



Davis Memorial Hospital
Where Your Care Counts.

NMSSB1

January 25, 2008

U.S. Nuclear Regulatory Commission
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, PA 19406

03029484

RECEIVED
REGION 1
2008 JAN 30 AM 9:26

RE: NRC License Number 47-24864-01- Notification

To Whom It May Concern:

We wish to notify NRC that the following two individuals have been permitted to use radioactive materials at our hospital for the uses they are presently authorized on RAM licenses from other institutions:

(1) Randall Blackburn, D.O.

Dr. Blackburn is listed as an authorized user on the Commonwealth of Kentucky Radioactive Material License No. 202-120-26 for the uses of I-131 (for treatment of hyperthyroidism and thyroid cancer), P-32 (for treatment of polycythemia vera, leukemia, and bone metastases and intracavitary treatment of malignant effusions), Sr-89 and Sm-153 (for treatment of pain from bone metastases); and I-125 (for interstitial treatment of cancer). A copy of Commonwealth of Kentucky RAM license is attached.

Dr. Blackburn is also listed as an authorized user of HDR units on RAM license No. GA 1178-1 issued to Atlanta Oncology Associates, P.C. by Georgia Department of Natural resources. A copy of this license is attached.

(2) Jagdish P. Bhatnagar, Sc.D., F.A.C.R.

Dr. Bhatnagar is an authorized medical physicist at West Virginia University Hospital (NRC Broad scope License No. 47-23066-02). A copy of the memorandum from RSO, Dr. Nasser Razmianfar, authorizing the use of the following radioactive sources is attached.

Sincerely,

D. Parker Haddix,
Chief Operating Officer

DPH/ald

Attachments

141721

NMSS/RGN1 MATERIALS-002

CABINET FOR HEALTH SERVICES
COMMONWEALTH OF KENTUCKY
RADIOACTIVE MATERIAL LICENSE

PAGE 1

1. LICENSEE AND 2. ADDRESS

MURRAY-CALLOWAY CO HOSPITAL
803 POPLAR STREET
MURRAY, KY 42071

ATTENTION: ISSAC COE
TELEPHONE: 270-762-1103

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: 202-120-26
AMENDMENT NO. 44
4. EXPIRATION DATE: AUGUST 31, 2004
5. REVIEWER: 41

6. LICENSED MATERIAL	7. FORM	8. POSSESSION LIMIT
A. ANY RADIOACTIVE MATERIAL IDENTIFIED IN 902 KAR 100:073, SECTIONS 29 AND 31	A. ANY RADIOPHARMACEUTICAL IDENTIFIED IN 902 KAR 100:073, SECTIONS 29 AND 31	A. AS NECESSARY FOR USES AUTHORIZED IN SUBITEM 9.A. AT LOCATIONS SPECIFIED IN CONDITION 11. TOTAL GENERATOR INVENTORY NOT TO EXCEED 4.0 CURIES

CABINET FOR HEALTH SERVICES
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B. XENON 133	B. GAS	B. 100 MILLICURIES
C. IODINE 131	C. SODIUM IODIDE	C. 500 MILLICURIES
D. PHOSPHOROUS 32	D. SOLUBLE PHOSPHATE	D. 50 MILLICURIES
E. PHOSPHOROUS 32	E. COLLOID CHROMIC PHOSPHATE	E. 50 MILLICURIES
F. STRONTIUM 89	F. CHLORIDE (METASTRON)	F. 20 MILLICURIES
G. SAMARIUM 153	G. LEXIDRON (LIQUID)	G. 200 MILLICURIES
H. IODINE 125	H. SEEDS	H. 300 MILLICURIES
I. PALLADIUM 103	I. SEEDS	I. 300 MILLICURIES

9. AUTHORIZED USE

- A. MEDICAL USE AS DESCRIBED IN 902 KAR 100:073, SECTIONS 29 AND 31.
- B. PULMONARY VENTILATION STUDIES.
- C. TREATMENT OF HYPERTHYROIDISM AND THYROID CARCINOMA.
- D. TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES.
- E. INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.
- F. TREATMENT OF PAIN FROM BONE METASTASES.
- G. TREATMENT OF PAIN FROM BONE METASTASES.
- H. INTERSTITIAL TREATMENT OF CANCER.
- I. INTERSTITIAL TREATMENT OF CANCER.

CABINET FOR HEALTH SERVICES
COMMONWEALTH OF KENTUCKY
RADIOACTIVE MATERIAL LICENSE

LICENSE NUMBER: 202-120-26

AMENDMENT 44

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CONDITIONS:

10. THE LICENSEE SHALL COMPLY WITH THE PROVISIONS OF THE KENTUCKY CABINET FOR HEALTH SERVICES ADMINISTRATIVE RADIATION REGULATIONS, 902 KAR 100.
11. RADIOACTIVE MATERIAL SHALL BE USED ONLY AT THE LICENSEE'S ADDRESS STATED IN ITEM 2.
12. RADIOACTIVE MATERIAL LISTED IN ITEM 6 ABOVE IS AUTHORIZED FOR USE BY, OR UNDER THE SUPERVISION OF, THE FOLLOWING INDIVIDUAL(S) FOR THE MATERIALS AND USES INDICATED:

A. ROBIN MARK FLOYD, M.D. H. CASEY HINES, M.D. PRUE W. KELLY, M.D. WILLIAM R. WILSON, M.D.	A. MATERIALS IDENTIFIED IN 902 KAR 100:073, SECTIONS 29 AND 31; XE-133
B. RANDALL BLACKBURN, D.O. WILLIAM W. MCDONALD, M.D. MICHAEL MURRAY, M.D.	B. I-131, P-32, SR-89, SM-153; I-125 AND PD-103 SEEDS
13. THE RADIATION SAFETY OFFICER FOR THE ACTIVITIES AUTHORIZED BY THIS LICENSE IS ROBIN MARK FLOYD, M.D. .
14. SEALED SOURCES CONTAINING RADIOACTIVE MATERIAL SHALL NOT BE OPENED.
15. EXCEPT AS OTHERWISE SPECIFIED BY LICENSE CONDITION, RECORDS MAINTAINED PURSUANT TO KENTUCKY ADMINISTRATIVE REGULATIONS 902 KAR 100 MAY BE DISPOSED OF AFTER A PERIOD OF FIVE (5) YEARS OF THE RECORDED EVENT EXCEPT RECORDS OF RECEIPT, TRANSFER AND DISPOSAL OF RADIOACTIVE MATERIAL SHALL BE MAINTAINED IN ACCORDANCE WITH 902 KAR 100:040, SECTION 14 AND 902 KAR 100:073, SECTION 28. RECORDS OF PERSONNEL MONITORING SHALL BE MAINTAINED UNTIL DISPOSAL IS AUTHORIZED BY THE CABINET.
16. 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, FOR ESTABLISHING DECOMMISSIONING FINANCIAL ASSURANCE.

CABINET FOR HEALTH SERVICES
COMMONWEALTH OF KENTUCKY
RADIOACTIVE MATERIAL LICENSE

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17. 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.
- A. APPLICATION DATED AUGUST 11, 1999, SIGNED BY STUART POSTON, PRESIDENT/CEO.
- B. LETTERS DATED:
1. MARCH 5, 1999, SIGNED BY WILLIAM WILSON, M.D., RADIATION SAFETY OFFICER.
 2. MAY 28, 1999, SIGNED BY WILLIAM WILSON, M.D., RADIATION SAFETY OFFICER AND MARTY G. BOZARTH, MS, MEDICAL PHYSICIST.
 3. AUGUST 3, 1999, SIGNED BY MARTY G. BOZARTH, MEDICAL PHYSICIST.
 4. JANUARY 26, 2000, SIGNED BY SHAWN MYERS, CNMT.
 5. FEBRUARY 9, 2000, SIGNED BY SHAWN MYERS, CNMT.
 6. AUGUST 28, 2000, SIGNED BY SHAWN MYERS, CNMT AND WILLIAM R. WILSON, M.D., RSO.
 7. OCTOBER 3, 2000, SIGNED BY SHAWN MYERS, CNMT AND WILLIAM R. WILSON, M.D., RSO.
 8. JULY 30, 2001, SIGNED BY ISAAC S. COE, CEO.
 9. JULY 26, 2002, SIGNED BY STEVE MEINERS, REGIONAL OFFICE MANAGER.
 9. JULY 26, 2002 (RECEIVED AUGUST 7, 2002), SIGNED BY FELIPE PATINO, JR., DIRECTOR OF RADIOLOGY AND MARK THOMPSON, ASSISTANT ADMINISTRATOR.



MANAGER
RADIATION HEALTH & TOXIC
AGENTS BRANCH

MARCIA R. MORGAN

SECRETARY
CABINET FOR HEALTH SERVICES

DATE ISSUED JULY 23, 2003

Atlanta Oncology Associates, P.C.
7820 Roswell Rd.
Atlanta, Ga. 30350

May 23, 2007

Lauren Palmer
Georgia Dept. of Natural Resources
4220 International Pkwy. Suite 100
Atlanta, Ga. 303Ei4

Dear Ms. Palmer:

Please find enclosed a notification to our radioactive material license (Ga. 1178-1 am.15) for Atlanta Oncology Associates, P.C. to permit the following:

14b. Add the following physician as an Authorized User:

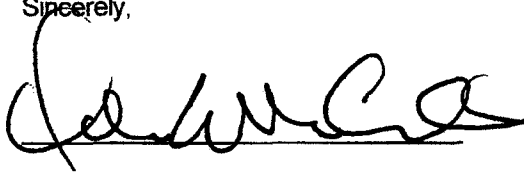
R. Randall Blackburn, D.O. see enclosed documents.

Dr. Blackburn has been employed by Atlanta Oncology Associates, P.C. for over 2 years and he is board certified by the Am. Osteopathic Board of Radiology in Radiation Oncology (see enclosed certificate #0988). Also enclosed is a preceptor by Dr. Dale McCord in his behave, as well as his resume and Georgia License.

If there are any questions or other supporting data required for this amendment, please don't hesitate to call me at 404-915-6806. Your immediate attention and response would greatly be appreciated.

8.
Dale L. McCord M.D., PresidentAOA

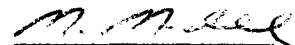
Sincerely,



"..

7L.

Peter
M.
Mondalek PhD., RSO



9.

American Professional Associates

Atlanta Oncology
Associates, P.C.
7820 Roswell Road
Atlanta, Georgia 30350
770-350-0126 770-512-
8937 Fax

Georgia Center for
Total Cancer Care
at Union General
750 Deep South Farm Road
Blairsville, Georgia 30512 706-
835-3030

Georgia Center for
Total Cancer Care
at Preston Ridge
3400B Old Milton Parkway
Alpharetta, Georgia 30005
770-442-1413

Georgia Center for
Total Cancer Care
at Gwinnett
698 Duluth Highway
Lawrenceville, Georgia 30045
770-962-8888

Georgia Center for
Total Cancer Care
Cowie's Clinic
1000 Cowie's Clinic Way
Magnolia Building Greensboro,
Georgia 30642 706-454-1624

Georgia Center for
Total Cancer Care at
Coliseum
308 Coliseum Drive
Macon, Georgia 31217
478-742-2278

Georgia Center for
Total Cancer Care at
Dan S. Maddock
Cancer Treatment Center
760 341 Boulevard
Hawkinsville, Georgia 31036
478-892-8585

Northlake Cancer
Treatment Center
1475 Montreal Road
Tucker, Georgia 30084
770-270-5085

Atlanta Medical Center
Radiation Therapy
320 Parkway NE
Atlanta, Georgia 30312
404-265-3521

Gulf Coast Cancer Institute
2100 State Avenue
Panama City, Florida 32405
850-763-0036

May 23, 2007

Ms. Lauren Palmer
Georgia Department of Natural Resources
Radioactive Materials Program
4244 International Parkway, Suite 114
Atlanta, GA 30354


RE: R. Randall Blackburn, D.O.

Dear Ms. Palmer:

Dr. Blackburn has been employed by Atlanta Oncology Associates for over two years. In that period of time he has observed many brachytherapy procedures. They are primarily prostate and GYN implants. Implants were done under the direct supervision of either Dr. Mark McCord or myself, as per our radioactive material license GA. 1178-1. This experience is in addition to brachytherapy experience, which he has accumulated during his residency program at the University of Iowa. In my opinion, he has met all state radioactive material license requirements and is fully qualified to be added to our AOA radioactive materials license to do HDR procedures.

If additional information is required, please contact my office at 770-350-0126.

ly,

 Yours Truly ~~~

Dal~ McCord, M.D.
President
Atlanta Oncology Associates, P.e.
DLM/tr

Georgia Department of Natural Resources

4220 International Parkway, Suite 100, Atlanta, Georgia 30354
 Noel Holenm!>, Commissioner Environmental Protection Division Dr. Carol A. Couch.
 Director (404) 362-2675

May 9, 2007

Peter M. Mondalek, Ph.D.
 Atlanta Oncology Associates, P.C.
 7820 Roswell Road
 Atlanta, Georgia 30350

Dear Dr. Mondafek:

In accordance with your request, I have amended your radioactive materials license, GA 1178-1. Please find enclosed Amendment Number .15. If I can be of any further service, please call me at (404) 362-2675.

Sincerely,



L- Lynn A. Palmer
 Principal Environmental Radiation Specialist
 Radioactive Materials Program

Georgia Department of Natural Resources

4220 International Parkway, Suite 100, Atlanta, Georgia 30354

NO.11 Holcomb, Commissioner Dr.
 Carol A. Couch, Director
 Environmental Protection Division
 404/382-2675

RADIOACTIVE MATERIALS PROGRAM GEORGIA RADIOACTIVE MATERIALS LICENSE

Pursuant to the Georgia Radiation Control Act O.C.G.A. 31-13 (H.R. 947) 1990 and the Georgia Department of Natural Resources Rules and Regulations, designated Chapter 391-3-17, and in reliance on statements and representations heretofore made, by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive, possess, and use the radioactive material(s) designated below; and to use such radioactive materials for the purpose(s) and in the place(s) designated below. This license is subject to all applicable federal and state regulations of the Georgia Department of Natural Resources and orders issued by the Department, now or hereafter in effect, and to any condition specified below.

Page 1 of 5 Pages
 License Number GA 1178-1
 Amendment Number, 15

License (1. Name and 2. Address)

Atlanta Oncology Associates, P.C.
 7820 Roswell Road
 Atlanta, Georgia 30350

3. In accordance with request dated May 4, 2007, License Number GA 1178-1 is amended in its entirety to read as follows;

4. Expiration Date: January 31, 2010

5. Telephone Number: (770) 270-5085
 Facsimile Number: (770) 436-1034

6. RADIOACTIVE MATERIAL (ELEMENT AND MASS NUMBER)

11. CHEMICAL AND/OR PHYSICAL FORM

8. MAXIMUM QUANTITY LICENSEE MAY POSSESS AT ANY ONE TIME

A. Iridium 192

A. Sealed Source (Models which are registered in accordance with Rule 391-3-17.02(11)(1) or equivalent regulations of the US NRC or another Agreement state)

A. 6 sources: three installed sources not to exceed 12 Curies per source, and three replacement sources in separate shipping containers not to exceed 13 Curies per source

B. strontium 90

R Sealed Source (IeN Tracerlab Model RA-1)

B. 50 millicuries

C. yttrium 90

C. Ibritumomab

C, 200 millicuries

D. Samarium 153

D. Lexidronam

D. 600 millicuries

Georgia Department of Natural Resources

Radioactive Materials License Supplementary Sheet

Page 2 of 5 Pages
License Number GA 1178-1
Amendment Number .15

9. AUTHORIZED USE

- A. For use in Nucletron Model 105,999 or MicroSelectron Classic mobile HDR remote afterloading brachytherapy units for interstitial, intracavitary, interluminal, and gynecological radiotherapy. One source in each unit; three sources in their shipping containers. to be in possession of the licensee as necessary for the replacement of the sources in the Nucletron Corporation mobile HDR remote afterloading units.
- B. For the treatment of superficial diseases of the eye.
- C. For the treatment of Hodgkin's Lymphoma, with the Zevalin regimen.
- D. For the treatment of bone metastases with The Quadromet regimen.

CONDITIONS

- 10. A. Radioactive material listed in 6.A shall be used at Northside Alpharetta Cancer Treatment Center, 3400-B Old Milton Parkway, Alpharetta, Georgia, 30202; Cancer Center of Gwinnett, 698 Duluth Highway, Lawrenceville, Georgia, 30245; Coliseum Radiation, Oncology, 308 Coliseum Drive, Macon, Georgia, 31217; Northlake Cancer Treatment Center, 1475 Montreal Road, Tucker, Georgia, 30084; Cancer Treatment Center at Union General, 750 Deep South Farm Road, Blairsville, Georgia, 30512; Cancer Treatment Center At Taylor Regional, 760341 Boulevard, Hawkinsville, Georgia, 31036; and at The Georgia Center for Total Cancer Care at Cowles Clinic, 1000 Cowles Clinic Way, Greensboro, Georgia, 30642 ..
- B. In addition, this condition authorizes licensed radioactive material listed in 6.A pertaining to one HDR unit and its replacement source for transportation in Georgia; this does not prohibit transportation in other Agreement States and States under the jurisdiction of the U.S. Nuclear Regulatory Commission under reciprocity procedures which may be established by an Agreement State or the U.S. Nuclear Regulatory Commission. The second HDR unit shall be permanently located at the Alpharetta address.
- C. Radioactive material listed in 6.8 shall be used at Northlake Cancer Treatment Center, 1475 Montreal Road, Tucker, Georgia, 30084; and at The Georgia Center for Total Cancer Care at Cowles Clinic, 1000 Cowles Clinic Way, Greensboro, Georgia, 30642.
- D. Radioactive material listed in 6.C and 6.D shall be used at Cancer Center of Gwinnett, 698 Duluth Highway, Lawrenceville, Georgia, 30245; Cancer Treatment Center at Union General, 750 Deep South Farm Road, Blairsville, Georgia, 30512; Coliseum Radiation Oncology, 308 Coliseum Drive, Macon, Georgia, 31217; and at The Georgia Center for Total Cancer Care at Cowles Clinic, 1000 Cowles Clinic Way, Greensboro, Georgia, 30642.

Georgia Department of Natural Resources

Radioactive Materials License Supplementary Sheet

Page 3 of 5 Pages
license Number GA 1178-1
Amendment Number .15

Conditions (Continued)

11. The licensee shall comply with the provisions of Georgia Department of Natural Resources Rule 391-3-17-.03, "Standards for Protection Against Radiation. Amended", Rule 391-3-17-.05, "Use of Radionuclides in the Healing Arts, Amended", Rule 391-3-17-.06, "Transportation of Radioactive Material. Amended", and Rule 391-3-17-.07, "Notice, Instructions and Reports to Workers: Inspection. Amended".
12. In accordance with DNR Board Policy adopted May 28, 2003 the fees associated with this license fee category, A.4, are:

Application fee	\$710.00	Annual fee	\$2400.00
Amendment fee	\$430.00	Non-routine Inspection fee	\$1500.00

Checks for the fees should be made payable to the Department of Natural Resources, Radioactive Materials Program, and mailed to the following address:

Radioactive Materials Fees P.O.
Box 101161

Atlanta, GA 30391

Mail license applications and amendment requests to the following address:

Radioactive Materials Program 4220
International Parkway, Suite 100 Atlanta,
GA 30354

All license applications, amendments and fee payments should be mailed the same day.

Annual fees are billed by the Department at the beginning of each fiscal year.

13. The Radiation Safety Officer in this program shall be Peter M. Mondalek.
14. Radioactive materials shall be used by:
 - A. Individuals permitted to work as an authorized user or authorized medical physicist in accordance with Rule 391-3-17-.05(10) and (11).

Georgia Department of Natural Resources

Radioactive Materials License Supplementary Sheet

Page 4 of 5 Pages
License Number GA 1178-1
Amendment Number .15

Condition 14 (Continued)

B. The following individuals are authorized users for medical use:

<u>Authorized User</u>	<u>Authorized Uses</u>
Henry D. Cline, M.D. Halvey	Iridium 192 and strontium 90
T. Simpson, M.D. Mark R.	Iridium 192 and strontium 90 Ir-192,
Williams, M.D. Jonathan	Sr-90, y-90, and Sm-153 Ir-192,
Barnes, M.D. Dale L.	Sr-90, y-90, and Sm-153 Ir-192,
McCord, M.D. Mark W.	Sr-90, Y-90, and Sm-153 Ir-192, Sr-
McCord, M.D., Mark	90. Y-90, and Sm-153 Ir-192, Sr-
Stephen Oun, M.D. Erich	90, V-90, and Sm-153 Ir-192, Sr-
G. Randolph, M.D. Kelly T.	90, Y-90, and Sm-153 Iridium 192
Drake, M.D.	and strontium 90 Iridium 192
Craig Wilkinson, M.D.	Ir-192, Sr-90, V-gO, and Sm-153
David Lowther, M.D.	Iridium 192
Hasan Murshed, M.D.	Ir-192, Sr-gO, Y-SO, and Sm-153
Angel Blanco, M.D.	

C. The following individuals are authorized medical physicists: Peter M. Mondalek, Ph.D., Susan D. Balsavage, M.S., Zhaowei Lai, Ph.D., Suran Chae, M.S. and Ishiuan Hargrove, M.S.

15. The licensee may receive, possess and use radioactive material for check. calibration, transmission, and reference sources as authorized by (32) of Rule 391-3-17-.05.
16. The licensee shall perform required tests for leakage or contamination at intervals not to exceed six (6) months in accordance with Rule 391-3-17-.03(6). Analysis of the tests shall be performed by persons specifically authorized by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform such services.
17. Sealed sources containing radioactive material shall not be opened by the licensee.
18. The licensee shall not transfer possession and/or control of materials or products containing radioactive material as a contaminant except:
 - A. By transfer of waste to an authorized recipient;
 - B. By transfer to a specifically licensed recipient; or
 - C. As provided otherwise by a specific condition of this license pursuant to the requirements of (13) of Rule 391-3-17-.03.
19. Documentation of training for Nuclear Medicine Technologists and Radiation Therapists outlined in Rule 391-3-17-.05(25) shall be maintained for Department inspection as required by Rule 391-3-17-.05(1 DO).

Georgia Department of Natural Resources **Radioactive Materials License Supplementary Sheet**

Page 5 of 5 Pages
 License Number GA 1178-1
 Amendment Number .15

Conditions (Continued)1

20. All records or copies of records pertaining to this license shall be maintained by the Radiation Safety Office at the address below:

Northlake Cancer Treatment Center
 1475 Montreal Road Tucker, Georgia
 30084
21. Patients who have been administered therapeutic quantities of radiopharmaceuticals shall be furnished with a patient information sheet supplied by the manufacturer (if applicable) or equivalent information on a hospital-generated information sheet. The "Instructions for Family of Released Patient" form, Appendix IV of NCRP Report 37, or its equivalent shall be provided to patients. Records of these instructions shall be kept on file for inspection by the Department
22. The licensee shall conduct a physical inventory every six months of sealed sources in accordance with Rule 391-3-17-.05(33)(d).
23. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash in accordance with Rule 391-3-17.05(40).
24. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the documents, including any enclosures and attachments, listed below:
 - A. Application dated January 11, 2005, and signed by Eric G. Randolph, M.D., Vice-President
 - R Facsimile dated January 24, 2005, and signed by Peter M. Mondalek, Ph.D., Director Medical Physics.
 - C. Facsimile dated January 29, 2005, and signed by Peter M. Mondalek, Ph.D., Director Medical Physics.
 - D. Letter dated January 23, 2007, and signed by Peter M. Mondalek, Ph.D., RSO, and by Dale L. McCord, M.D., President AOA.
 - E. Letter dated May 4, 2007, and signed by Peter M. Mondalek, Ph.D., RSO, and by Dale L. McCord, M.D., President ADA

This license condition does not limit the licensee's ability to make changes to the Radiation Protection Program as provided for in Rule 391-3-17-.05(16). The Georgia Department of Natural Resources' Regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the Regulations.

FOR THE DEPARTMENT OF NUCLEAR RESOURCES

DATE: May 9, 2007 BY: Lauren Ann Palmer

Official Use Only - Security-Related Information

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 7 PAGES
Amendment No. 26

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, 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 byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		In accordance with the letters dated May 18 and June 8, 2006, 3. License number 47-23066-02 is amended in its entirety to read as follows:
1. West Virginia University Hospitals, Inc.		
2. Medical Center, Box 9006 Morgantown, West Virginia 26506-9006		4. Expiration date December 31, 2011 5. Docket No. 03020233 Reference No.
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
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
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 3 curies
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed Sources	D. 4 curies
E. Iridium 192	E. Sealed Sources (Amersham Models ICW.1, ICW.12, and ICW.22)	E. 500 millicuries
F. Any byproduct material permitted by 10 CFR 31.11	F. Prepackaged Kits	F. 1 millicurie
G. Any byproduct material with atomic numbers 3 through 83 and half life less than 120 days	G. Any	G. 10 millicuries per radionuclide and 1 curie total

Official Use Only - Security-Related Information

Official Use Only - Security-Related Information

NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
47-23066-02

Docket or Reference Number
03020233

Amendment No. 26

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
H. Hydrogen 3	H. Any	H. 20 millicuries
I. Carbon 14	I. Any	I. 50 millicuries
J. Phosphorus 32	J. Any	J. 100 millicuries
K. Sulfur 35	K. Any	K. 100 millicuries
L. Chromium 51	L. Any	L. 100 millicuries
M. Iodine 125	M. Any	M. 100 millicuries
N. Iodine 131	N. Any	N. 100 millicuries
O. Americium 241	O. Sealed Sources (Amersham Model Dwg. ARC 10048B and 10040B)	O. 30 millicuries
P. Cesium 137	P. Sealed Sources (MDS Nordion Model C-3001)	P. 1524 curies per source and 3048 curies total
Q. Iridium 192 permitted by 10 CFR 35.600	Q. Sealed Sources (Varian Medical Systems Model VS2000)	Q. 13 curies per source and 23 curies total
R. Yttrium 90	R. Resin microspheres (Sirtex Medical Model SIR-Spheres)	R. 108 millicuries per vial and 540 millicuries total

9. Authorized use:

- A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
- B. Any imaging and localization study permitted by 10 CFR 35.200.
- C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300.
- D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
- E. Interstitial treatment of cancer.
- F. In vitro studies.

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- G. through N. Research and development as defined in 10 CFR 30.4. Calibration and checking of the licensee's instruments. In vitro studies. Instrument calibration.
- O. Storage incident to disposal
- P. For irradiation of materials in an MDS Nordion Gammacell 1000 Elite self shielded irradiator device that has been registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and which has been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess, and use the device.
- Q. One source for medical use permitted by 10 CFR 35.600, in a Varian-TEN Ltd. Model Varisource HDR remote afterloader unit. The source activity may not exceed 10 curies at the time of medical use. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.
- R. For manual brachytherapy use in the Sirtex Medical Limited SIR-Spheres delivery system.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Ruby Memorial Hospital, Mary Babb Randolph Cancer Center, and Health Sciences Center South Building, Medical Center Drive, Morgantown, West Virginia; and at Jefferson Memorial Hospital, 300 South Preston Street, Ranson, West Virginia.
11. The Radiation Safety Officer for this license is Nasser Razmanfar, Ed.D.
12. A. The use of licensed material in or on humans shall be by an authorized user as defined in 10 CFR 35.2.
- B. Individuals designated to work as authorized users, authorized nuclear pharmacists or authorized medical physicists, as defined in 10 CFR 35.2, shall meet the training, experience, and recentness of training criteria established in 10 CFR Part 35, and shall be designated, in writing, by the licensee's Radiation Safety Committee.
- C. Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.

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13. The licensee will comply with the requirements for "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern" (IC) (accession No. ML053130364) published in the Federal Register (FR) on December 1, 2005 (70 FR 72128) as Attachment B to EA-05-090, "Order Imposing Increased Controls," (accession No. ML053130218). The licensee will complete implementation of the IC requirements by the first day that radionuclides specified in Table 1, Radionuclides of Concern, (accession No. ML053130250) of the IC are possessed at or above the limits specified in the table. Notwithstanding any provisions of the Commission regulations to the contrary, all measures implemented or actions taken in response to the IC requirements shall be maintained until the Commission orders otherwise or until the Commission explicitly modifies its regulations to reflect increased controls, and states in modifying its regulations that the revisions are to supercede Order EA-05-090. The licensee shall notify the Director, Office of Federal and State Materials and Environmental Management Programs, USNRC, Washington, DC, 20555, in writing, within 25 days after it has completed the requirements of this condition. In addition, licensee responses applicable to this license condition shall be marked as "Withhold From Public Disclosure Under 10 CFR 2.390."
14. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
15. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of the license.
16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
17. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
- A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
 - B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
 - C. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

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- D. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- E. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
- F. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- G. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2); and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
- H. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- I. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
18. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
19. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

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20. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.
- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
21. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
- A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
- B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
- C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
22. The licensee shall not repair, remove, replace, or alter any of the following electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, or any component that may affect safe operation of the irradiator. These activities shall be performed by a person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
23. The procedures contained in the manufacturer's instruction manual for the irradiator authorized by this license shall be followed, and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.
24. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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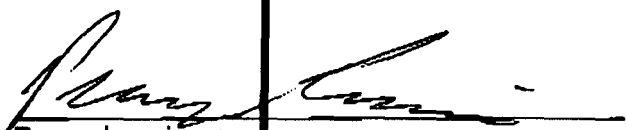
25. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Letter dated November 20, 1991 [ML020180117]
- B. Application dated February 25, 1992 [ML020180118]
- C. Letter dated March 6, 1992 [ML020180115]
- D. Letter dated May 12, 1992 [ML020180110]
- E. Letter dated January 3, 1995 [ML020180092]
- F. Letter dated April 16, 1997, enclosing Radiation Safety Manual revised December 1996 [ML012620243]
- G. Letter dated November 30, 2000 [ML003774597]
- H. Letter dated June 26, 2001 [ML011800169]
- I. Letter dated March 27, 2002 [ML020980484]
- J. Application dated November 21, 2005 [ML053290270]
- K. Letter dated January 13, 2006 [ML060480448]
- L. Letter dated February 14, 2006 [ML060740690]
- M. Letter dated August 8, 2006 [ML062200477]
- N. Letter dated September 18, 2007 [ML072620470]
- O. Facsimile dated October 4, 2007

For the U.S. Nuclear Regulatory Commission

Date October 5, 2007

By



Penny Lanzisera
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406
Friday, October 05, 2007 12:09:30 PM

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West Virginia University
ROBERT C. BYRD HEALTH SCIENCES CENTER

COPY

MEMORANDUM

TO: Jagdish P. Bhatnager, Sc.D.
Radiology
Radiation Oncology
PO Box 8150

FROM: Nasser Razmianfar
Director/RSO

DATE: December 2, 2002

RE: Permanent Authorization for Use of Radionuclides in Human Subjects

I would like to formally notify you that your application requesting permission to use radionuclides under the WVU Hospital, Inc. (License #47-23066-02) was ratified by the Human Use of Radiation and Radionuclides Committee at its meeting on October 24, 2002. Your temporary authorization has been upgraded to permanent as a user of radioactive materials and devices (PI/AU). Any modifications to this approval should be addressed in writing to the Radiation Safety Officer.

Your authorization is for the following radionuclides:

- 1) Ir-192 (HDR)
- 2) Ir-192 (LDR)
- 3) I-125
- 4) Cs-137
- 5) Pd-103
- 6) Sr-90/Y-90

Thank you.

Xc: Human Use of Radiation and Radionuclides Committee

Phone: 304-293-3413
Fax: 304-293-4529

Radiation Safety
G-139 Health Sciences North
PO Box 9006
Morgantown, WV 26506-9006

Equal Opportunity/Affirmative Action Institution

This is to acknowledge the receipt of your letter/application dated

1/25/2008, and to inform you that the initial processing which includes an administrative review has been performed.

☒ AMEND. 47-24864-01
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 141720.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.