

November 29, 2016

Region IV
U.S. Nuclear Regulatory Commission
DNMS/NMSB-B
1600 E. Lamar Boulevard
Arlington, TX 76011-4511

RECEIVED
DEC 1 2016

DNMS

Dear State Regulator:

We, DMS Health Technologies, wish to amend our Radioactive Material License number 40-32477-01 to conduct the following:

- Add the following physicians under condition 12.B.;
 - Richard M. Levey, M.D. for material and use of 35.100 and 35.200. Enclosed is DMS Health Technologies Pennsylvania Radioactive Material license number 1006 with Dr. Levey on as an Authorized User under condition 13.B.
 - Timothy G. Raveill, M.D. for material and use of 35.100 and 35.200. Enclosed is Liberty Hospital's Radioactive Material License number 24-16178-01 with Dr. Raveill on as an Authorized User under condition 12.B.
 - Randall C. Newth, M.D. for material and use of 35.100 and 35.200. Enclosed is Liberty Hospital's Radioactive Material License number 24-16178-01 with Dr. Newth on as an Authorized User under condition 12.B.
 - Michael P. Green, D.O. for material and use of 35.100 and 35.200. Enclosed is Liberty Hospital's Radioactive Material License number 24-16178-01 with Dr. Green on as an Authorized User under condition 12.B.
 - Joseph Careslo, M.D. for material and use of 35.100 and 35.200. Enclosed is Liberty Hospital's Radioactive Material License number 24-16178-01 with Dr. Careslo on as an Authorized User under condition 12.B.
 - John Brian Hope, M.D. for material and use of 35.100 and 35.200. Enclosed is Liberty Hospital's Radioactive Material License number 24-16178-01 with Dr. Hope on as an Authorized User under condition 12.B.
- Delete the following physicians from under condition 12.B.;
 - Robert C. Newth, M.D.,
 - Robert A. MacNaughton, II, M.D.,
 - Christine Keelsing, M.D.

PUBLIC

- ☐ Immediate Release
☒ Normal Release

NON-PUBLIC

- ☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other:

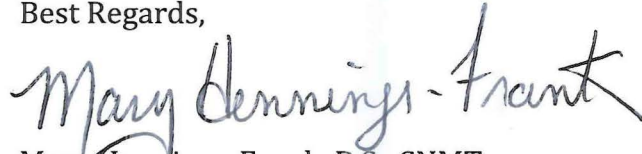
Reviewer: Reed

Date: 12-7-16

No. 592429

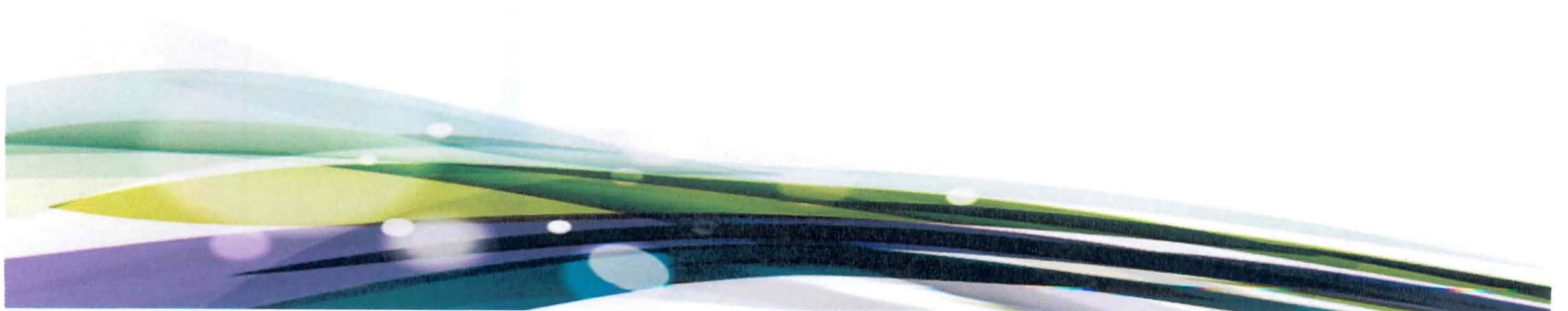
If you have questions please feel free contact me at 605-357-2612 or e-mail
mary.hennings-frank@dmshealth.com.

Best Regards,



Mary Hennings-Frank, B.S., CNMT
Radiation Safety Officer
DMS Health Technologies

Enclosed: Liberty Hospital RML 24-16178-01
 DMS Pennsylvania RML 1006



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, 37, 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 1. Liberty Hospital Nuclear Medicine Department 2. 2525 Glenn W. Hendren Drive Liberty, MO 64069-1002	In accordance with the letter dated July 30, 2015, 3. License number 24-16178-01 is amended in its entirety to read as follows: 4. Expiration date April 30, 2021 5. Docket No. 030-10532 Reference No.
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- | | | |
|--|---|---|
| 6. Byproduct, source, and/or special nuclear material

A. Any byproduct material permitted by 10 CFR 35.100

B. Any byproduct material permitted by 10 CFR 35.200

C. Any byproduct material permitted by 10 CFR 35.300

D. Palladium-103, permitted by 10 CFR 35.400

E. Depleted Uranium | 7. Chemical and/or physical form

A. Any

B. Any

C. Any

D. Sealed Sources (Theragenics Corporation Model TheraSeed 200)

E. Stainless steel covered metal | 8. Maximum amount that licensee may possess at any one time under this license

A. As needed

B. As needed

C. 1 curie

D. 1 curie

E. 4 shields, not to exceed 12 kilograms each |
|--|---|---|

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. Shielding in ADAC Laboratories MCD-AC attenuation correction system.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
24-16178-01Docket or Reference Number
030-10532**Amendment No. 46**CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 2521 Glenn W. Hendren Drive, Liberty, Missouri and 2525 Glenn W. Hendren Drive, Liberty, Missouri.
11. The Radiation Safety Officer for this license is Joseph Caresio, M.D.
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical use as indicated:

Authorized UsersMaterial and Use

Robert C. Newth, M.D.

10 CFR 35.100, 35.200, and 35.300.

Robert A. MacNaughton, II, M.D.

10 CFR 35.100, 35.200, and 35.300.

Richard A. Morrison, M.D.

10 CFR 35.400.

Gordon D. Stillie, M.D.

10 CFR 35.400.

Scott C. Cozad, M.D.

10 CFR 35.400.

John I. Halloran, M.D.

10 CFR 35.100, 35.200, and 35.300.

Timothy G. Raveill, M.D.

10 CFR 35.100 and 35.200.

Randall C. Newth, M.D.

10 CFR 35.100 and 35.200.

Michael P. Green, D.O.

10 CFR 35.100 and 35.200.

Joseph Caresio, M.D.

10 CFR 35.100 and 35.200.

John Brian Pope, M.D.

10 CFR 35.100, 35.200, and 35.300 (limited to oral administration of sodium iodide iodine-131).

Arnold Pollak, M.D.

10 CFR 35.200.

Dwarakraj Soundarraaj, M.D.

10 CFR 35.200.

Christine Keesling, M.D.

10 CFR 35.100, 35.200, and 35.300.

Daniel H. Dunker, M.D.

10 CFR 35.100 and 35.200.

Martina Milcevic, M.D.

10 CFR 35.200.

13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
24-16178-01Docket or Reference Number
030-10532**Amendment No. 46**

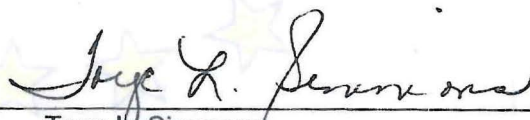
14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are 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. Application dated September 27, 2010 (ML102780663)
- B. Facsimile dated March 16, 2011 (ML110750577)
- C. Facsimile dated March 17, 2011 (ML110760650)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date OCT 29 2015

By

Toye L. Simmons
Materials Licensing Branch
Region III



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF RADIATION PROTECTION

Page 1 of 4 Pages

License No. PA - 1006

RADIOACTIVE MATERIALS LICENSE

Amendment No. 15

Pursuant to the Radiation Protection Act, the Act of July 10, 1984 (No. 147, P.L. 688)(35 P.S. §§ 7110.101 – 7110.703) and Title 25. Rules and Regulations, Article V. Radiological Health of the Pennsylvania Department of Environmental Protection, and in reliance on statements and representations heretofore Licensee to receive, acquire, possess, transfer, and use radioactive material listed below for the purposes and at the places designated below. This license shall be deemed subject to all applicable rules, regulations, or orders of the Pennsylvania Department of Environmental Protection now or hereafter in effect and to any conditions specified below.

Licensee	In response to correspondence dated April 12, 2016
1. DMS Health Technologies	3. License No. PA – 1006 is amended as follows:
2. 109 South Petro Avenue Sioux Falls, SD 57107	4. Expiration Date: July 31, 2017
	5. Client ID: 257378 Program Code: 2220 Priority: 3

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. Fluorine-18	A. Any	A. As needed

9. Authorized use:

- A. Human use, imaging and localization studies.

CONDITIONS

10. Licensed material may be used at temporary job sites established at client facilities in Pennsylvania. This condition does not prohibit use in an area of exclusive federal jurisdiction or in another State, when approved by the appropriate competent federal or State authority for that venue.
11. The Radiation Safety Officer for this license is: Mary Hennings-Frank.
12. The license is authorized to provide PET imaging services to client facilities in Pennsylvania with a Pennsylvania Radioactive Material License provided services are performed in accordance with 10 CFR 35.80 in its entirety.
13. Licensed Material in item 6 is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for the materials and uses indicated:

Authorized Users	Material and Use
Terri-Ann Gizienski, M.D.	Fluorine-18
Ashima Lall, M.D.	Fluorine-18

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<u>Authorized Users</u>	<u>Material and Use</u>
Richard M. Levey, M.D.	Fluorine-18
Frank Madonna, M.D.	Fluorine-18
Richard A. Pica, M.D.	Fluorine-18
Terry D. Shaffer, M.D.	Fluorine-18
Albert B. Shaw, M.D.	Fluorine-18
Theodore C. Whitford, M.D.	Fluorine-18

14. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210.
- B. 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, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- C. Sealed sources in storage need not be tested if they 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.
- D. 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 Department 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 Department regulations.
- E. 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 to perform such services.
- F. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
15. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the Bureau, 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.

17. Before moving a trailer to a new location, the licensee shall conduct a physical inventory at the conclusion of activities at each site to account for all sources and/or devices received and possessed under the license which were at the site. The licensee shall remove any sealed sources, unused radiopharmaceuticals and associated waste under this license from temporary job sites. A confirmatory survey shall be recorded for each area of use and retained for 3 years.
18. A copy of the latest sealed source leak test results and emergency procedures shall be available for inspection at temporary job sites.
19. The licensee is authorized to hold licensed material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if it:
 - A. Monitors licensed 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 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.
20. The Department shall be notified at least 72 hours in advance of the licensee's arrival at temporary job sites. Notification shall include the locations, the expected durations and a means of contacting licensee personnel at the sites.
21. The licensee may transport licensed material, or deliver licensed material to a carrier for transport, in accordance with 25 PA Code Chapter 230, "Packaging and Transportation of Radioactive Material" and the provisions of 10 CFR Part 71 incorporated by reference.
22. 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 and incorporated by reference in 10 CFR 30.35(d) for establishing financial assurance for decommissioning relative to isotopes with half life greater than 120 days.
23. Notwithstanding the requirements set forth in this license, the license shall comply with the regulations set forth in Title 25 of the Pennsylvania Code Article V "Radiological Health" and the U.S. Nuclear Regulatory Commission, Title 10 Code Of Federal Regulations Parts 19-150 incorporated by reference.

24. 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 Department of Environmental Protection's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. License application dated June, 14 2007 and supporting documentation dated June 29, 2007
- B. Letter dated December 8, 2008
- C. Letter dated January 24, 2011 (DEP)
- D. Letters dated February 7, 2012 and March 5, 2012 (DEP)
- E. Letter dated March 18, 2012 (DEP)
- F. Letter dated June 4, 2015 (DEP)
- G. Letter dated October 14, 2015 (DEP)




For the Pennsylvania Department of Environmental Protection

John S. Chippo
Bureau of Radiation Protection
P. O. Box 8469
Harrisburg, PA 17105-8469

Date: May 2, 2016

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Insert shipping document here.

Extremely Urgent

Page 1 of 1

ORIGIN ID: FSDA (605) 366-3358
MARY HENNINGS-FRANK
DMS HEALTH TECHNOLOGIES
109 S. PETRO AVE.

SIOUX FALLS, SD 57107
UNITED STATES US

SHIP DATE: 29NOV16
ACTWGT: 1.00 LB
CAD: 8142843/NET3790

BILL SENDER

TO REGION IV
U.S. NUCLEAR REGULATORY COMMISSION
1600 EAST LAMAR BOULEVARD

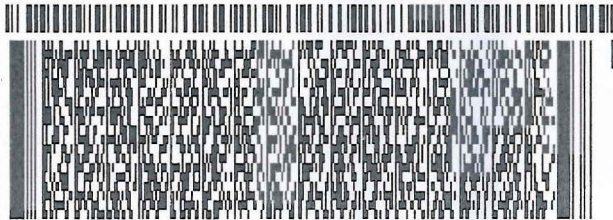
ARLINGTON TX 76011

(605) 357-2612

REF:

INV:
PO:

DEPT:



FedEx
Express



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EXPRESS SAVER

TRK# 7778 1950 6355

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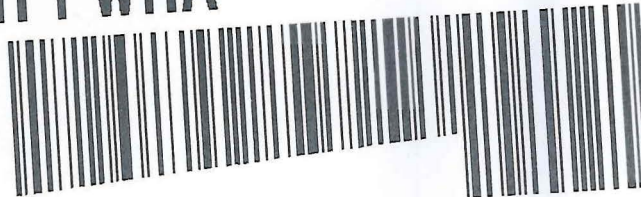
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MON - 05 DEC AA
EXPRESS SAVER

6011
DFW

76011
TX-US
DFW

SH FWHA



FROM: Mary Frank
CARR: Federal Express
TRK#: 00777819506355
RCVD: 12/1/2016

1427

TO: HILL, Carol

PH:
BDG:
RM:



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee Ms. Mary Hennings-Frank, Radiation Safety Officer DMS Health Technologies 109 South Petro Avenue Sioux Falls, SD 57107	Date
	12/05/2016
	License Number(s)
	40-32477-01
	Mail Control Number(s)
	592429
	Licensing and/or Technical Reviewer or Branch
	CHill

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 11/29/2016

The initial processing, which included an administrative review, has been performed.

☒ Amendment ☐ Termination ☐ New License ☐ Renewal

☐ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
Follow the instructions on the form for submission.

☐ The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region IV
U. S. Nuclear Regulatory Commission
DNMS/NMSB - B
1600 E. Lamar Boulevard
Arlington, TX 76011-4511
(817) 200-1209 or (817) 200-1140

✓ 12/5/16

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 02220
Status Code: Pending Amendment
Fee Category: 7C
Exp. Date: 12/31/2011
Fee Comments:
Decom Fin Assur Reqd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: DMS Health Technologies
Received Date: 12/01/2016
Docket Number: 3036404
Mail Control Number: 592429
License Number: 40-32477-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: _____

Date: _____

Carol R. Heise
12/5/16

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment: _____

Renewal: _____

License: _____

3. OTHER _____

Signed: _____

Date: _____