

9/20/19

TO: US NRC

MATERIALS LICENSING

ATTN: TERRA

610-337-5269

From:

RAY A. CARLSON, MD

CELL: 734-395-7361

PAGES: 5

DR GETACHEW T. ZELEKE  
5375 FORT WARD DR  
NEW ALBANY, OH 43054

03039086  
47-35463-01  
615336

Location: Mountaineer Cardiovascular Care

Date of Inspection: March 11, 2019

### SEALED SOURCE INVENTORY

Nuclide	Type	Location	Calibration Activity	Calibration Date	Mfr.	M/N	S/N
Cs-137	Vial	Hot Lab	221.3 uCi	07/01/05	NAS	MED 3550	65912
Ba-133	Vial	Hot Lab	283.8 uCi	06/01/05	NAS	MED 3550	64664
Cs-137	Rod	Hot Lab	0.5 uCi	06/01/05	IPL	GF-0008	1034-90-50

RSO: 

### SEALED SOURCE LEAK TEST

Nuclide	Type	Location	Calibration Activity	Calibration Date	Mfr.	M/N	S/N
Cs-137	Vial	Hot Lab	221.3 uCi	07/01/05	NAS	MED 3550	65912
Ba-133	Vial	Hot Lab	283.8 uCi	06/01/05	NAS	MED 3550	64664

COMMENT: *The sources listed above were leak tested using a wipe technique and were found to have less than 0.005 uCi removable activity.*

TESTED BY: Ray A. Carlson, M.S.

DATE: March 11, 2019

RSO: 

**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.

<b>Licensee</b>	
<b>1. Name:</b> <b>UNIVERSITY NUCLEAR &amp; DIAGNOSTICS, LLC</b>	<b>3. License Number:</b> <b>4072-7</b> is hereby amended in its entirety with reference to correspondence dated May 31, 2018.
<b>2. Address:</b> <b>12277 SW 55th Street, Suite 906 Cooper City, FL 33330</b>	<b>4. Expiration Date:</b> <b>12/31/2021</b> <b>5. Category:</b> <b>5F(I)</b>

<b>6. Radioactive Material (element and mass number)</b>	<b>7. Chemical And/Or Physical Form</b>	<b>8. Maximum Quantity Licensee May Possess At Any One Time</b>
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- |  |  |                           |
|--|--|---------------------------|
| <b>A. Any radioactive material described in section 64E-5.626(1), F.A.C.</b> | <b>Any radiopharmaceutical for diagnostic use involving measurements of uptake, dilution or excretion as described in section 64E-5.626(1), F.A.C.</b> | <b>A. 500 millicuries</b> |
| <b>B. Any radioactive material described in section 64E-5.627(1), F.A.C.</b> | <b>B. Any radiopharmaceutical for diagnostic use involving imaging and localization as described in section 64E-5.627(1), F.A.C.</b>                   | <b>* B. 2 curies</b>      |

**9. Authorized Use**

- A. Any medical use described in section 64E-5.626(1), F.A.C.**
- B. Any medical use described in section 64E-5.627(1), F.A.C.**

License Number:      4072-7  
Amendment No.:      7  
Control Number: 20180605-0860

**LICENSEE COPY**

Page 1 of 4 Page(s)

Category:      [5F(I)]

Expiration Date: 12/31/2021

STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
BUREAU OF RADIATION CONTROL

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. Sealed sources containing licensed material shall not be opened.
15. The licensee shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical until:
- A. The dose rate is less than 5 millirem (50 microsieverts) per hour at a distance of 1 meter; or
  - B. The amount of radioactive material in the patient is less than 30 millicuries.
16. The licensee is required to retain all records specified in condition 17 and as required by Chapter 64E-5, F.A.C. in the mobile nuclear medicine facility vehicle for at least 2 years for inspection by the department. All records that exceed 2 years will be kept at the licensee's permanent facility for the duration specified in Chapter 64E-5, F.A.C.
17. 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 November 10, 2016, signed by Armando Clavero, Owner and correspondence dated:
- February 5, 2018 (change source address and submit facility diagram), signed by Armando Normandys, Senior Vice President, and
- March 29, 2018 (submit closed out survey of old facility), signed by Armando Clavero, President, CEO.

License Number: 4072.7  
Amendment No.: 7  
Control Number: 20180605-0860

LICENSEE COPY

Page 3 of 4 Page(s)

Category: [5F(1)]

Expiration Date: 12/31/2021

STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
BUREAU OF RADIATION CONTROL

17. 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.

For the Bureau of Radiation Control:

Issuance Date: JUN 14 2018

  
Kimberly Farmer  
Regulatory Specialist I  
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 850-410-1446. 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.

License Number: 4072-7  
Amendment No:  
Control Number: 20180605-0860

LICENSEE COPY

Category: [5F(i)]

Page 4 of 4 Page(s)

Expiration Date: 12/31/2021

STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
BUREAU OF RADIATION CONTROL

RADIOACTIVE MATERIALS LICENSE  
SUPPLEMENTAL SHEET

UNIVERSITY NUCLEAR & DIAGNOSTICS, LLC  
12277 SW 55th Street, Suite 906  
Cooper City, FL 33330

With reference to correspondence dated May 20, 2019, State of Florida Radioactive Materials License Number 4072-7 is hereby amended.

TO CHANGE CONDITION 12 TO READ:

CONDITIONS

12. A. Radiopharmaceuticals which are prepared from generators and/or reagent kits shall be either a FDA approved NDA, ANDA, IND, or prescribed by an Authorized User. The following individuals or persons under their supervision are authorized for the materials and uses as indicated:

Authorized Material and Uses as  
Described in Items 6, 7, 8 and 9

Names

64E-5.626(1) and 64E-5.627(1) F.A.C.

Robert Hyman, MD  
Ravikanti Chiravuri, MD  
Adam Splaver, MD  
Carlos E. Alfonso, MD

- B. The radiation safety officer is Robert J. Hyman, MD

License Number 4072-7

Amendment No. 10

Control Number 20190524-0833

LICENSEE COPY

Page 1 of 2 Page(s)

Category: [5F(II)]

Expiration Date: 12/31/2024

STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
BUREAU OF RADIATION CONTROL

RADIOACTIVE MATERIALS LICENSE  
SUPPLEMENTAL SHEET

12. C. Radiologic technologists who use and administer radioactive materials or perform brachytherapy or teletherapy procedures under the general supervision of an authorized user shall hold a valid certificate as required by Chapter 468, F.S.



For the Bureau of Radiation Control:

Issuance Date: JUN 07 2019

*Kimberly Farmer*  
Kimberly Farmer  
Regulatory Specialist I  
4052 Bald Cypress Way - Bld 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 850-467-0435. 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 Appeals in the appropriate District Court. The notice must be filed within 30 days of rendition of the final order.

License Number: 4072-7

Amendment No: 10

Control Number: 20190524-0833

LICENSEE COPY

Category: (5F(1))

Page 2 of 2 Page(s)

Expiration Date: 12/31/2021