

Diagnostic Laboratories, LLC

101 Dillon Court, Gray, Tennessee 37615
Phone: (423) 477-2440 Fax: (423) 477-3233

30 November 2020

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

Re: Diagnostic Laboratories, LLC (Docket No. 03038552, License No. 41-31476-01,
Control No. 577686) Amendment Request

To Whom it May Concern,

Diagnostic Laboratories, LLC wishes to amend its radioactive materials license to change the Radiation Safety Officer (RSO) from Alexandra Coll, B.S., CNMT, R.T.(CT)(ARRT) to Blaine J. Beining, B.S., CNMT, NMTCB(RS), PET, R.T.(N)(CT)(ARRT).

Mr. Beining has been the RSO of this same Nuclear Regulatory Commission (NRC) radioactive materials license (number 41-31476-01) in past years. Mr. Beining is also currently the RSO of Tennessee radioactive materials license number R-90053-K20 for the past three years, Virginia radioactive materials license number 000-571-1 for the past four years, Kentucky radioactive materials license 202-417-29 for the past three years, and South Carolina radioactive materials license number 940 for the past six years.

The correlating licenses are attached for your reference. Please feel free to contact me if you require any further information.

Respectfully,



Michele Carpenter-Sagona
Director of Operations

Attachments: Tennessee License R-90053-K20
Virginia License 000-571-1
Kentucky License 202-417-29
South Carolina License 940

Diagnostic Laboratories, LLC
Docket 030-38552 Control No. 577686
USNRC License # 41-31476-01

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TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH

William R. Snodgrass Tennessee Tower 312 Rosa L. Parks Avenue, 15th Floor Nashville, Tennessee 37243
615-532-0364

RADIOACTIVE MATERIAL LICENSE

Amendment 10

Pursuant to Tennessee Department of Environment and Conservation Regulations, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules and regulations of the Tennessee Department of Environment and Conservation and orders of the Division of Radiological Health, now or hereafter in effect and to any conditions specified below.

<p>LICENSEE</p> <p>1. Name Diagnostic Laboratories, LLC</p>		<p>3. License Number</p> <p>R-90053-K20</p>	
<p>2. Address 101 Dillon Court Gray, Tennessee 37615</p>		<p>4. Expiration Date</p> <p>November 30, 2020</p>	
		<p>5. File No.</p> <p>R-90053</p>	
<p>6. Radioactive Material (Element and Mass Number)</p>	<p>8. Chemical and/or physical form</p>	<p>9. Maximum Radioactivity and/or quantity of material which licensee may possess at any one time.</p>	
<p>SEE SUPPLEMENTARY SHEETS</p>			
<p>10. Authorized Use</p> <p style="text-align: center;">SEE SUPPLEMENTARY SHEETS</p>			

CONDITIONS

11. Unless otherwise specified, the authorized place of use is the licensee's address stated in Item 2 above.

For the Commissioner
Tennessee Department of Environment and Conservation

Date of Issuance: April 1, 2020

By:

Amy McKenna

Amy McKenna, Environmental Scientist 2
Division of Radiological Health



TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH
William R. Snodgrass Tennessee Tower 312 Rosa L. Parks Avenue, 15th Floor
Nashville, Tennessee 37243
615-532-0364

RADIOACTIVE MATERIAL LICENSE

Amendment 10

License No. R-90053-K20

S U P P L E M E N T A R Y S H E E T

6. Radioactive Material (Element and <u>Mass Number</u>)	8. Chemical and/or <u>Physical Form</u>	9. Maximum Radioactivity and/or Quantity of Material Which Licensee May <u>Possess at Any One Time</u>
A. Any radioactive material as permitted in Rule 0400-20-07- .40 of "State Regulations for Protection Against Radiation."	A. Any, except generators	A. As necessary for the uses authorized in Item 10.A.
B. Any radioactive material	B. As specified in "State Regulations for Protection Against Radiation." 0400-20- 07-.31.	B. As specified in "State Regulations for Protection Against Radiation." 0400-20- 07-.31.

10. Authorized Use

- A. Imaging and localization studies for which a written directive is not required.
(Rule 0400-20-07-.40 of "State Regulations for Protection Against Radiation).
- B. Calibration, reference, or transmission sources.
(Rule 0400-20-07-.31 of "State Regulations for Protection Against Radiation.")

Conditions (continued)

- 12. The licensee shall comply with applicable provisions of 0400-20-04, 0400-20-05, 0400-20-07, and 0400-20-10 of "State Regulations for Protection Against Radiation."



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DIVISION OF RADIOLOGICAL HEALTH
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RADIOACTIVE MATERIAL LICENSE

Amendment 10

License No. R-90053-K20

S U P P L E M E N T A R Y S H E E T

- 13. The Radiation Safety Officer for this license is Blaine J. Beining, CNMT.
- 14. Licensed material is only authorized for use by, or under the supervision of:
 - A. Individuals permitted to work as authorized users in accordance with "State Regulations for Protection Against Radiation" 0400-20-07-.13 and 0400-20-07-.14.
 - B. The following authorized users for the material and medical uses as specified:

All radioactive material authorized for this license:

- | | |
|-------------------------------|-------------------------------|
| Arthur F. Adams, M.D. | Zachary Jumper, M.D. |
| Arthur Rhett Austin, M.D. | Edson Knapp, M.D. |
| Daniel A. Baker M.D. | Jonathan V. Mai, M.D. |
| Jason R. Cameron, M.D. | Samuel L. Maynard, M.D. |
| Francis Gregory Curtin, M.D. | Hejung Press, M.D. |
| Diane L. Edge, M.D. | Kenneth H. Pryor, M.D. |
| Benjamin J. Enger, M.D. | Kris Saadeh, M.D. |
| Andrew Evancho, M.D. | Daniel W. Walsh, M.D. |
| Deanna Taylor-Gantte, M.D. | Gert van der Westhuizen, M.D. |
| Jack Hoffnung, M.D. | Lane P. Williams, M.D. |
| Joe Breese Johnson, Jr., M.D. | Ahmed Zaza, M.D. |

This supervision is not interpreted to be adequate to serve as preceptorship for the training of nuclear medicine physicians.

- 15. Radioactive material authorized by this license may be stored at 101 Dillon Court, Gray, Tennessee.
- 16. Radioactive material authorized by this license may be transported and used by the licensee for nuclear medicine operations at the location(s) specified below, all in accordance with the statements, representations, and procedures contained in the documents referenced in Condition 27 of this license:



TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH
William R. Snodgrass Tennessee Tower 312 Rosa L. Parks Avenue, 15th Floor
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RADIOACTIVE MATERIAL LICENSE

Amendment 10

License No. R-90053-K20

S U P P L E M E N T A R Y S H E E T

Laughlin Memorial Hospital
1420 Tusculum Boulevard
Greeneville, Tennessee 37745-5825

Veterans Affairs Medical Center
8033 Ray Mears Blvd.
Knoxville, Tennessee 37919

Morristown-Hamblen Healthcare
System
908 West North Street
Morristown, Tennessee 37814

Wellmont Bristol Regional Medical
Center
1 Medical Park Boulevard
Bristol, Tennessee 37620

Mountain States Health Alliance d/b/a
Indian Path Medical Center
2000 Brookside Drive
Kingsport, Tennessee 37660

Wellmont Holston Valley Medical
Center
130 West Ravine Road
Kingsport, Tennessee 37660

North Knoxville Medical Center
7565 Dannaher Drive
Powell, Tennessee 37849

Wellmont Holston Valley Medical
Center Outpatient Imaging Center
103 West Stone Drive
Kingsport, Tennessee 37660

Thompson Cancer Survival Center
LeConte Medical Center
710 Middle Creek Road
Sevierville, Tennessee 37682

- 17. A. Sealed sources authorized by this license shall be tested for leakage and/or contamination in accordance with "State Regulations for Protection Against Radiation" 0400-20-07-.32.
 - B. Records of leak tests shall be retained in accordance with "State Regulations for Protection Against Radiation" 0400-20-07-.111.
 - C. Tests for leakage and/or contamination shall be performed by persons authorized by this Department, the U.S. Nuclear Regulatory Commission, or another Agreement State to perform such services.
18. The licensee shall not open sealed sources containing radioactive material.



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DIVISION OF RADIOLOGICAL HEALTH
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RADIOACTIVE MATERIAL LICENSE

Amendment 10

License No. R-90053-K20

S U P P L E M E N T A R Y S H E E T

19. The licensee is authorized to hold radioactive material with a physical half-life of 120 days or less for decay-in-storage before disposal in ordinary trash provided:
 - A. Before disposal as ordinary trash, radioactive waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - B. A record of each disposal made under this condition shall be retained for three years. The record must include the date of disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
20. The licensee may use a shield device for performing linearity tests of his dose calibrator provided he or she follows the manufacturer's procedures for its use. These procedures shall be maintained for inspection by the Department.
21. Diagnostic instrumentation transported by the licensee shall be calibrated at each location of use prior to conducting nuclear medicine procedures.
22. The licensee shall maintain, for inspection by the Department, a daily log showing the preparation, administration, and disposition of radioactive material authorized by this license.
23. Radioactive material authorized by this license shall be used only in specifically designated areas at and/or inside each medical facility authorized in Condition 16.
24. The licensee shall at the conclusion of nuclear medicine procedures at each medical facility perform and document a contamination survey of the designated nuclear medicine area inside each facility. Any contamination shall be removed by the licensee.



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DIVISION OF RADIOLOGICAL HEALTH
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RADIOACTIVE MATERIAL LICENSE

Amendment 10

License No. R-90053-K20

S U P P L E M E N T A R Y S H E E T

25. The licensee shall furnish to the hospital staff a copy of instructions concerning handling of the patient after the licensee has left the premises.
26. No provision of this license relieves the licensee from compliance with other Federal, State, and local laws, ordinances, and regulations applicable to the licensee's activities.
27. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 8, and 9 of this license in accordance with statements, representations, and procedures contained in the following:
 - Application dated October 12, 2010, with attachments
 - E-mails dated April 16, 2015, with attachments, September 20, 2016, with attached Memorandum of Understanding, and September 20, 2016, with attached floor plan, March 12, 2020.
 - Letters dated November 9, 2010, with attachments, May 23, 2012, with attachments, June 6, 2012, with attachments, December 4, 2013, July 22, 2014, with attachments, March 25, 2015, with attachments, March 4, 2016, with attachment, and May 5, 2017, with attachments, and March 23, 2020, with attachments.



**COMMONWEALTH OF VIRGINIA
DEPARTMENT OF HEALTH**

RADIOACTIVE MATERIALS LICENSE

Under the Code of Virginia Section 32.1-229.3 and 12VAC5-481, Virginia Radiation Protection Regulations, and in reliance on statements and representations made by the licensee, a license is issued authorizing the licensee to receive, acquire, possess and transfer radioactive material designated below; to use the material for the purpose(s) and at the place(s) designated below; and to deliver or transfer the material to persons authorized to receive it in accordance with 12VAC5-481, Virginia Radiation Protection Regulations. This license is subject to all applicable rules and orders of the Virginia Department of Health now or hereafter in effect, and to any conditions specified below.

Licensee Name and Address		In accordance with letter dated February 19, 2018	
1. Diagnostic Laboratories, LLC 2. 101 Dillon Court Gray, TN 37615		3. License Number: 000-571-1 is hereby amended in its entirety.	
		4. Amendment No.: 5	
		5. Expiration Date: December 31, 2021	
6. Radioactive material	7. Chemical and/or physical form	8. Maximum amount of radioactive materials that the licensee may possess at any one time under this license:	9. Authorized Use:
A. Any radioactive material permitted by 12VAC5-481-1900	A. Any	A. As needed	A. Any uptake, dilution and excretion study permitted by 12VAC5-481-1900
B. Any radioactive material permitted by 12VAC5-481-1920	B. Any	B. As needed	B. Any imaging and localization study permitted by 12VAC5-481-1920

CONDITIONS

10. Licensed material may be delivered to the licensee's mobile van located at locations listed below only when trained licensee personnel are present to receive the licensed material. Licensed material may not be stored in the mobile van when trained licensee personnel are not present.
- A. Mountain View Regional Medical Center, 310 3rd Street NE, Norton, Virginia.
 - B. Norton Community Hospital, 100 15th Street NW, Norton, Virginia.
 - C. Wellmont Lonesome Pine Hospital, 1990 Holton Avenue, Big Stone Gap, Virginia.
 - D. Johnston Memorial Hospital, 16000 Johnston Memorial Avenue, Abingdon, Virginia.
 - E. Southwest Virginia Cancer Center, 671 Highway 58 East, Norton, Virginia.

RADIOACTIVE MATERIALS LICENSE

License Number: 000-571-1

Amendment No: 5

- F. Blue Ridge Isotopes, LLC, 1630 Midland Road, Salem, Virginia.
 G. New River Valley Medical Center, 2900 Lamb Circle, Christianburg, Virginia

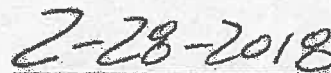
11. The Radiation Safety Officer for this license is Blaine J. Beining.
12. Licensed material is only authorized for use by, or under the supervision of the authorized users listed below:

<u>Authorized User</u>	<u>Material and Use</u>
Kathleen DePonte, M.D.	12VAC5-481-1900; 12VAC5-481-1920
Garland Thomas Haines, M.D.	12VAC5-481-1900; 12VAC5-481-1920
Manahanallur R. Ramakrishnan, M.D.	12VAC5-481-1900; 12VAC5-481-1920
John Richard Mullens, M.D.	12VAC5-481-1900; 12VAC5-481-1920
Jocelyn H. Medina, M.D.	12VAC5-481-1900; 12VAC5-481-1920
Donna Aubrey, M.D.	12VAC5-481-1900; 12VAC5-481-1920
Susan M. Sypolt, M.D.	12VAC5-481-1900; 12VAC5-481-1920
Jackson W. Kiser, M.D.	12VAC5-481-1900; 12VAC5-481-1920

13. The licensee is authorized to transport licensed material in accordance with the provisions of Chapter 481, Part XIII, 'Transportation of Radioactive Material.
14. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 12VAC5-481-450 C for establishing decommissioning financial assurance.
15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. Chapter 481 'Virginia Radiation Protection Regulations' shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated November 28, 2016.
 B. **Letter dated February 19, 2018.**

FOR THE VIRGINIA DEPARTMENT OF HEALTH


 SIGNATURE
 DIRECTOR, RADIOACTIVE MATERIALS PROGRAM


 DATE

CABINET FOR HEALTH SERVICES
COMMONWEALTH OF KENTUCKY
RADIOACTIVE MATERIAL LICENSE

PAGE 1

1. LICENSEE AND 2. ADDRESS

INVIVO MOLECULAR IMAGING
101 DILLON COURT
GRAY, TN 37615

ATTENTION: SCOTT HOLBROOK
TELEPHONE: 423-477-2440

PURSUANT TO KRS 211.842 ET SEQ., THE KENTUCKY CABINET FOR HUMAN
RESOURCES REGULATIONS, 902 KAR 100, AND IN RELIANCE ON STATEMENTS
AND REPRESENTATIONS HERETOFORE MADE BY THE LICENSEE, A LICENSE IS
HEREBY ISSUED TO RECEIVE, ACQUIRE, OWN, POSSESS AND TRANSFER
RADIOACTIVE MATERIAL LISTED BELOW; AND TO USE SUCH RADIOACTIVE
MATERIAL FOR THE PURPOSE(S) AND AT THE PLACE(S) DESIGNATED BELOW.
THIS LICENSE IS SUBJECT TO ALL APPLICABLE RULES, REGULATIONS, AND
ORDERS OF THE CABINET FOR HEALTH SERVICES, NOW OR HEREINAFTER IN
EFFECT AND TO ANY CONDITIONS SPECIFIED BELOW.

3. LICENSE NUMBER: 202-417-29
AMENDMENT NO. 6
4. EXPIRATION DATE: JULY 31, 2021
5. REVIEWER: 81

6. LICENSED MATERIAL 7. FORM 8. POSSESSION LIMIT
A. ANY BYPRODUCT MATERIAL PERMITTED BY 10 CFR 35.100 A. ANY A. AS NEEDED
B. ANY BYPRODUCT MATERIAL PERMITTED BY 10 CFR 35.200 B. ANY B. AS NEEDED

CABINET FOR HEALTH SERVICES
COMMONWEALTH OF KENTUCKY
RADIOACTIVE MATERIAL LICENSE

LICENSE NUMBER: 202-417-29

AMENDMENT 6

PAGE 2

9. AUTHORIZED USE

- A. FOR UPTAKE, DILUTION, AND EXCRETION STUDY PERMITTED BY 10 CFR 35.100.
 - B. FOR IMAGING AND LOCALIZATION STUDY PERMITTED BY 10 CFR 35.200.
-

CONDITIONS:

- 10. THE LICENSEE SHALL COMPLY WITH THE PROVISIONS OF THE KENTUCKY CABINET FOR HEALTH SERVICES ADMINISTRATIVE RADIATION REGULATIONS, 902 KAR 100.
- 11. COPIES OF RECORDS REQUIRED PURSUANT TO 902 KAR 100 OR CONDITIONS OF THE LICENSE SHALL BE MAINTAINED FOR INSPECTION BY THE CABINET AT THE MOBILE COACH
- 12. THIS LICENSE AND THE RIGHT TO POSSESS OR UTILIZE RADIOACTIVE MATERIAL GRANTED BY THIS LICENSE ISSUED UNDER 902 KAR CHAPTER 100 SHALL NOT BE TRANSFERRED, ASSIGNED, OR OTHERWISE DISPOSED OF, THROUGH TRANSFER OF CONTROL OF A LICENSE TO A PERSON UNLESS THE CABINET, AFTER SECURING FULL INFORMATION, FINDS THAT THE TRANSFER IS IN ACCORDANCE WITH THE REQUIREMENTS OF 902 KAR CHAPTER 100 AND GIVES ITS CONSENT IN WRITING IN ACCORDANCE WITH 902 KAR 100:040, SECTION 11.
- 13. RADIOACTIVE MATERIAL SHALL BE USED OR STORED AT:

BAPTIST OUTPATIENT DIAGNOSTIC CENTER
60 BRYAN BLVD., SUITE 100
CORBIN, KY 40701
- 14. LICENSED MATERIAL SHALL ONLY BE USED BY, OR UNDER THE SUPERVISION OF:
 - A. INDIVIDUALS PERMITTED TO WORK AS AN AUTHORIZED USER, AUTHORIZED MEDICAL PHYSICIST, AND AUTHORIZED NUCLEAR PHARMACIST IN ACCORDANCE WITH 10 CFR 35.13 AND 10 CFR 35.14 (902 KAR 100:072).
 - B. THE FOLLOWING INDIVIDUALS ARE AUTHORIZED USERS FOR MEDICAL USE AS INDICATED:

CABINET FOR HEALTH SERVICES
COMMONWEALTH OF KENTUCKY
RADIOACTIVE MATERIAL LICENSE

LICENSE NUMBER: 202-417-29

AMENDMENT 6

PAGE 3

AUTHORIZED USER:

MATERIAL AND USE:

902 KAR 100:072:

LONNIE JOSEPH BARGO, M.D.

10 CFR 35.100; 35.200

WILIAM T. DANIEL II, M.D.

10 CFR 35.100; 35.200

HAROLD W. REEDY, JR.

10 CFR 35.100; 35.200

15. THE RADIATION SAFETY OFFICER FOR THE ACTIVITIES AUTHORIZED BY THIS LICENSE IS BLAINE J. BEINING .
16. TESTS FOR LEAKAGE AND/OR CONTAMINATION SHALL BE PERFORMED BY PERSONS SPECIFICALLY AUTHORIZED BY THE CABINET, U.S. NUCLEAR REGULATORY COMMISSION, OR AN AGREEMENT STATE.
17. SEALED SOURCES CONTAINING RADIOACTIVE MATERIAL SHALL NOT BE OPENED.
18. THE LICENSEE SHALL CONDUCT A PHYSICAL INVENTORY AT LEAST EVERY SIX (6) MONTHS TO ACCOUNT FOR ALL SEALED SOURCES AND/OR DEVICES RECEIVED AND POSSESSED UNDER THE LICENSE. THE RECORDS OF THE INVENTORIES SHALL BE MAINTAINED FOR THREE (3) YEARS FROM THE DATE OF THE INVENTORY FOR INSPECTION BY THE CABINET, AND SHALL INCLUDE THE MODEL NUMBER OF EACH SOURCE, SERIAL NUMBER IF ONE HAS BEEN ASSIGNED, THE IDENTITY OF EACH SOURCE BY RADIONUCLIDE AND ITS NOMINAL ACTIVITY, THE LOCATION OF EACH SOURCE, THE DATE OF THE INVENTORY, AND THE NAME OF THE INDIVIDUAL WHO PERFORMED THE INVENTORY.
19. IN ADDITION TO THE POSSESSION LIMITS IN ITEM 8, THE LICENSEE SHALL FURTHER RESTRICT THE POSSESSION OF RADIOACTIVE MATERIAL TO QUANTITIES BELOW THE MINIMUM LIMIT SPECIFIED IN 902 KAR 100:042, SECTION 11, 12 AND 13 FOR ESTABLISHING DECOMMISSIONING FINANCIAL ASSURANCE.
20. EXCEPT AS SPECIFICALLY PROVIDED OTHERWISE IN THIS LICENSE, THE LICENSEE SHALL CONDUCT ITS PROGRAM IN ACCORDANCE WITH THE STATEMENTS, REPRESENTATIONS, AND PROCEDURES CONTAINED IN THE DOCUMENTS, INCLUDING ANY ENCLOSURES, LISTED BELOW. THE CABINET FOR HEALTH SERVICES REGULATIONS, 902 KAR 100, SHALL GOVERN UNLESS STATEMENTS, REPRESENTATIONS, AND PROCEDURES IN THE LICENSEE'S APPLICATION AND CORRESPONDENCE ARE MORE RESTRICTIVE THAN THE REGULATION.

CABINET FOR HEALTH SERVICES
COMMONWEALTH OF KENTUCKY
RADIOACTIVE MATERIAL LICENSE

LICENSE NUMBER: 202-417-29

AMENDMENT 6

PAGE 4

- A. APPLICATION DATED FEBRUARY 24, 2011, SIGNED BY WARE MITCHELL, RSO.
- B. LETTERS DATED:
1. JULY 5, 2012, SIGNED BY WARE MITCHELL, RSO (ADD AUTHORIZED USERS).
 2. JULY 30, 2015, SIGNED BY D. SCOTT HOLBROOK, PARTNER, TRANSFEROR AND RICHARD L. VAN SANT, DIRECTOR, TRANSFEREE (TRANSFER OF CONTROL).
 3. MAY 5, 2017, SIGNED BY WARE MITCHELL, PHARM.D., RSO (CHANGE OF RSO).



MANAGER
RADIATION HEALTH BRANCH

ERIC C. FRIEDLANDER

SECRETARY
CABINET FOR HEALTH AND FAMILY
SERVICES

DATE ISSUED JUNE 12, 2020

**SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
RADIOACTIVE MATERIAL LICENSE**

Pursuant to the Atomic Energy and Radiation Control Act, Section 13-7-40 et.seq. of S.C. Code of Laws of 1976, as amended, and Supplements thereto, and the South Carolina Department of Health and Environmental Control Regulation 61-63, Radioactive Material (Title A), and in reliance on statements and representations heretofore made by the applicant, a license is hereby issued authorizing the licensee to receive, acquire, possess and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules and regulations of the South Carolina Department of Health and Environmental Control now or hereafter in effect and to any conditions specified below.

Amendment No. 01 amends

LICENSEE		3. License Number:
1. Name:	Diagnostic Laboratories, LLC	940 in its entirety
2. Address:	101 Dillon Court Gray, TN 37615	4. Expiration Date: February 28, 2023
5. Radioactive Material (Element & Mass No.)	6. Chemical and/or Physical Form	7. Maximum Radioactivity and/or quantity of material which licensee may possess at any one time.
A. Any radioactive material identified in RHA 4.35, Part IV, Department Regulation 61-63.	A. Any radiopharmaceutical identified in RHA 4.35, Department Regulation 61-63.	A. As needed.
B. Any radioactive material identified in RHA 4.37, Part IV, Department Regulation 61-63.	B. Any radiopharmaceutical identified in RHA 4.37, Department Regulation 61-63, except radioactive gases.	B. As needed.
C. Fluorine-18	C. Any	C. 1000 millicuries
D. Carbon-11	D. Any	D. 1000 millicuries
E. Oxygen-15	E. Any	E. 1000 millicuries
F. Nitrogen-13	F. Any	F. 1000 millicuries
8. Authorized Use:		
A. For use in uptake, dilution and excretion studies as described in RHA 4.35, Department Regulation 61-63.		
B. For use in imaging and localization studies as described in RHA 4.37, Department Regulation 61-63.		
C. through F. For use in imaging and localization studies as described in RHA 4.37, Department Regulation 61-63.		

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
Radioactive Material License
Supplementary Sheet

License No. 940
 Amendment No. 01

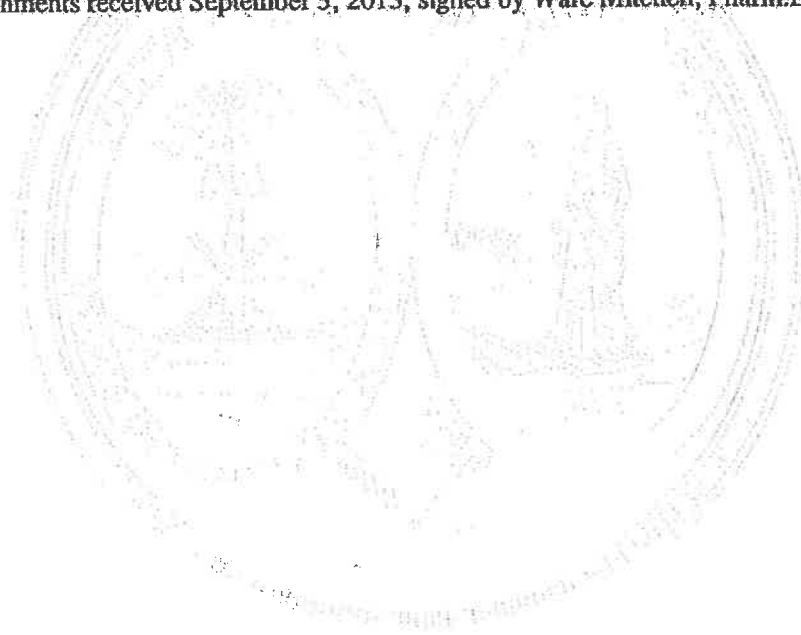
Conditions

9. Radioactive material may be used at AnMeds Health Medical Center, 800 North Fant Street, Anderson, SC, 29621, AnMeds Women and Children's Hospital, 2000 East Greenville Street, Anderson, SC 29621, and Bon Secours St. Francis Eastside, 125 Commonwealth Drive, Greenville, SC 29615, in accordance with RHA 4.11, Department Regulation 61-63. The licensee shall comply with the requirements of RHA 4.33, Department Regulation 61-63. The licensee shall maintain all applicable records for inspection by the Department at AnMeds Women and Children's Hospital, 2000 East Greenville Street, Anderson, SC 29621. Authorization for use of radioactive materials at job sites in other Agreement States shall be obtained from the appropriate State regulatory agency.
10. Radiation Safety Officer: Ware Mitchell, Pharm.D.
 Alternate Radiation Safety Officer: James T. Davis, R.Ph.
11. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as authorized users, authorized nuclear pharmacists, and/or authorized medical physicists in accordance with RHA 4.8 and RHA 4.9, Department Regulation 61-63.
- B. The following individuals are authorized users for the material and medical uses indicated:
- AnMed Health Medical Center and AnMed Women and Children's Hospital:
- | | <u>Material and Use</u> |
|-------------------------|---|
| David J. Holt, M.D. | RHA 4.35, RHA 4.37, Department Regulation 61-63 |
| Joseph W. Yori, M.D. | RHA 4.35, RHA 4.37, Department Regulation 61-63 |
| Veena Rani Mathur, M.D. | RHA 4.35, RHA 4.37, Department Regulation 61-63 |
- Bon Secours St. Francis Eastside:
- | | <u>Material and Use</u> |
|-----------------------------|---|
| James B. Haswell, M.D. | RHA 4.35, RHA 4.37, Department Regulation 61-63 |
| Paul D. Kountz, Jr., M.D. | RHA 4.35, RHA 4.37, Department Regulation 61-63 |
| William T. Joyce, III, M.D. | RHA 4.35, RHA 4.37, Department Regulation 61-63 |
12. In addition to the possession limits in Item 7. of this license, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in Table 1: Radionuclides of Concern, and to quantities below the minimum limit specified in RHA 1.15, Department Regulation 61-63, for establishing decommissioning financial assurance.
13. At least one authorized user listed on this license shall be within a three-hour travel time of the nuclear medicine facility when it is in use within the State of South Carolina.
14. The Radiation Safety Officer shall be physically present to review the supervised individual's use of radioactive material at least once every 30 days. Records shall be maintained for Department review.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
Radioactive Material License
Supplementary Sheet

License No. 940
Amendment No. 01

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15. Radioactive material shall be transported in accordance with requirements of RHA 2.22 - Transportation of Radioactive Materials, Department Regulation 61-63, Title A.
16. Except as specifically provided otherwise in this license and except as provided by RHA 4.14, Department Regulation 61-63, the licensee shall conduct his program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures listed below. The Department's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated January 3, 2013, signed by Ware Mitchell, Pharm.D.
 - B. Additional information letter dated January 24, 2013, signed by Ware Mitchell, Pharm.D.
 - C. Letter with attachments received September 3, 2013, signed by Ware Mitchell, Pharm.D.



For the South Carolina Department
of Health and Environmental Control

By: _____

Aaron A. Gantt
Aaron A. Gantt, Chief
Bureau of Radiological Health

Date of Issuance: September 20, 2013

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
Radioactive Material License
Supplementary Sheet

License No. 940
Amendment No. 02

Diagnostic Laboratories, LLC
101 Dillon Court
Gray, TN 37615

In accordance with correspondence dated August 26, 2014, received from Ware Mitchell, S.C. Radioactive Material License No. 940 is hereby AMENDED:

TO CHANGE:

Condition 9.

9. Radioactive material may be used at AnMeds Health Medical Center, 800 North Fant Street, Anderson, SC, 29621, AnMeds Women and Children's Hospital, 2000 East Greenville Street, Anderson, SC 29621, Bon Secours St. Francis Eastside, 125 Commonwealth Drive, Greenville, SC 29615, and Bon Secours St. Francis Millennium, 104 Innovation Drive, Greenville, SC 29615, in accordance with RHA 4.11, Department Regulation 61-63. The licensee shall comply with the requirements of RHA 4.33, Department Regulation 61-63. The licensee shall maintain all applicable records for inspection by the Department at AnMeds Women and Children's Hospital, 2000 East Greenville Street, Anderson, SC 29621. Authorization for use of radioactive materials at job sites in other Agreement States shall be obtained from the appropriate State regulatory agency.

TO CHANGE:

Condition 10.

10. Radiation Safety Officer: Ware Mitchell, Pharm.D.
Alternate Radiation Safety Officer: Blaine J. Beining, CNMT

Date of Issuance: September 3, 2014

For the South Carolina Department
of Health and Environmental Control

BY: 

Aaron A. Gant, Chief
Bureau of Radiological Health

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
Radioactive Material License
Supplementary Sheet

License No. 940
Amendment No. 03

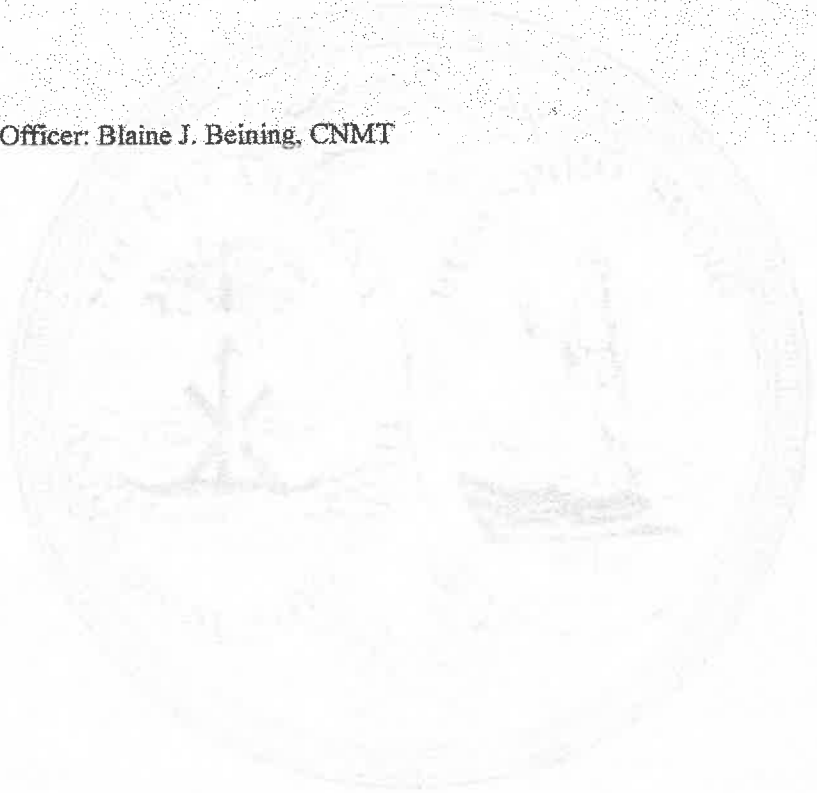
Diagnostic Laboratories, LLC
101 Dillon Court
Gray, TN 37615

In accordance with correspondence dated May 5, 2017, received from Ware Mitchell, S.C. Radioactive Material License No. 940 is hereby AMENDED:

TO CHANGE:

Condition 10.

10. Radiation Safety Officer: Blaine J. Beining, CNMT



Date of Issuance: May 25, 2017

For the South Carolina Department
of Health and Environmental Control

BY: 

Aaron A. Gantt, Chief
Bureau of Radiological Health

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
Radioactive Material License
Supplementary Sheet

License No. 940
Amendment No. 04

Diagnostic Laboratories, LLC
101 Dillon Court
Gray, TN 37615

In accordance with letter dated October 29, 2019, signed by Blaine J. Beining, S.C. Radioactive Material License No. 940 is hereby AMENDED:

TO CHANGE:

Condition 9.

9. Licensed material may be used at temporary job sites of the licensee anywhere in South Carolina where the Department maintains jurisdiction for regulating the use of licensed material.

TO CHANGE:

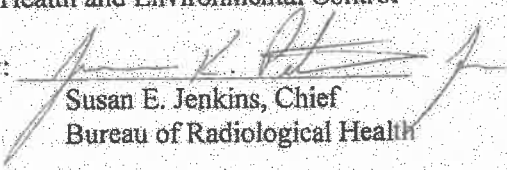
Condition 11.

11. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as authorized users, authorized nuclear pharmacists, and/or authorized medical physicists in accordance with RHA 4.8 and RHA 4.9, Department Regulation 61-63.
 - B. The following individuals are authorized users for the material and medical uses indicated:

	<u>Material and Use</u>
David J. Holt, M.D.	RHA 4.35; RHA 4.37
Veena Rani Mathur, M.D.	RHA 4.35; RHA 4.37
James B. Haswell, M.D.	RHA 4.35; RHA 4.37
Paul D. Kountz, Jr., M.D.	RHA 4.35; RHA 4.37
William T. Joyce, III, M.D.	RHA 4.35; RHA 4.37
Thomas Alex Tuten, M.D.	RHA 4.37
Samuel Carey Venturella, M.D.	RHA 4.37

For the South Carolina Department
of Health and Environmental Control

Date of Issuance: November 21, 2019

By: 
Susan E. Jenkins, Chief
Bureau of Radiological Health