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	In accordance with letter dated April 15, 2022,	4. Expiration Date: May 31, 2025
1. Cardinal Health 414, LLC		5. Docket No.: 030-38748 Reference No.:
2. 7000 Cardinal Place Dublin, OH 43017	3. License No.: 34-31473-03MD is amended in its entirety to read as follows:	

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. Radium-223	A. Any	A. 1 curie total	A. For preparation and distribution of radioactive drugs in unit doses to authorized recipients in accordance with 10 CFR 32.72.
B. Thorium-227	B. Any	B. 1 curie total	B. For preparation and distribution of radioactive drugs in unit doses to authorized recipients in accordance with 10 CFR 32.72.
C. Any byproduct material permitted by 10 CFR 35.65	C. Sealed Sources	C. 30 millicuries per source and 100 millicuries total	C. For use in calibration and checking of the licensee's instruments.
D. Any byproduct material permitted by 10 CFR 35.65	D. Any	D. 15 millicuries per source and 50 millicuries total	D. Same as Subitem No. 9.C.
E. Any byproduct material permitted by 10 CFR 35.65	E. Any	E. 10 microcuries per source and 30 microcuries total	E. Same as Subitem No. 9.C.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License No.: 34-31473-03MD

Amendment No. 15

Docket or Reference No.: 030-38748

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
F. Americium-241	F. Solid (Eckert & Ziegler, Model AMRB20270)	F. 1 microcurie total	F. Same as Subitem No. 9.C.
G. Chlorine-36	G. Solid (Eckert & Ziegler, Model CIRB20271)	G. 1 microcurie total	G. Same as Subitem No. 9.C.
H. Germanium-68/ Gallium-68 permitted by 10 CFR 35.1000	H. Generators	H. 50 millicuries per source and 1000 millicuries total	H. For receipt of IRE Galli-Eo® germanium-68/ gallium-68 generators from IRE EliT, S.A., for distribution to authorized recipients. For receipt of IRE Galli-Eo® germanium-68/gallium-68 generators from Cardinal Health facilities or from licensees that have a return agreement with Cardinal Health for return to IRE EliT, S.A.
I. Actinium-225	I. Any	I. 500 millicuries total	I. For preparation and distribution of radioactive drugs and radiochemicals to authorized recipients in accordance with 10 CFR 32.72. For research and development as defined in 10 CFR 30.4 and calibration and checking of the licensee's instruments.
J. Any byproduct material with Atomic Numbers 1 through 83 with half-life less than or equal to 120 days	J. Any	J. 5 curies total	J. Same as Subitem No. 9.I.
K. Actinium-227	K. Any	K. 50 millicuries total	K. For possession as contaminant in actinium-225. For research and development as defined in 10 CFR 30.4. For preparation and distribution of radioactive drugs and radiochemicals to authorized recipients in accordance with 10 CFR 32.72.

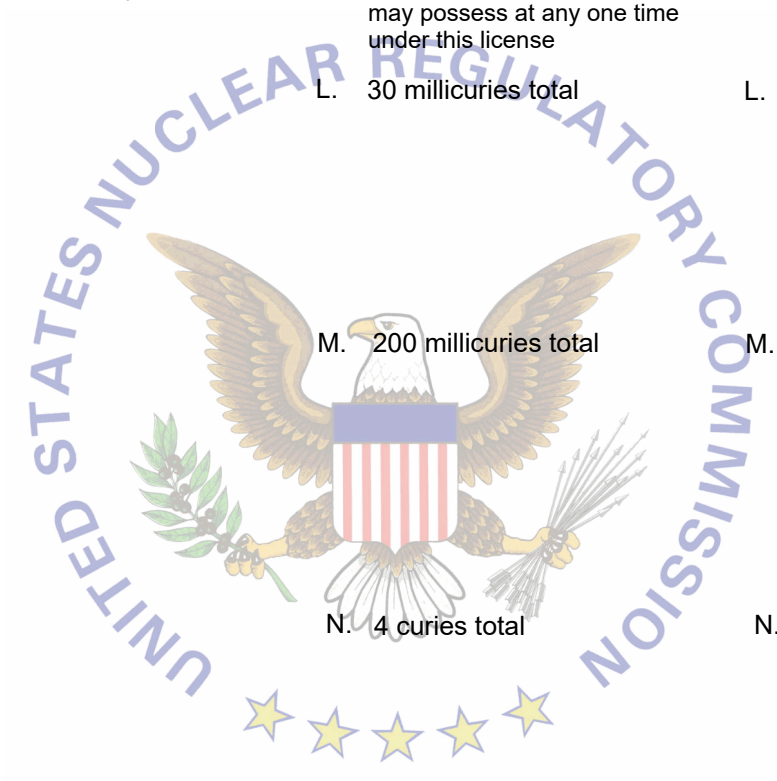
MATERIALS LICENSE SUPPLEMENTARY SHEET

License No.: 34-31473-03MD

Amendment No. 15

Docket or Reference No.: 030-38748

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
L. Thorium-229	L. Any	L. 30 millicuries total	L. For research and development as defined in 10 CFR 30.4 and calibration and checking of the licensee's instruments. For preparation and distribution of radiochemicals to persons authorized to receive the licensed material in accordance with the terms and conditions of specific licenses issued by the U.S. Nuclear Regulatory Commission or any Agreement State.
M. Thorium-228	M. Any	M. 200 millicuries total	M. For possession as contaminant in thorium-229. For research and development as defined in 10 CFR 30.4 and calibration and checking of the licensee's instruments. For preparation and distribution of radiochemicals to persons authorized to receive the licensed material in accordance with the terms and conditions of specific licenses issued by the U.S. Nuclear Regulatory Commission or any Agreement State.
N. Thorium-229	N. Any	N. 4 curies total	N. For temporary storage only prior to transferring to persons authorized to receive the licensed material in accordance with the terms and conditions of specific licenses issued by the U.S. Nuclear Regulatory Commission or any Agreement State. Licensed material will remain in its unopen original shipping containers.
O. Thorium-228	O. Any	O. 30 curies total	O. For possession as contaminant in thorium-229. For temporary storage only prior to transferring to persons authorized to receive the licensed material in accordance with the terms and conditions of specific licenses issued by the U.S. Nuclear Regulatory Commission or any Agreement State. Licensed material will remain in its unopen original shipping containers.



MATERIALS LICENSE SUPPLEMENTARY SHEET	License No.: 34-31473-03MD	Docket or Reference No.: 030-38748
	Amendment No. 15	

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. Thorium-232	P. Any	P. 1.5 kilograms total	P. Same as Subitem No. 9.L.
Q. Radium-224	Q. Any	Q. 2 millicuries total	Q. Same as Subitem No. 9.L.
R. Radium-225	R. Any	R. 2 millicuries total	R. Same as Subitem No. 9.L.
S. Uranium-233	S. Any	S. 5 microcuries total	S. Same as Subitem No. 9.L.

CONDITIONS

10. A. Licensed material in Items 6.A. through 6.G., and 6.I. through 6.S. shall be used or stored at the licensee's facilities located at 7920 Georgetown Road, Indianapolis, Indiana, 46268.

B. Licensed material in Item 6.H. may be possessed, stored and distributed from the licensee's facilities at 7920 Georgetown Road, Indianapolis, Indiana, 46268.

11. The Radiation Safety Officer (RSO) for this license is Kevin Stahl, R.Ph.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License No.: 34-31473-03MD Amendment No. 15	Docket or Reference No.: 030-38748

12. Licensed material shall only be used by, or under the supervision of:

A. A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2)(i) or (4).

B. Authorized Nuclear Pharmacists:

Shane Branscum, R.Ph.	Benjamin Ellert, R.Ph.	Gregory Even, R.Ph.
Melissa George, R.Ph.	Kimberly Gomez, R.Ph.	Amanda Jehl, R.Ph.
Keith Koontz, R.Ph.	Ryan Kunkel, R.Ph.	Nicole M. Kuznia, R.Ph.
Adam Timm, R.Ph.	Kaitlin Tyler, Pharm.D.	

C. Authorized Users (Non-pharmacist):

James Brading	Robert Droege	Christopher T. Fullerton, M.S.
Luke Hartline	Andrew B. Hughes	Mehmet Husnu
Tyler B. Keller	Jacob Kilian	Norman Medina
Troy S. Sambyal	Kevin Stahl	Avery Stephens
Glenn Sullivan	Jace-Cameron Taylor	Albert Tondreau
Chad R. Warkentien	Evan Western	Jacob Wolfla

D. Authorized Users (Non-pharmacist), with authorized use limitations to licensed materials listed in Subitem Nos. 6.I. and 6.J:

Jacob Kilian
Avery Stephens
Chad R. Warkentien

MATERIALS LICENSE SUPPLEMENTARY SHEET	License No.: 34-31473-03MD	Docket or Reference No.: 030-38748
	Amendment No. 15	

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 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 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.

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.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License No.: 34-31473-03MD	Docket or Reference No.: 030-38748
	Amendment No. 15	

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 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 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.

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.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License No.: 34-31473-03MD	Docket or Reference No.: 030-38748
	Amendment No. 15	

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

19. Notwithstanding the requirements of 10 CFR 30.35(a)(1), the licensee is exempt from the requirement to have a decommissioning funding plan needed for the possession and distribution of IRE Galli-Eo® germanium-68/gallium-68 generators based on the commitments between the licensee and IRE EliT, S.A. The licensee shall return the generators to IRE EliT, S.A. in accordance with the generator return agreement described in the letter dated September 7, 2018 (ML18254A346).

20. 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. 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 June 24, 2014 (ML14177A279)
    B. Letter dated January 5, 2015 (ML15020A661)
    C. Letter dated February 25, 2015 (ML15069A650)
    D. Letter dated March 20, 2015 (ML15085A536)
    E. Letter dated April 27, 2015 (ML15119A563)
    F. Letter dated May 27, 2015 (ML15155B513)
    G. Letter dated May 28, 2015 (ML15155B506)
    H. Letter dated October 27, 2015 (ML15303A544)
    I. Letter dated May 10, 2016 (ML16141A349)
    J. Letter dated October 24, 2016 (ML16300A213)
    K. Letter dated December 8, 2017 (excluding 2nd letter, with attachments, dated December 8, 2017 re: IRE Ge-68/Ga-68 generators) (ML17345A547)
    L. Letter dated April 24, 2018 (ML18123A528)
    M. Letter dated September 7, 2018 (ML18254A346)

MATERIALS LICENSE SUPPLEMENTARY SHEET	License No.: 34-31473-03MD	Docket or Reference No.: 030-38748
	Amendment No. 15	

N. Letter dated November 6, 2018 (ML18310A424)
O. Letter dated July 10, 2019 (ML19193A150)
P. Letter dated July 31, 2019 (ML19213A047)
Q. Letter dated June 5, 2020 (ML20161A384)
R. Letter dated June 26, 2020 (ML20181A265)
S. Letter dated June 26, 2020 (ML20234A395)
T. Letter dated February 26, 2021 (ML21060B419)
U. Letter dated May 21, 2021 (ML21144A009)
V. Letter dated July 26, 2021 (ML21222A083)
W. Letter dated April 15, 2022 (ML22110A023)
X. Letter dated May 10, 2022 (ML22130A757)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Sara A. Forster

Digitally signed by Sara A. Forster
Date: 2022.05.13 07:56:17 -05'00'

Date: May 13, 2022

By: _____

Sara A. Forster
Region III