Radiotherapy Centers OF KENTUCKIANA | The US Oncology Network

September 4, 2018

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

Re: Radioactive Material License 13-35276-01
Radiotherapy Centers of Kentuckiana

To Whom It May Concern:

This is a notification to revise the radioactive material license above. Please revise the license as listed below:

1. We respectfully request that Dr. Don Stacey be removed as an authorized user on radioactive material license; he is no longer with the organization.

2. Please add Dr. Lawrence Hochman to the license for material use in 10 CFR 35.300
   a. Please see the enclosed State of Florida radioactive material license 4386-1, page 2, listing Dr. Hochman as authorized for:
      i. 64E-5.630(2) and (4) corresponding to NRC 10 CFR 35.300 for I-131 less than or equal to 33 mCi of I-131 and parenteral use of radioactive material
   b. Please see the enclosed State of Florida Administrative Code 64E-5.630

If you require further information, please contact the Radiation Safety Officer, Sarah Hughes, at 502-552-5454 or sarahch72@yahoo.com

Sincerely,

Christine Lamm
Practice Administrator

3920 B Dupont Square | Suite B | Louisville | KY | 40207 | 502-409-9701 | 502-409-9717 | KentuckianaRadiationOncology.com

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: **OCALA ONCOLOGY CENTER, P.L.** **d/b/a Florida Cancer Affiliates**	3. License Number: **4386-1** is hereby amended in its entirety with reference to correspondence received January 26, 2015.
2. Address: **7324 Little Road** **New Port Richey, FL 34654**	4. Expiration Date: **8/31/2018** 5. Category: **5F(I)**

6. Radioactive Material (element and mass number)	7. Chemical And/Or Physical Form	8. Maximum Quantity Licensee May Possess At Any One Time
A. Any radioactive material described in section 64E-5.627(1), F.A.C.	A. Any radiopharmaceutical for diagnostic use involving imaging and localization as described in section 64E-5.627(1), F.A.C.	A. 2 curies
B. Any radioactive material described in section 64E-5.630(2) and (4), F.A.C.	B. Any radiopharmaceutical for diagnostic use involving measurements of uptake, dilution or excretion as described in section 64E-5.630(2) and (4), F.A.C.	B. 2 curies

9. Authorized Use

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

B. Any medical use described in section 64E-5.630(2) and (4), F.A.C.

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CONDITIONS

10. A. The authorized place of storage is the licensee's facility located at 3611 Little Road, New Port Richey, Florida, 34655. This location can be used for quality assurance and quality control testing.

    B. The authorized place of use is the licensee's mobile nuclear medicine vehicle, VIN 1LH142UH641013273, at temporary job sites throughout the State of Florida. This condition does not prohibit use in other Agreement States and States under the jurisdiction of the U.S. Nuclear Regulatory Commission under reciprocity that has been approved by an Agreement State or the U.S. Nuclear Regulatory Commission.

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. 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-5.627(1) and 64E-5.630(2) and (4)	Lawrence Hochman, D.O. Vincent G. Cotroneo, M.D. Claudia G. Berman, M.D. Jamie L. Montilla-Soler, M.D.
64E-5.627(1)	Todd M. Kaplan, M.D. Howard Kahen, M.D. William L. Nyman, M.D. Denis W. Stewart, M.D. Charles R. Anthony, M.D. Steven D. Johnson, M.D. Wendie K. Moore, M.D. Mark Willard, M.D. Lance Trigg, M.D. John Cain, M.D. Kerry B. Raduns, M.D. Mark A. Yap, M.D. Scott R. Kerns, M.D. David C. McKay, M.D. Rolando E. Prieto, M.D. Caleb Rivera, M.D.

12. A. Continued:

Authorized Material and Uses as Described in Items 6, 7, 8 and 9	Names
64E-5.627(1)	John D. Boon, IV, M.D. Malcolm E. Williamson, II, M.D. Ryan K Tomkins, M.D. Dana M. Allen, M.D. Frederic C. Wollett, M.D. Ralf R. Barckhausen, M.D. Edson G. Cortes, M.D. Kenneth Gage, M.D.

B. The radiation safety officer is Lawrence Hochman, D.O.

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.

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. Any dose of iodine 131 shall be received in capsule form only.

17. The licensee is required to retain all records specified in condition 19 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.

18. The licensee shall implement the quality management program (QMP) as stated in Condition 19 and section 64E-5.611, F.A.C.

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19. 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 June 26, 2013, signed by Thomas Cartwright, M.D., Manager.

June 26, 2013 (certifying official to Larry Burchell), also signed by Thomas Cartwright, M.D., Manager.
November 24, 2014 (new permanent storage location); and correspondence received:
January 26, 2015 (facility diagram/survey commitment), both signed by Larry Burchell, CMD.

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: FEB 0 4 2015

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.

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Florida Administrative Code (Last Updated: August 28, 2018)
- 64. Department of Health
  - 64E. Division of Environmental Health
    - 64E-5. Control Of Radiation Hazards

64E-5.630. Use of Radiopharmaceuticals for Therapy

Effective on Thursday, December 26, 2013

A licensee is allowed to use any unsealed radioactive material in a radiopharmaceutical that requires a written directive as described in subsection 64E-5.607(3), F.A.C., and for a therapeutic medical use provided the following is met:

(1) For any unsealed radiopharmaceutical including parenteral use listed in subsection 64E-5.630(4), F.A.C., and sodium iodide I-131 use listed in subsections 64E-5.630(2) and (3), F.A.C., the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of a physician who is an authorized user under subparagraph 64E-5.630(1)(d)2., F.A.C., as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

(e) The authorized user must satisfy the applicable training and experience specified in Rule 64E-5.660 or 64E-5.657, F.A.C.

(2) For oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of a physician who is an authorized user under subparagraph 64E-5.626(1)(d)2., F.A.C., and as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

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Rulemaking Events:

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Historical Versions(2)

Select effective date to view different version.

02/11/2010 Go

Related Statutes:

404.022, F.S.

404.051, F.S.

404.061, F.S.

404.071, F.S.

404.081, F.S.

404.141, F.S.

Related Notices (7)

13891096. Definitions, Subsurface Tracer Studies, Storage ...

13845409. Definitions, Subsurface Tracer Studies, Storage ...

13716690. Definitions, Subsurface Tracer Studies, Storage ...

.....

(c) The authorized user must satisfy the training and experience specified in Rule 64E-5.661 or 64E-5.657, F.A.C.

(3) For oral administration of sodium iodide I-131 in quantities greater than 33 millicuries (1.22 gigabecquerels) the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of a physician who is an authorized user under subparagraph 64E-5.626(1)(d)2., F.A.C., and as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

(e) The authorized user must satisfy the training and experience specified in Rule 64E-5.662 or 64E-5.657, F.A.C.

(4) For parenteral use of radioactive materials the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of a physician who is an authorized user under subparagraph 64E-5.626(1)(d)2., F.A.C., and as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

(e) The authorized user must satisfy the training and experience specified in Rule 64E-5.663 or 64E-5.657, F.A.C.

Rulemaking Authority **404.051, 404.061, 404.071, 404.081, 404.141 FS.** *Law Implemented* **404.022, 404.051(1),** *(4), (5), (6), (8), (9), (10), (11),* **404.061(2),** *(3),* **404.071(1), 404.081, 404.141 FS.** *History–New 8-25-91, Amended 5-12-93, Formerly 10D-91.739, Amended 8-6-01, 2-11-10, 12-26-13.*

RCL
3920B Dupont Sq
Louisville, KY 40207

LOUISVILLE KY 402
FRI 07 SEP 2018 PM

US. Nuclear Regulatory Committee
Material Licensing Section
2443 Warrenville Rd, Suite 210
Lisle, IL
60532-4352

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