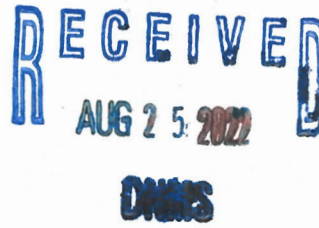




Mail Control Number: 632367
Docket Number : 3011624
License Number : 40-16775-01
Licensee Name : Prairie Lakes Healthcare System

August 19, 2022

U.S. Nuclear Regulatory Commission
Licensing Branch Region IV
1600 East Lamar Blvd.
Arlington, TX 76011-4511




To Whom It May Concern,

Please amend our Radioactive Materials License #40-16775-01 (Prairie Lakes Healthcare Systems, Inc., P.O. Box 1210, 401 9th Avenue NW; Watertown, SD 57201-6210) to include the following revision.

1. We are requesting addition of Joni L. Buechler-Price, MD as an Authorized User to our Radioactive Materials License for uses 35.100, 35.200 and 35.300. We have included the following document for your review which shows Dr. Buechler-Price is currently on another license for the requested uses.
 - a. North Dakota Radioactive Material License #33-02604-01 (Innovis Health, LLC; 3000 – 32nd Avenue S; Fargo, ND 58103)
2. Please also remove Rene DuCret, MD as he is no longer affiliated with our facility.

Your attention in this matter is greatly appreciated.

Sincerely,


Shaun Pattrin
Radiation Safety Officer
Prairie Lakes Healthcare Center

NORTH DAKOTA DEPARTMENT OF ENVIRONMENTAL QUALITY

RADIOACTIVE MATERIAL LICENSE

Pursuant to Section 23.1-03-01 through Section 23.1-03-15 of Chapter 23.1-03 of the North Dakota Century Code, and Article 33.1-10 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 Environmental Quality and to any conditions specified below:

<p style="text-align: center;">Licensee</p> <p>1. Name Innovis Health, LLC</p> <p>2. Address 3000 – 32nd Avenue S Fargo, ND 58103</p>	<p>3. License Number 33-02604-01 is amended in its entirety. Amendment No. 50</p> <p>4. Expiration Date February 28, 2025</p> <p>5. Reference Number 019</p>
--	---

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 33.1-10-07.2-01 [10 CFR 35.100]	A. Any	A. As needed	A. As needed
B. Any byproduct material permitted by 33.1-10-07.2-01 [10 CFR 35.200]	B. Any	B. As needed	B. As needed
C. Any byproduct material permitted by 33.1-10-07.2-01 [10 CFR 35.300]	C. Any	C. As needed	C. Total activity not to exceed 14.8 gigabecquerels (400 millicuries)
D. Iodine-125 permitted by 33.1-10-07.2-01 [10 CFR 35.400]	D. Sealed sources (Medi-Physics by Amersham Model 6711 or 6733)	D. Not to exceed the maximum activity permitted by the Sealed Source and Device Registry certificate of registration	D. Total activity not to exceed 1.1 gigabecquerels (300 millicuries)

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
E. Palladium-103 permitted by 33.1-10-07.2-01 [10 CFR 35.400]	E. Sealed sources (Theragenics Corporation Model 200)	E. Not to exceed the maximum activity permitted by the Sealed Source and Device Registry certificate of registration	E. Total activity not to exceed 27.75 gigabecquerels (750 millicuries)
F. Cesium-131 permitted by 33.1-10-07.2-01 [10 CFR 35.400]	F. Sealed sources (IsoRay Medical, Inc. Model CS-1)	F. Not to exceed the maximum activity permitted by the Sealed Source and Device Registry certificate of registration	F. Total activity not to exceed 88.8 gigabecquerels (2400 millicuries)
G. Yttrium-90 permitted by 33.1-10-07.2-01 [10 CFR 35.1000]	G. Sealed sources (Sirtex Wilmington LLC Model SIR-Spheres® microspheres	G. 6.99 gigabecquerels per vial (189 millicuries per vial)	G. Total activity not to exceed 37 gigabecquerels (1 curie)
H. Yttrium-90 permitted by 33.1-10-07.2-01 [10 CFR 35.1000]	H. Sealed sources (MDS Nordian Model TheraSphere® microspheres	H. 19.98 gigabecquerels per vial (540 millicuries per vial)	H. Total activity not to exceed 37 gigabecquerels (1 curie)

9. Authorized Use:

- A. Any uptake, dilution, or excretion studies permitted by 10 CFR 35.100.
- B. Any imaging and localization studies permitted by 10 CFR 35.200.
- C. Any use permitted by 10 CFR 35.300.
- D-F. Topical, intracavitary, and intraluminal treatment of cancer.
- G. For microsphere brachytherapy using Sirtex Medical Limited SIR-Spheres® delivery system permitted by 10 CFR 35.1000.
- H. For microsphere brachytherapy using MDS Nordian TheraSphere® delivery system permitted by 10 CFR 35.1000.

CONDITIONS

- 10. A. Licensed material may be used or stored only at the licensee's facilities located at 3000 – 32nd Avenue S. Fargo, North Dakota.

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

Chapter 33.1-10-01	General Provisions
Chapter 33.1-10-03.1	Licensing of Radioactive Material
Chapter 33.1-10-04.2	Standards for Protection Against Radiation
Chapter 33.1-10-07.2	Medical Use of Radioactive Material
Chapter 33.1-10-10.1	Notices, Instructions, and Reports to Workers - Inspections
Chapter 33.1-10-11	Fees for Issuance of License and Registration Certificates and Inspections
Chapter 33.1-10-13.1	Packaging and Transportation of Radioactive Material

12. Radioactive 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 33.1-10-07.2-01 [10 CFR 35.13] and 33.1-10-07.2-01 [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>
Aaron David Lee Wright, M.D.	35.100; 35.200
Jerome Sampson, M.D.	35.100; 35.200
Mark C. Cooper, M.D.	35.300; 35.400
Mitchell H. Crider, M.D.	35.100; 35.200
Joni L. Buechler-Price, M.D.	35.100; 35.200; 35.300
Scott Reardon, M.D.	35.100; 35.200
Aaron R. Jones, M.D.	35.100; 35.200; 35.300 only sodium iodide I-131 for oral administration
Adam Stibbe, M.D.	35.100; 35.200; 35.300 only sodium iodide I-131 for oral administration
Adam DeFoe, M.D.	35.100; 35.200; 35.300 only sodium iodide I-131 for oral administration; 35.1000 only TheraSphere® Yttrium-90 microspheres

- C. The Radiation Safety Officer for this license is David J. Eastman, MEHS.

13. For sealed sources not associated with 33.1-10-07.2-01 [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 Manager, Radiation Control Program, North Dakota Department of Environmental Quality, 4201 Normandy Street, Bismarck, North Dakota, 58503-1324, 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 comply with the current revision of U.S. Nuclear Regulatory Commission's guidance entitled "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance."
 - 18. 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.

19. 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 33.1-10-03.1-01 [10 CFR 30.35] for establishing financial assurance for decommissioning.
20. 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.
21. 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 33.1-10-07.2-01 [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 12, 2015.
 - B. Amendment letter dated May 16, 2016.
 - C. Amendment emails dated March 14, 2017, March 17, 2017, March 31, 2017, and April 14, 2017.
 - D. Amendment email dated December 7, 2017, and amendment letter dated December 7, 2017.
 - E. Amendment emails dated January 10, 2018, February 23, 2018, March 13, 2018, March 14, 2018, March 15, 2018, March 20, 2018, March 27, 2018, March 28, 2018, April 2, 2018, and April 19, 2018.
 - F. Amendment email dated May 25, 2018.
 - G. Amendment letter dated January 2, 2020; emails dated January 2, 2020, and January 6, 2020.
 - H. Amendment letter dated September 7, 2021; email dated September 29, 2021.

FOR THE NORTH DAKOTA DEPARTMENT
OF ENVIRONMENTAL QUALITY

Date: 9/29/21

By: 
Chuck R. Hyatt, Director
Division of Waste Management

Align top of FedEx Express® shipping label here.

FROM: (402) 734-8045
Traci Jorgensen
Cardinal Health
5840 F Street
OMAHA NE 68117
US

SHIP DATE: 19AUG22
ACTWGT: 1.00 LB
CAD: 104744132/NET4490

BILL SENDER

TO Licensing Branch Region IV
U.S. Nuclear Regulatory Commission
1600 East Lamar Blvd.

ARLINGTON TX 76011
(402) 319-2668

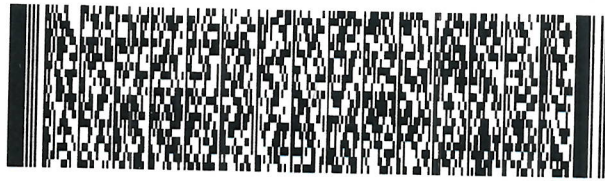
REF: 2250000952

(US)

58112/F39D/FE2D

INV
PO

DEPT



FedEx
Ground



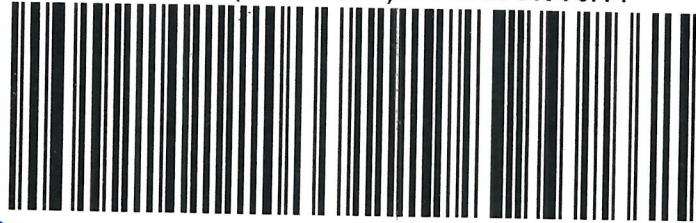
12220202041201uv

FedEx Ship Manager - Print Your Label(s)

TRK# 2769 9194 6771

76011

9622 0019 0 (000 000 0000) 0 00 2769 9194 6771



RECEIVED
AUG 22 2022

8/19/22, 3:50 PM
DMS

0704 WEL 00:28 GO TO SEP-2023 701101
U.S. NUCLEAR REGULATORY COMMISSION
1600 E LAMAR BLVD
ARLINGTON TX 76011-4511-99

815-7543
ETR:1
96220015000018/2/001000/0001943/11

PDSP:100-Y

-RAYE





ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Jenna Hulscher, CRA
Director of Radiology
Prairie Lakes Healthcare System
401 9th Ave NW
PO Box 1210
Watertown, SD 57201-6210

Date

09/15/2022

License Number(s)

40-16775-01

Mail Control Number(s)

632367

Licensing and/or Technical Reviewer or Branch

C. Hill

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 08/19/2022

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

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 02120
Status Code: Pending Amendment
Fee Category: 7C
Exp. Date: 11/30/2023
Fee Comments: CODE 23
Decom Fin Assur Req: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: Prairie Lakes Healthcare System
Received Date: 08/25/2022
Docket Number: 3011624
Mail Control Number: 632367
License Number: 40-16775-01
Action Type: Amendment

2. FEE ATTACHED

Amount: N/A

Check No.: N/A

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: _____

Agency: NRC

WBL WORKSHEET

DOCKET NUMBER: 3011624	LICENSE NUMBER: 40-16775-01	STATUS: Pending Amendment
MAIL CONTROL NUMBER: 632367	RECEIPT DATE: 08/25/2022	ACTION TYPE: Amendment
DUE DATE: 11/23/2022	INST. CODE: 16775	LICENSE REGION: Region 4
LICENSE TYPE: 30	ENTITY TYPE: C	LICENSE GROUP: Medical
ISSUE DATE:	ORIGINAL DATE: 11/07/1988	EXPIRATION DATE: 11/30/2023
DECOMMISSIONING CATEGORY: Group 1	LAST ISSUE DATE:	
LICENSEE NAME: Prairie Lakes Healthcare System	DECOM FIN ASSUR REQD: N SUBM: N	
MAILING ADDRESS LINE1: 401 9th Avenue Northwest	CONT PLAN REQD: N	APPRV: N
MAILING ADDRESS LINE 2: P.O. Box 1210		
CITY: Watertown	STATE: SD	ZIP: 57201-6210
CONTACT PERSON: PREFIX:	FIRST NAME: Bryan	MIDDLE INITIAL:
LAST NAME: Beckedahl	SUFFIX:	
JOB TITLE: Director of Radiology	PHONE: 605-882-7986 FAX: 605-882-7070	EMAIL: Bryan.Beckedahl@prai
BILLING ADDRESS LINE 1:		
BILLING ADDRESS LINE 2:		
CITY:	STATE: South Dakota	ZIP:
BILLING CONTACT PERSON: FIRST NAME:	MIDDLE INITIAL:	LAST NAME:
PHONE:	EMAIL:	FAX:
PRIMARY PGM CODE: 02120	SECONDARY PGM CODE:	
INSPECTION REGION: Region 4	PRIORITY: 3	
RSO: PREFIX:	FIRST NAME: Shaun	MIDDLE INITIAL: LAST NAME Pattrin
SUFFIX: BA, AS	RSO JOB TITLE: Radiation Safety Officer	
RSO PHONE: 402-734-8045	RSO FAX:	RSO EMAIL: shaun.pattrin@cardinalhealth.com
STATES WHERE USE IS AUTHORIZED: 1	0- ALL LISTED STATES 1- SAME AS STATE IN ADDRESS 2- ALL STATES 3- NON-AGREEMENT-STATES	
AUTHORIZED STATES (USE ONLY IF ABOVE IS ZERO):		