AKUMIN & ALLIANCE HEALTHCARE RADIOLOGY

Alliance HealthCare Services is Now An Akumin Company

December 3, 2021

U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

RE: Alliance 47-25570-01

Dear Sir or Madam,
This is a request to update Authorized Users for Alliance 47-25570-01.
Add the following AUs for uses allowed under 10 CFR 35.200:

Physician	Reference License
Peerawut Deeprasertkul, MD	33-06507-01
Andrew T. Miller, MD	33-06507-01
John Holmen, MD	33-11320-01

If you require anything further at this time, please contact me.
Sincerely,

Kay Kassel MS CNMT, NMTCB(RS)
Corporate Radiation Safety Officer
Office 561.701.1311
Fax 480.212.8560
kkassel@alliancehealthcareservices-us.com
18201 Von Karman #600 Irvine, CA 92612

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:

Licensee	3. License Number 33-06507-01 is amended in its entirety Amendment No. 30
1. Name Mercy Medical Center dba CHI St. Alexius Health Williston	4. Expiration Date May 31, 2029
2. Address 1301 - 15th Avenue West Williston, ND 58801	5. Reference Number 095

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

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.

CONDITIONS

10. Licensed material may be stored or used only at the licensee's facility located at 1301 – 15th Avenue West, Williston, 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. 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 33.1-10-07.2-01 [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:

Authorized Users	Material and Use
Peerawut Deeprasertkul, M.D.	35.100; 35.200
Andrew T. Miller, M.D.	35.100; 35.200

C. The Radiation Safety Officer for this license is Yaxiang Yang, M.D.

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, 918 E Divide Avenue, 2nd 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 33.1-10-03.1-01 [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 33.1-10-07.2-01 [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 August 1, 2019; and email dated September 5, 2019.
B. Amendment letter dated October 26, 2021.

FOR THE NORTH DAKOTA DEPARTMENT OF ENVIRONMENTAL QUALITY

Date: 11/23/21

By: _____
Charles R. Hyatt, Director
Division of Waste Management

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:

Licensee	3. License Number 33-11320-01 is renewed and amended in its entirety Amendment No. 53
1. Name CHI St. Alexius Health	4. Expiration Date August 31, 2031
2. Address 900 E Broadway Bismarck, ND 58501	5. Reference Number 013

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. 37 gigabecquerels (1 curie)
D. Yttrium-90 permitted by 33.1-10-07.2-01 [10 CFR 35.1000]	D. Microspheres (Sirtex Medical, Inc. Model SIR-Spheres)	D. 7.28 gigabecquerels (197 millicuries/vial)	D. 21.84 gigabecquerels (590 millicuries)
E. Yttrium-90 permitted by 33.1-10-07.2-01 [10 CFR 35.1000]	E. Microspheres (MDS Nordion, Inc. Model TheraSpheres)	E. 20 gigabecquerels (540 millicuries)	E. 111 gigabecquerels (3 curies)

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. Any use permitted by 10 CFR 35.300.

D. For medical use permitted by 10 CFR 35.1000 in a SIR-Sphere® dose delivery system.

E. For medical use permitted by 10 CFR 35.1000 in a TheraSphere® dose delivery system.

CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at:

A. 900 E Broadway, Bismarck, ND 58501.

B. PET Imaging may be conducted by DMS Imaging's mobile PET imaging coaches at CHI St. Alexius Health, 900 E Broadway, Bismarck, or Medical Arts Plaza, 810 E Rosser Avenue, Bismarck, utilizing radioactive materials listed in Subitems B of Items 6, 7, 8 and 9. Licensed material may be delivered by DMS Imaging's mobile PET imaging coaches at CHI St. Alexius Health or Medical Arts Plaza.

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. 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 33.1-10-07.2-01 [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:

Authorized Users	Material and Use
Douglas Peterson, M.D.	35.100; 35.200; 35.300
Michael Schirado, M.D.	35.100; 35.200; 35.300
John Holmen, M.D.	35.100; 35.200; 35.300
Michael Fortney, M.D.	35.100; 35.200; 35.300
Nicholas Bradbury, M.D.	35.100; 35.200; 35.300 only sodium iodide I-131 for oral administration; 35.1000 only Yttrium-90 microspheres
Agnieszka O. Solberg, M.D.	35.100; 35.200; 35.300; 35.1000 only Yttrium-90 SIR-Spheres microspheres
Luke B. Roller, M.D.	35.100; 35.200; 35.300

C. The Radiation Safety Officer for this license is John Holmen, MD.

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, 918 E Divide Avenue, 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 three 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 February 16, 2021; emails dated February 22, 2021, April 14, 2021, May 26, 2021, July 7, 2021, and July 28, 2021.

FOR THE NORTH DAKOTA DEPARTMENT OF ENVIRONMENTAL QUALITY

Date: 7/29/21

By: _____
Charles R. Hyatt, Director
Division of Waste Management

PRESS FIRMLY TO SEAL

PRESS FIRMLY TO SEAL

PRIORITY MAIL
FLAT RATE ENVELOPE
POSTAGE REQUIRED

UNITED STATES POSTAL SERVICE®

PRIORITY® MAIL

UNITED STATES POSTAL SERVICE. Retail

P

US POSTAGE PAID

$8.70

Origin: 33455
12/03/21
1139450400-02

PRIORITY MAIL 2-DAY®

0 Lb 3.00 Oz

1006

EXPECTED DELIVERY DAY: 12/06/21

C021

SHIP TO:
2443 WARRENVILLE RD
STE 210
LISLE IL 60532-4352

USPS TRACKING® #

rance (restrictions apply).*

tional destinations.

rm is required.

ns exclusions see the

ty and limitations of coverage.

To schedule free Package Pickup, scan the QR code.

FROM:
K. Kassel
Alliance Health Care Services
PO Box 19532
Irvine CA 92623

TO:
U.S. Nuclear Regulatory Comm
Region III
2443 Warrenville Road
Suite 210
Lisle, IL
60532-43

RECEIVED DEC 14 2021