Cardinal Health 414, LLC
Quality & Regulatory
7000 Cardinal Place
Dublin, OH 43017
tel 614.757.4120
fax 614.652.4598

www.cardinalhealth.com

CardinalHealth

August 20, 2024

U.S. Nuclear Regulatory Commission Region I
Radioactive Materials Licensing
475 Allendale Road, Suite 102
King of Prussia, PA 19406-1415

Re: Amendment Request for Cardinal Health P.R. 120, Inc., Radioactive Materials License No. 34-31473-02MD, Guaynabo, Puerto Rico

Radioactive Materials Licensing:

Cardinal Health P.R. 120, Inc., (hereafter Cardinal Health) requests an amendment for the above referenced license to remove Glenn P. Sullivan as the Corporate Radiation Safety Officer (CRSO) and add David W. Pellicciarini, CHP as the CRSO. Mr. Pellicciarini is listed as an Authorized User and the Corporate Radiation Safety Officer for NRC license number 34-29200-01MD, Cardinal Health 414, LLC and he is familiar with the radiation safety program. A CRSO Delegation of Authority letter signed by the President of Cardinal Health 414, LLC is attached, as is RAM license 34-29200-01MD, listing Mr. Pellicciarini as the CRSO.

Additionally, Amendment 12 of RAM license 34-31473-02MD lists Cardinal Health 414, LLC as the licensee along with Cardinal Health P.R. 120, Inc. The business entity associated with this licensee is Cardinal Health P.R. 120, Inc.and Cardinal Health 414, LLC should not be listed.

If you have any questions regarding this request, please contact me at 765.702.1000.

Sincerely,

Cami Still
Director, Health Physics
Nuclear & Precision Health Solutions

Attachment: CRSO Delegation of Authority
Radioactive Materials License 34-29200-01MD, Amendment 77

cc: Shirley Danner, RSO, Location 7650
License File Location 7650 (3)

ATTACHMENTS

Corporate Radiation Safety Officer Delegation of Authority

Radioactive Materials License 34-29200-01MD, Amendment 77

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Dublin, OH 43017
tel 614.757.5000
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FROM: Michael Pintek, President, Cardinal Health 414, LLC

CC: All Cardinal Health Nuclear & Precision Health Solutions Employees

DATE: May 5, 2023

SUBJECT: Corporate Radiation Safety Officer Delegation of Authority

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David Pellicciarini, CHP, Vice President, Pharmacy Safety, Practice, & Technical Operations has been appointed Corporate Radiation Safety Officer for Cardinal Health 414, LLC (Nuclear & Precision Health Solutions and PET Manufacturing Services, hereafter Cardinal Health). The Corporate Radiation Safety Officer (CRSO) has the responsibility for:

- Managing the corporate radiation safety program;
- Ensuring the safe use of radioactive materials within the company;
- Identifying radiation safety problems through direct observation or through appointees;
- Recommending corrective actions and verifying implementation of such actions; and
- Ensuring compliance with regulations and license conditions.

David Pellicciarini is hereby delegated the authority necessary to meet the above listed responsibilities. This specifically includes having sufficient authority, organizational freedom, and management prerogative to:

- Make legally binding statements pertaining to radioactive materials licenses operated by Cardinal Health;
- Have unhampered access to all activities at any Cardinal Health facility involving radioactive materials to identify radiation safety problems;
- Immediately stop, without coordination with management, any activity at his any Cardinal Health facility involving the use of licensed materials by any user that might result in an unsafe situation or a violation of license conditions;
- Recommend corrective actions; and
- Verify the implementation of actions taken to correct radiation safety problems.

All of us have a critical responsibility in ensuring the safe use of radioactive materials. I refer you to one of our six values: "The health and safety of our employees, customers and community will never be compromised."

David Pellicciarini, CHP, CRSO — May 5, 2023 Date

Michael Pintek (May 5, 2023 14:47 CDT)
Michael Pintek, President, Cardinal Health 414, LLC — May 5, 2023 Date

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 77

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. Cardinal Health 414, LLC

2. 7000 Cardinal Place
Dublin, OH 43017

In accordance with letter dated November 27, 2023,

3. License No.: 34-29200-01MD is amended in its entirety to read as follows:

4. Expiration Date: June 30, 2037

5. Docket No.: 030-36973
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 with Atomic Numbers 1 through 83 with half-life less than or equal to 120 days	A. Any	A. 5 curies per location listed in Condition No. 10	A. For preparation, distribution and redistribution of radioactive drugs and radiochemicals - including compounding of iodine-131; redistribution of used and unused molybdenum-99/technetium-99m and strontium-82/rubidium-82 generators; preparation and distribution of gallium-68 and actinium-225 radioactive drugs; and distribution of radium-223 - for non-medical use to authorized recipients, and for medical use in accordance with 10 CFR 32.72 to authorized recipients.
B. Molybdenum-99	B. Any	B. 200 curies per location listed in Condition No. 10	B. Same as Item No. 9.A.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License No.: 34-29200-01MD

Amendment No. 77

Docket or Reference No.: 030-36973

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
C. Technetium-99m	C. Any	C. 200 curies per location listed in Condition No. 10	C. Same as Item No. 9.A.
D. Xenon-133	D. Any	D. 7 curies per location listed in Condition No. 10	D. Same as Item No. 9.A.
E. Iodine-131	E. Any	E. 6 curies per location listed in Condition No. 10	E. Same as Item No. 9.A.
F. Fluorine-18	F. Any	F. 20 curies per location listed in Condition No. 10	F. Same as Item No. 9.A.
G. Rubidium-82	G. Any	G. 400 millicuries per location listed in Condition No. 10	G. Same as Item No. 9.A.
H. Strontium-82	H. Solid	H. 400 millicuries per location listed in Condition No. 10	H. Same as Item No. 9.A.
I. Strontium-85	I. Any	I. 2 curies per location listed in Condition No. 10	I. For use and/or possession as an impurity in strontium-82/rubidium-82 generators.
J. Radium-223	J. Liquid	J. 5 millicuries per location listed in Condition No. 10	J. Same as Item No. 9.A.
K. Actinium-225	K. Any	K. 5 millicuries per location listed in Condition No. 10	K. Same as Item No. 9.A.
L. Gallium-68	L. Any	L. 10 curies per location listed in Condition No. 10	L. Same as Item No. 9.A.

MATERIALS LICENSE SUPPLEMENTARY SHEET

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Docket or Reference No.: 030-36973

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
M. Germanium-68	M. Any	M. 8 curies total, 1 curie per location listed in Condition No. 10	M. For preparation and distribution of radioactive drugs and radiochemicals - using Eckert & Ziegler GalliaPharm™ and/or IRE Elit Galli-Eo® generators - for non-medical use to authorized recipients, for redistribution of used and unused germanium-68/gallium-68 generators to authorized recipients; and for medical use in accordance with 10 CFR 32.72 to authorized recipients.
N. Gallium-68	N. Any	N. 8 curies total, 1 curie per location listed in Condition No. 10	N. Same as Item No. 9.M.
O. Any byproduct material permitted in 10 CFR 35.400	O. Sealed Sources	O. 500 millicuries per location listed in Condition No. 10	O. For redistribution of sealed sources initially distributed by a manufacturer licensed in accordance to 10 CFR 32.74 to authorized recipients for medical use. For redistribution of sealed sources that have been registered either with NRC under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with an NRC or Agreement State specific license authorizing distribution to persons specifically authorized by an NRC or Agreement State license to receive, possess and use the authorized device.

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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
P. Any byproduct material permitted by 10 CFR 35.500	P. Sealed Sources	P. 4.5 curies total, no single source to exceed 1.5 curies, per location listed in Condition No. 10	P. Same as Item No. 9.O.
Q. Any byproduct material permitted by 10 CFR 35.65	Q. Sealed Sources	Q. 100 millicuries total, no single source to exceed 30 millicuries, per location listed in Condition No. 10	Q. For use in calibration and checking of the licensee's instruments. For redistribution of sealed sources initially distributed by a manufacturer licensed in accordance with 10 CFR 32.74 to authorized recipients for medical use and to authorized recipients for non-medical use.
R. Any byproduct material with Atomic Numbers 1 through 83	R. Analytical Samples	R. 100 millicuries total, no single analytical sample to exceed 10 millicuries, per location listed in Condition No. 10	R. For possession incident to the performance of test for leakage on customers sealed sources as a commercial service.
S. Yttrium-90 permitted by 10 CFR 35.1000	S. Microspheres (BWXT Medical Ltd., Model TheraSphere Y-90 Glass Microsphere)	S. 3 curies per location listed in Condition No. 10	S. For preparation and redistribution of yttrium-90 microspheres that have been registered either with NRC under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with an NRC or Agreement State specific license authorizing distribution to persons specifically authorized by an NRC or Agreement State license to receive, possess and use the microspheres for medical use as permitted by 10 CFR 35.1000.

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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
T. Yttrium-90 permitted by 10 CFR 35.1000	T. Microspheres (Sirtex, Model SIR-Spheres)	T. 3 curies per location listed in Condition No. 10	T. Same as Item No. 9.S.
U. Uranium- depleted in Uranium-235	U. Solid	U. 900 kilograms per licensed facility listed in Condition No. 10	U. For shielding for generators and shipping containers.
V. Carbon-14	V. Capsules	V. 50 microcuries total, no capsule to exceed 1 microcurie, per location listed in Condition No. 10	V. For redistribution to authorized recipients in accordance with 10 CFR 32.21.
W. Molybdenum-99	W. Liquid NorthStar Mo-99/Tc-99m to be used in the RadioGenix® System	W. 19 curies of Mo-99/Tc-99m per source vessel, not to exceed 80 curies total, per location listed in Condition No. 10.V.	W. For preparation and distribution of radioactive drugs and radiochemicals - using the NorthStar RadioGenix® System - for non-medical use to authorized recipients, and for medical use in accordance with 10 CFR 32.72 to authorized recipients.
X. Lutetium-177	X. Any	X. 30 curies per location listed in Condition No. 10	X. For preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.

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CONDITIONS

10. Except as specified otherwise in this license, licensed material listed in Item Nos. 6.A. through 6.V. and 6.X. shall be used or stored only at the licensee's facilities located at:

A. 5630 Silverado Way, Suite 1, Anchorage, Alaska, 99518
B. 131 Hartland St., East Hartford, Connecticut, 06108
C. 28 Omega Dr., Bldg. #7, Stamford, Connecticut, 06907
D. 10250 Stone Creek Dr., Laurel, Delaware, 19956
E. 525 Kokea St., Suite B-2, Honolulu, Hawaii, 96817
F. 2141 Airport Way, Suite 900, Boise, Idaho, 83705
G. 1100 Airport North Office Park, Suite D, Fort Wayne, Indiana, 46825
H. 2715 W. Main St., Highland, Indiana, 46322
I. 7920 Georgetown Rd., Suite 100, Indianapolis, Indiana, 46268
J. 3305 Lathrop St., Suite 100, South Bend, Indiana, 46628
K. 846 Service Rd., Room E137, East Lansing, Michigan, 48824
L. 1864 Pine Ridge Dr., Suite A, Jenison, Michigan, 49428
M. 21681 Melrose Ave., Southfield, Michigan, 48075
N. 5370 Miller Rd., Suite 25, Swartz Creek, Michigan, 48473
O. Marion Ridge Business Park, 9668 Marion Ridge, Kansas City, Missouri, 64137
P. 3040 E. Elm St., Springfield, Missouri, 65802
Q. 1909 Beltway Dr., St. Louis, Missouri, 63114
R. 1603 "C" Ave., Sioux Falls, South Dakota, 57104
S. 115 Dingess St., Barboursville, West Virginia, 25504
T. 296 New Hope Rd., Suite 4, Princeton, West Virginia, 24740

MATERIALS LICENSE SUPPLEMENTARY SHEET	License No.: 34-29200-01MD	Docket or Reference No.: 030-36973
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U. Licensed material listed in Item Nos. 6.C., 6.Q., and 6.R. may also be used at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States. 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 not under exclusive Federal jurisdiction should be obtained from the appropriate state regulatory agency.

V. Licensed material listed in Item No. 6.W. may only be used or stored at the licensee's facilities located at 7920 Georgetown Rd., Ste. 100, Indianapolis, Indiana 46268 and 1909 Beltway Dr., St. Louis, Missouri 63114.

11. The Radiation Safety Officer (RSO) for this license is David W. Pellicciarini.

12. A. Licensed material shall only be used by, or under the supervision of, a pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2)(i) or (4).

B. Notwithstanding the requirements in 10 CFR 32.72(b)(2)(ii), licensed material in Item Nos. 6.A. through 6.V. and 6.X. shall only be used by, or under the supervision of, nuclear pharmacists who have received training and have been designated, in writing, as described in letters dated December 8, 2006 (ML063550293), January 21, 2013 (ML13030A444), May 1, 2013 (ML13135A155), and December 22, 2021 (ML21363A011). The licensee shall maintain records of individuals designated as authorized nuclear pharmacists for three years after the individual's last use of licensed material.

C. Licensed material in Item Nos. 6.A. through 6.V. and 6.X. used for other than radiopharmaceutical use shall only be used by, or under the supervision of, non-medical authorized individuals trained, approved, and designated, in writing, as described in letters dated December 8, 2006 (ML063550293), January 21, 2013 (ML13030A444), May 1, 2013 (ML13135A155), and December 22, 2021 (ML21363A011). The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.

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D. Licensed material listed in Item No. 6.W. shall only be used by, or under the supervision of, Shane Branscum, Christopher Dyga, Melissa George, Nicole Kuznia, Kaitlyn Tyler, Janet Frigo, RPh, Tara Bernal, or Scott Early for the elution of technetium-99m from the NorthStar RadioGenix® System.

13. A. Sealed sources and detector cells 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 by an Agreement State. In the absence of a registration certificate, sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months, or at such other intervals as specified.

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 three 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 by 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.

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.

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F. The leak test shall be capable of detecting the presence of 185 becquerels (0.005 microcuries) of radioactive material on the test sample. If the test reveals the presence of 185 becquerels (0.005 microcuries) 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 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 becquerels (microcuries) and shall be maintained for 3 years.

14. Sealed sources containing licensed material shall not be opened nor 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 sealed 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. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash provided:

A. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated, 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.

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B. A record of each such disposal permitted under this license condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

17. Except for maintaining labeling as required by 10 CFR Part 20, or Part 71, the licensee shall obtain authorization from the U.S. Nuclear Regulatory Commission before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective certificate of registration issued either by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or by an Agreement State.

18. The licensee is authorized to retrieve, receive and dispose of radioactive waste from its customers limited to radiopharmacy supplied syringes and vials and their contents.

19. Notwithstanding the requirements of 10 CFR 32.72(c), the licensee may re-distribute alpha-, beta-, or photon-emitting radioactive drugs, which have been initially distributed by another radiopharmaceutical supplier licensed pursuant to 10 CFR 32.72, without verifying the radioactivity of the dosage. The licensee must not manipulate the dosage, including the packaging and label.

20. This license does not authorize distribution to persons exempt from licensing.

21. In accordance with letter dated July 24, 2019 (ML19207A599), the licensee may make changes to its radiation safety program, as it relates to the use of germanium-68/gallium-68 generators.

22. The licensee shall not modify the RadioGenix® System from the manufacturer's design and shall only use manufacturer approved consumable replacement parts.

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23. The licensee applied for and is authorized to revise its radiation safety program to:

    A. Permit revisions to existing RadioGenix® System radiation safety programs to conform to future changes in licensing guidance and additional safety recommendations from the manufacturer.

    B. Permit individuals who have received training resulting from safety and operational changes to the RadioGenix® System to use the RadioGenix® System after these changes are made by the manufacturer.

24. The licensee applied for and is authorized to notify the NRC within 30 days when experienced RadioGenix® System Authorized Users and Authorized Nuclear Pharmacists begin working at the facility.

25. 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 statements, representations, and procedures that are required to be submitted in accordance with the regulations. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence impose on the licensee requirements that are more restrictive than or in addition to the regulations.

    A. Letter dated December 22, 2021 (ML21363A011)
    B. Letter dated February 8, 2007 (ML070510598)
    C. Letter dated December 18, 2006 (ML063550293)
    D. Letter dated January 21, 2013 (ML13030A444)
    E. Letter dated May 1, 2013 (ML13135A155)
    F. Letter dated January 30, 2012 (ML120340529)
    G. Letter dated April 8, 2020 (ML20101H664)

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H. Letter dated November 28, 2016 (ML16335A431)
I. Letter dated February 13, 2017 (ML17047A712)
J. Letter dated September 22, 2017 (ML17275A909)
K. Letter dated January 30, 2018 (ML18037A496)
L. Letter dated June 11, 2018 (ML18166A335)
M. Letter dated May 2, 2019 (ML19127A242)
N. Letter dated July 26, 2019 (ML19207A599)
O. Letter dated July 31, 2018 (ML18220B192)
P. Letter dated October 8, 2018 (ML18284A057)
Q. Letter dated April 19, 2019 (ML19113A243)
R. Letter dated July 1, 2019 (ML19196A249)
S. Letter dated June 4, 2020 (ML20162A058)
T. Letter dated August 20, 2020 (ML20246G546)
U. Letter dated April 15, 2021 (ML21109A140)
V. Letter dated October 26, 2022 (ML22300A216)
W. Letter dated March 9, 2023 (ML23081A018)
X. Letter dated May 15, 2023 (ML23136A547)
Y. Letter dated May 16, 2023 (ML23139A254)
Z. Letter dated May 15, 2023 (ML23180A251)
ZA Letter dated August 14, 2023 (ML23229A476)

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ZB Letter dated September 12, 2023 (ML23256A344)

ZC Letter dated November 27, 2023 (ML23332A111)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: January 23, 2024

By: _____

Sara A. Forster
Region 3