

## U.S. NUCLEAR REGULATORY COMMISSION

## 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, and 70, 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		3. License No. 34-32780-04MD
2. 7000 Cardinal Place Dublin, Ohio 43017		4. Expiration Date: May 31, 2026
		5. Docket No. 030-38867 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
A. Radium-223	A. Any	A. 6.1 curies
B. Actinium-227	B. Any	B. 6.1 curies
C. Any byproduct material with Atomic Nos. 3 through 83	C. Any	C. 100 millicuries total, and no single source to exceed 30 millicuries
D. Any byproduct material with Atomic Nos. 84 through 95	D. Any	D. 50 microcuries total, and no single source to exceed 10 microcuries
E. Thorium-228	E. Any	E. 130 millicuries
F. Radium-226	F. Any	F. 65 millicuries

## 9. Authorized use:

- A. and B. Validation testing, manufacturing, preparation, packaging and distribution of radiopharmaceuticals to authorized recipients in accordance with 10 CFR 32.72.
- C. and D. Calibration and checking of the licensee's instruments.
- E. and F. Specified maximum impurities in actinium-227.

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CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 4343 West 62<sup>nd</sup> Street, Indianapolis, Indiana.
11. A. The Radiation Safety Officer (RSO) for this license is Cami Still.  
B. The Alternate RSO for this license is Glenn Sullivan.
12. Licensed material shall be used by, or under the supervision of Cami Still, Glenn Sullivan, William Scott Claunch, R.Ph., Mehmet Husnu, Derrick Alcaide, Henry Padgett, Ph.D., Albert Trondreau, Robert Droege and Norman Medina.
13. 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 NRC under 10 CFR 32.210 or by 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 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 NRC under 10 CFR 32.210 or by an Agreement State prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- 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 0.005 microcurie (185 Becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 Becquerels) 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.

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- G. Tests for leakage and/or contamination shall be performed by the licensee or other persons specifically licensed by the Commission or an Agreement State to perform such services.
- H. Records of leak test results shall be kept in units of microcuries and shall be maintained for three years.
14. The licensee shall conduct a physical inventory every six months, or at other intervals approved by NRC, to account for all sealed sources and/or devices received and possessed under the license.
15. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
16. Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from NRC 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 Registration Certificates issued either by the Commission pursuant to 10 CFR 32.210 or by an Agreement State.
17. The licensee is not required to establish an Emergency Plan pursuant to 10 CFR 30.32(i) based on the evaluation and dose assessment contained in letters dated April 15, 2016 (ML16118A340) and April 18, 2016 (ML16118A341).
18. This license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR Part 31 or to persons exempt from licensing pursuant to 10 CFR 30.14 through 30.22, inclusive, or equivalent regulations of any Agreement State.
19. The licensee is authorized to hold byproduct 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, byproduct material 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.
- B. A record of each disposal permitted under this License Condition shall be retained for three 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 measured at the surface of each waste container, and the name of the individual who performed the disposal.
20. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

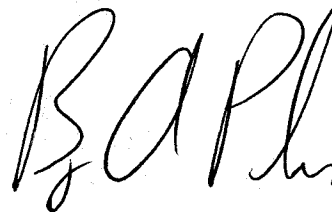
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21. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U. S. Nuclear 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 August 28, 2015 (ML15244A621)
  - B. Letter dated January 11, 2016 (ML16015A063)
  - C. Letter dated March 16, 2016 (ML16077A354)
  - D. Letter dated April 12, 2016 (ML16118A496)
  - E. Letter dated April 15, 2016 (ML16118A340)
  - F. Letter dated April 18, 2016 (ML16118A341)
  - G. Letter dated April 28, 2016 (ML16120A434)

FOR THE U. S. NUCLEAR REGULATORY COMMISSION



Date MAY 02 2016

By \_\_\_\_\_  
Bryan A. Parker  
Materials Licensing Branch  
Region III