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March 7, 2019

DNMS

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

PUBLIC

- ☐ Immediate Release
☒ Normal Release

NON-PUBLIC

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

Reviewer: Proz Date: 3/15/19

Re: Amendment to our RML #40-32477-01

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 physician under condition 12.B.:
 - Daniel R. Fritz, M.D.
 - Leslie H. Lenter, M.D.
 - Stephen R. Peters, M.D.
 - Supporting document listing all three physicians as Authorized Users is Avera St. Luke's' dba Avera St. Luke's Hospital's NRC RML #40-18000-01.

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

Kind Regards,



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

Enclosed:

- Avera St. Luke's RML #40-18000-01

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, 70 and 71, 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. Avera St. Luke's dba Avera St. Luke's Hospital 2. 305 South State Street Aberdeen, SD 57401		In accordance with letters dated May 21, 2018, and June 13, 2018.	4. Expiration Date: November 30, 2025
		3. License number: 40-18000-01 is amended in its entirety to read as follows:	5. Docket No.: 030-13778 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	9. Authorized use
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As Needed	A. For use in uptake, dilution and excretion studies permitted by 10 CFR 35.100.
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As Needed	B. For use in imaging and localization studies permitted by 10 CFR 35.200.
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 400 millicuries total	C. For any use permitted by 10 CFR 35.300.
D. Cesium-137 permitted by 10 CFR 35.400	D. Sealed Sources (3M Health, Model 6500 Series; Amersham-Buchler GmbH & Co. KG (Medi-Physics, Inc. d/b/a GE Healthcare), Model CDC.N2 [Product codes CDCS.S16-18, CDCS.S4, S5, S40])	D. 940 millicuries total	D. For any manual brachytherapy procedure permitted by 10 CFR 35.400.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
40-18000-01

Amendment No. 38

Docket or Reference Number
030-13778

- | | | | |
|---|--|--|--|
| 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 | 9. Authorized use |
| E. Any byproduct material permitted by 10 CFR 31.11 | E. Prepackaged Kits | E. 100 millicuries total | E. For use in in-vitro studies. |
| F. Yttrium-90 permitted by 10 CFR 35.1000 | F. Microspheres (manufacturer as listed in SSDR MA-1229-D-101-S, SIR-Spheres®) | F. 189 mCi per vial and 1 curie total | F. SIR-Spheres® for permanent brachytherapy using delivery system as listed in SSDR MA-1229-D-101-S permitted by 10 CFR 35.1000. |

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Avera St. Luke's Hospital, 305 South State Street, Aberdeen, South Dakota, 57401.
11. The Radiation Safety Officer (RSO) for this license is Leslie H. Lenter, M.D.
12. Licensed material shall only be used by, or under the supervision of:

A. Individuals permitted to work as an authorized users in accordance with 10 CFR 35.13 and 10 CFR 35.14.

B. The following individuals are authorized users for the material and medical uses as indicated:

Authorized Users

Daniel R. Fritz, M.D.

Leslie H. Lenter, M.D.

Stephen R. Peters, M.D.

Material and Use

35.100; 35.200; 31.11; oral administration of sodium iodide I-131

35.100; 35.200; 35.300; 35.400, 35.1000 only Yttrium-90 SIR-Spheres®

35.100; 35.200; 35.300; 31.11

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13. 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 10 CFR 30.35(d) for establishing decommissioning financial assurance.
14. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
15. The licensee shall conduct a physical inventory every 6 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 3 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.
16. 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 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. 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.
 - D. 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.

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- E. 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.
- F. 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.
- G. 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.
- H. Records of leak test results shall be kept in units of microcuries and shall be maintained for 3 years.

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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. 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 and applicable guidance updates for 10 CFR 35.1000 uses. 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 May 8, 2015 (ML15156B311)

B. Letter dated October 3, 2016 (ML16298A415)

C. Letter dated November 1, 2017(ML17325A483) (commitment to follow "NRC's February 2016 Microspheres Guidance" only)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: July 16, 2018By: Roberto J. Torres
Region IV

61158

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Extremely

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: 07MAR19
ACTWGT: 1.00 LB
CAD: 8142843/INET4100

BILL SENDER

TO REGION IV, DNMS/NMSB-B
U.S. NUCLEAR REGULATORY COMMISSION
1600 EAST LAMAR BOULEVARD

ARLINGTON TX 76011

(605) 366-3358
INV:
PO:

REF: PC10

DEPT:



FedEx
Express



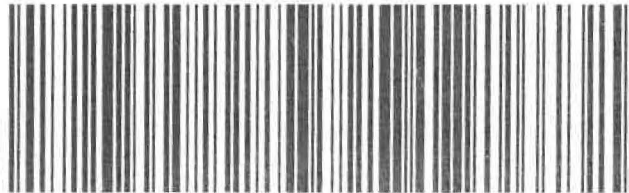
FRI - 08 MAR 3:00P

STANDARD OVERNIGHT

TRK# 7746 4838 7664
0201

XH FWHA

76011
TX-US DFW



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ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Ms. Mary Hennings-Frank
Corporate Radiation Safety Officer
DMS Health Technologies
109 South Petro Avenue
Sioux Falls, SD 57107

Date

03/14/2019

License Number(s)

40-32477-01

Mail Control Number(s)

611584

Licensing and/or Technical Reviewer or Branch

C. Hill

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 03/07/2019

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) 200-1103 or (817) 200-1140

✓ 3/14

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: 04/30/2022
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: 03/13/2019
Docket Number: 3036404
Mail Control Number: 611584
License Number: 40-32477-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: _____

Date: _____

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: _____