



RECEIVED  
APR 18 2016

109 South Petro Avenue  
Sioux Falls, SD 57107  
Phone: 605.330.9060  
Toll Free: 800.437.4628  
Fax: 877.595.8108  
[www.DMSHealthTechnologies.com](http://www.DMSHealthTechnologies.com)

April 12, 2016

DNMS

Nuclear Materials Safety Branch B  
U.S. Nuclear Regulatory Commission  
Region IV  
1600 E. Lamar Blvd.  
Arlington, Texas 76011-4511

**Re: Radioactive Material License 40-32477-01**

To Whom It May Concern:

DMS Health Technologies wish to remove Michelle White as Radiation Safety Officer under Item 11 and add Mary Hennings-Frank. Included is documentation of Ms. Hennings-Frank's credentials in the form of a current North Dakota Department of Health Radioactive Material License listing her as Radiation Safety Officer. A Delegation of Authority is included from the Chief Executive Officer.

If you have any further questions, please don't hesitate to call Mary Hennings-Frank at 605-366-3358 or [mary.hennings-frank@dmshealth.com](mailto:mary.hennings-frank@dmshealth.com).

Sincerely,

*Michelle White, RSO*

Michelle White  
Radiation Safety Officer  
DMS Health Technologies

**PUBLIC**  
☐ Immediate Release  
☒ Normal Release  
**NON-PUBLIC**  
☒ A3 Sensitive-Security Related  
☐ A7 Sensitive Internal  
☐ Other: \_\_\_\_\_  
Reviewer: JWC Date: 4/22/16

-590686



HEALTH TECHNOLOGIES

109 South Petro Avenue  
Sioux Falls, SD 57107  
Phone: 605.330.9060  
Toll Free: 800.437.4628  
Fax: 877.595.8108  
[www.DMSHealthTechnologies.com](http://www.DMSHealthTechnologies.com)

## Delegation of Authority

As Chief Executive Officer of DMS Health Technologies, Inc., I have appointed Mary Hennings-Frank as the Radiation Safety Officer and she is responsible for ensuring the safe use of radiation. Mary will be responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with the rule.

Mary is hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety.

I also grant Ms. Hennings-Frank the authorization to be the main contact person for all radioactive material licensing and regulatory issues. Ms. Hennings-Frank has the authority to make commitments, amendments, renew license, etc. on behalf of the DMS Health Technologies.

Signature of Management Representative  
William Vogel, Chief Executive Officer

Date

I accept the above responsibilities,

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

Date

# NORTH DAKOTA DEPARTMENT OF HEALTH

## RADIOACTIVE MATERIAL LICENSE

Pursuant to Section 23-20.1-01 through Section 23-20.1-11 of Chapter 23-20.1 of the North Dakota Century Code, and Article 33-10 of the North Dakota Administrative Code, 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 materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders now or hereafter in effect of the North Dakota Department of Health and to any conditions specified below:

<b>Licensee</b>  1.    Name DMS Health Technologies  2.    Address 109 South Petro Avenue Sioux Falls, SD 57107	3.    License Number 33-11325-01 is renewed and amended in its entirety  Amendment No. 55
	4.    Expiration Date  February 28, 2026
	5.    Reference Number  010

6. Radioactive materials (element and mass number)	7. Chemical and/or physical form	8A. Maximum activity per source	8B. Maximum quantity which licensee may possess at any one time
A. Any byproduct material permitted by 33-10-07.2[10 CFR 35.100]	A. Any	A. As needed	A. As needed
B. Any byproduct material permitted by 33-10-07.2[10 CFR 35.200]	B. Any	B. As needed	B. As needed
C. Strontium-85	C. Any	C. 18.5 gigabecquerels (500 millicuries)	C. Total activity not to exceed 37.0 gigabecquerels (1000 millicuries)

### 9.    Authorized Use:

- A.    Any uptake, dilution, and excretion studies permitted by 10 CFR 35.100.
- B.    Any imaging and localization studies permitted by 10 CFR 35.200.
- C.    Impurity in Sr-82/Rb-82 generators.

---

CONDITIONS

10. A. Licensed material may be received by licensee personnel only, stored, and dispatched from the licensee's facilities located at:
- (1) DMS Imaging/Health Technologies, 2101 North University Drive, Fargo, North Dakota.
  - (2) U-Store Rental Properties at Lot #7, Block 2, First Addition, Carrington, North Dakota.
  - (3) IPR Building, 830 South 48<sup>th</sup> Street, Grand Forks, North Dakota.
- B. Licensed material may be received by licensee personnel only and used at temporary job sites of the licensee anywhere in the state of North Dakota, except in areas of exclusive federal jurisdiction. You must obtain reciprocity to work outside of North Dakota or in areas of exclusive federal jurisdiction.

If the jurisdiction status of a federal facility within an Agreement State is unknown, the licensee should contact the federal agency controlling the job site in question to determine whether the proposed job site is an area of exclusive federal jurisdiction. Authorization for use of radioactive materials at job sites in Agreement States under exclusive federal jurisdiction shall be obtained from the U.S. Nuclear Regulatory Commission.

11. The licensee shall comply with the following chapters of the North Dakota Radiological Health Rules:

Chapter 33-10-01	General Provisions
Chapter 33-10-03.1	Licensing of Radioactive Material
Chapter 33-10-04.2	Standards for Protection Against Radiation
Chapter 33-10-07.2	Medical Use of Radioactive Material
Chapter 33-10-10.1	Notices, Instructions, and Reports to Workers - Inspections
Chapter 33-10-11	Fees for Issuance of License and Registration Certificates and Inspections
Chapter 33-10-13.1	Transportation of Radioactive Material

12. Licensed material is only authorized for use by, or under the supervision of:

- A. Individuals permitted to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist in accordance with North Dakota Radiological Health Rules Chapters 33-10-07.2[10 CFR 35.13] and 33-10-07.2[10 CFR 35.14].
- B. The following individuals are authorized users for the material and medical uses indicated:

<u>Authorized Users</u>	<u>Material and Use</u>
Mitchell H. Crider, M.D.	35.100; 35.200 except Sr-82/Rb-82 generators
Christopher H. Crowe, M.D.	35.100; 35.200 except Sr-82/Rb-82 generators
Christopher D. Fischer, M.D.	35.100; 35.200 except Sr-82/Rb-82 generators
Michael Fortney, M.D.	35.100; 35.200 except Sr-82/Rb-82 generators

Matthew M. Iwamoto, M.D.	35.100; 35.200 except Sr-82/Rb-82 generators
Fred Clinton Lovrien, M.D.	35.100; 35.200 except Sr-82/Rb-82 generators
Michael J. McIntee, M.D.	35.100; 35.200
Douglas Peterson, M.D.	35.100; 35.200 except Sr-82/Rb-82 generators
Joshua Rampton, M.D.	35.100; 35.200 except Sr-82/Rb-82 generators
Jerome Sampson, M.D.	35.100; 35.200 except Sr-82/Rb-82 generators
Christina M. Tello-Skjerseth, M.D.	35.100; 35.200 except Sr-82/Rb-82 generators
Aaron David Lee Wright, M.D.	35.100; 35.200 except Sr-82/Rb-82 generators

C. The following individuals are authorized users for non-medical uses indicated:

<u>Authorized Users</u>	<u>Material and Use</u>
Michael J. McIntee, M.D.	Strontium-85 as in impurity in Sr-82/Rb-82 generators

D. The Radiation Safety Officer for this license is Mary Hennings-Frank.

13. For sealed sources not associated with 33-10-07.2[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. 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 no more than 100 microcuries of beta-and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
- 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. The leak test shall be capable of detecting the presence of 185 becquerels (0.005 microcurie) of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate.
- F. If the test reveals the presence of 185 becquerels (0.005 microcurie) or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Department regulations. A report

shall be filed within 5 days of the test with the Director, Division of Air Quality, North Dakota Department of Health, Gold Seal Center, 918 E Divide Avenue, 2<sup>nd</sup> Floor, Bismarck, North Dakota 58501-1947, describing the equipment involved, the test results, and the corrective action taken.

- G. Tests for leakage and/or contamination, limited to leak test sample collection, 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. The licensee is not authorized to perform the analysis; analysis of leak test samples must be performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
  - H. Sealed sources need not be tested if they are in storage and 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.
  - I. Records of leak test results shall be kept in units of becquerels or microcuries and maintained for 3 years.
- 14. Licensed material to be administered to humans shall be manufactured and prepared under appropriate pharmaceutical controls related to assay, identity, quality, purity, sterility, and nonpyrogenicity.
  - 15. Technetium-99m sulfur colloid preparations which appear flocculent or aggregated shall not be used in humans.
  - 16. Sealed sources or detector cells containing radioactive material shall not be opened or sources removed from source holders by the licensee.
  - 17. The licensee shall conduct a physical inventory every 6 months 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, location, and the date of the inventory.
  - 18. 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 North Dakota Radiological Health Rules Chapter 33-10-03.1[10 CFR 30.35] for establishing financial assurance for decommissioning.
  - 19. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.
  - 20. Except as specifically provided otherwise by 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 does not limit the licensee's ability to make changes to the radiation protection program as provided for in North Dakota Radiological Health Rules Chapter 33-10-07.2[10 CFR 35.26]. The North Dakota Radiological Health Rules shall govern unless the statements, representations, and procedures in

the licensee's application and correspondence are more restrictive than the North Dakota Radiological Health Rules.

- A. Application dated January 20, 2016; email dated February 17, 2016.

FOR THE NORTH DAKOTA DEPARTMENT OF HEALTH

Date: 2/18/16

By: Terry L. O'Clair  
Terry L. O'Clair, P.E.  
Director  
Division of Air Quality





ORIGIN ID: FSDA (605) 366-3358  
 MICHELLE WHITE  
 DMS HEALTH TECHNOLOGIES  
 109 S. PETRO AVE.  
 SIOUX FALLS, SD 57107  
 UNITED STATES US

SHIP DATE: 13APR16  
 ACTWGT: 1.00 LB  
 CAD: 8142843/INET3730

BILL SENDER

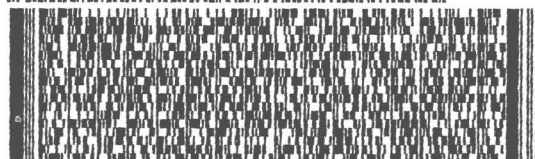
TO **REGION IV**  
**U.S. NUCLEAR REGULATORY COMMISSION**  
**1600 E. LAMAR BLVD.**

**ARLINGTON TX 76011**

(605) 366-1293  
 INV:  
 PO:

REF:

DEPT:



**FedEx**  
 Express



**THU - 14 APR 3:00P**  
**STANDARD OVERNIGHT**

TRK# 7760 9490 8194  
 0201

**XH FWHA**

**76011**  
**TX-US DFW**



After re-labeling this label: This means to void your label in your laser or initial printer

Extreme

**A**  
**2** 15:00 8194 04.14

**219**  
 RT 8 ST 8

590686





DATE

04/20/2016

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE

Ms. Michelle White, Radiation Safety Officer  
DMS Health Technologies  
109 South Petro Avenue  
Sioux Falls, SD 57107

LICENSE NUMBER

40-32477-01

MAIL CONTROL NUMBER

590686

LICENSING AND/OR TECHNICAL REVIEWER

JAB

This is to acknowledge the receipt of your:

☒ LETTER and/or ☐ APPLICATION

DATED: 04/12/2016

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 fill out NRC Form 531, located at the following link:

<http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>

Send the completed NRC Form 531, by facsimile, to the following number: (301) 415-5387

A copy of your action has been emailed to our License Fee and Accounts Receivable Branch, in our Headquarters office in Rockville, MD. You will be contacted separately if there is a fee issue involved.

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) 200-1140

✓ 4-20-16

**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 Req: N

---

## License Fee Worksheet - License Fee Transmittal

---

### A. REGION

#### 1. APPLICATION ATTACHED

Applicant/Licensee: DMS Health Technologies  
Received Date: 04/18/2016  
Docket Number: 3036404  
Mail Control Number: 590686  
License Number: 40-32477-01  
Action Type: Amendment

#### 2. FEE ATTACHED

Amount: \_\_\_\_\_

Check No.: \_\_\_\_\_

#### 3. COMMENTS

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

*Jennifer Budge*  
APR 20, 2016

### 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: \_\_\_\_\_