weight Credit Card Auth.

611

fedex.com 1.800.GoFedEx 1.800.463.3339

13012
06264027

FedEx
TRK# 0215 8109 7603 4710

MON - 19 FEB 10:30A
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