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Consolidated NRC (1)



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, ILLINOIS 60532-4352

MAR 07 2012

FEB 29 2012

Willie Regits, Ph.D.  
Radiation Safety Officer  
Cardinal Health  
Nuclear Pharmacy Services  
7000 Cardinal Place  
Dublin, Ohio 43017

Dear Dr. Regits:

Enclosed is Amendment No. 37 amending your NRC Material License No. 34-29200-01MD in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in accordance with 10 Code of Federal Regulations 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present security vulnerability. The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf> and the link for frequently asked questions regarding protection of security related sensitive information may be located at: <http://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

A handwritten signature in black ink, appearing to read "Cassandra F. Frazier".

Cassandra F. Frazier  
Senior Health Physicist  
Materials Licensing Branch

License No. 34-29200-01MD  
Docket No. 030-36973

Enclosure: Amendment No. 37

The enclosed document contains sensitive security-related information.  
When separated from this cover letter this letter is uncontrolled.

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**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, 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.

<p align="center">Licensee</p> <p>1. Cardinal Health Nuclear Pharmacy Services</p> <p>2. 7000 Cardinal Place Dublin, Ohio 43017</p>	<p>In accordance with letter dated <b>December 7, 2011,</b></p> <hr/> <p>3. License number 34-29200-01MD is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date January 31, 2022</p> <hr/> <p>5. Docket No. 030-36973 Reference No. Docket 030-33224 &amp; License No. 04-26507-01MD</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with atomic numbers 3 through 83 with half-life less than 120 days, except iodine-131, fluorine-18, rubidium-82, molybdenum-99, strontium-82, technetium-99m, xenon-133, and strontium-85</p> <p>B. Molybdenum-99</p> <p>C. Technetium-99m</p> <p>D. Xenon-133</p> <p>E. Iodine-131</p> <p>F. Any byproduct material in a brachytherapy source listed in 10 CFR 35.400</p> <p>G. Any byproduct material in a sealed source for diagnosis listed in 10 CFR 35.500</p>	<p>7. Chemical and/or physical form</p> <p>A. Solid or Liquid</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> <p>F. Sealed sources</p> <p>G. Sealed sources</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p align="center"><b>Maximum amount per licensed facility identified in Condition 10</b></p> <p>A. 5 Curies</p> <p>B. 200 curies</p> <p>C. 200 curies</p> <p>D. 5 curies</p> <p>E. 6 curies</p> <p>F. 500 millicuries</p> <p>G. 4.5 curies total and no single source to exceed 1.5 curies</p>
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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
H. Cesium-137	H. Sealed sources (J.L. Shepherd Model 6810 or Amersham 72602)	Maximum amount per licensed facility identified in Condition 10 H. 100 millicuries for the Kansas City, Missouri facility only
I. Cesium-137	I. Sealed source (Technical Operations Model 773)	I. 100 millicuries for the 7920 Georgetown Road, Indianapolis, Indiana facility only
J. Any byproduct material authorized under 10 CFR 35.65(a)	J. Sealed sources	J. 100 millicuries total, and no single source to exceed 30 millicuries
K. Depleted Uranium	K. Solid	K. 660 kilograms
L. Any byproduct material with atomic numbers 1-83, inclusive	L. Solid or Liquid (Analytical samples)	L. Not to exceed 10 millicuries per analytical sample and 100 millicuries total except as specified in condition 22.
M. Fluorine-18	M. Any	M. 10 curies
N. Strontium-82	N. Solid	N. 400 millicuries
O. Rubidium-82	O. Any	O. 400 millicuries
P. Strontium-85	P. Any	P. 2 curies

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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      |
| Q. Radium-223   | Q. Liquid                        | Maximum amount per licensed facility identified in Condition 10<br>Q. 5 millicuries |

9. Authorized use:

- A. through E, M, N, and O Preparation and distribution of radioactive drugs including compounding of iodine-131 and redistribution of used and unused molybdenum-99/technetium-99m generators and strontium-82/rubidium-82 generators to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals including compounding of iodine-131 and redistribution of used and unused molybdenum 99/technetium 99m generators to authorized recipients for non-medical use.
- F. and G. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. 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 devices.
- H. To be used in a J.L. Shepherd and Associates Model 28-6A calibrator or Amersham (formerly Technical Operations) Model 726 calibrator at the Kansas City, Missouri facility for instrument calibration including calibration of survey meters as a service for customers and other clients.
- I. To be used in a Victoreen Gamma Survey Instrument Calibrator at the licensee's 7920 Georgetown Road, Indianapolis, Indiana facility for instrument calibration including calibration of survey meters as a service for customers and other clients.
- J. Calibration and checking of the licensee's instruments. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 to authorized recipients and to authorized recipients for non-medical use.
- K. Shielding for Mo99/Tc99m generators.
- L. Possession incident to the performance of swipe testing of customer's sealed sources
- P. Impurity in Sr-82/Rb-82 generators.
- C. and J. To be used for client instrument calibrations.

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Q. For distribution to authorized recipients.

CONDITIONS

10. Except as specified otherwise in this license, licensed material identified in Items 6.A through 6.Q. shall be used only at the licensee's facilities located at:
- A. 34 New Hope Road #4, Princeton, West Virginia 24740
  - B. 1100 Airport North Office Park, Suite D, Fort Wayne, Indiana 46825
  - C. 7920 Georgetown Road, Suite 100, Indianapolis, Indiana 46268
  - D. 1864 Pine Ridge Drive, #A, Jenison, Michigan 49428
  - E. 2131 E. 32<sup>nd</sup> Street, Suite 1, Joplin, Missouri 64804
  - F. Marion Ridge Business Park, 9668 Marion Ridge, Kansas City, Missouri 64137
  - G. 131 Hartland Street, East Hartford, Connecticut 06108
  - H. 5630 Silverado Way, # 1, Anchorage, Alaska 99518
  - I. 1603 "C" Avenue, Sioux Falls, South Dakota 57104
  - J. 3305 Lathrop Street, Suite 100, South Bend, Indiana 46628
  - K. 21681 Melrose Avenue, Southfield, Michigan 48075
  - L. 3040 East Elm Street, Springfield, Missouri 65802
  - M. 1909 Beltway Drive, St. Louis, Missouri 63114
  - N. 527 Honey Creek Drive, Terre Haute, Indiana 47802
  - O. 28 Omega Drive, Building #7, Stamford, Connecticut 06907
  - P. 5370 Miller Road, Suite #25, Swartz Creek, Michigan 48473
  - Q. 115 Dingess Street, Barboursville, West Virginia 25504
  - R. 2141 Airport Way, Suite 900, Boise, Idaho 83705
  - S. 10250 Stone Creek Drive, Laurel, Delaware 19956
  - T. 2715 West Main Street, Highland, Indiana 46322
  - U. 846 Service Road, Room E137, East Lansing, Michigan 48824
11. Licensed material identified in Subitems 6.C., 6.J. and 6.L. may be used at the licensee's facilities listed in Condition 10 and 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.
12. A Licensed material shall 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. (1) Licensed material for other than radiopharmaceutical use shall be used by or under the supervision of individuals approved in accordance with letters, dated December 18, 2006, and February 8, 2007.

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(2) Licensed material for other than radiopharmaceutical use shall be used by or under the supervision of:

Tony Adamo	Cheryl Holmes	Wes Rogers
T. John Alexander	Anjuni Mingus	Dan Schmitz
Kory Kodimer, Ph.D.	Matthew Komornik	Mark Vorhees
Jack L. Coffey	Robert E. Lewis	David Wilson
Edward A. Corros	Brenda K. Norkosky	Michael Young
W. Robert Davis	Evan T. Western	Adam J. Fleshner
Tara J. Simonian	David W. Pellicciarini	James T. Chimelewski, Jr.
Candice Goodyear	Robert Lapena	Carl Collier
Colleen M. Glynn	Corey W. Woods	Willie Regits, Ph.D.
Dean Polar	Burr Johnson	Lonze Townsend
Amy Schnees	Dennis Kephart	Edward E. Gann III
Jason Luper	Jason K. Steincamp	Richard B. Hasselkus
Paul Friedenber	Elias Garcia	Brent Marlow
Jason Cash	John Haag	Andrew Fu
Thaibinh Dang	Alonzo Keys	Craig O'Dell
Barbara M. Atunrase	Cami Still	Vai Paye
Lisa Frantz	Michael Koniski	Laura Delagrange
Asma Abbasi	W. Dan Hill	

13. The Radiation Safety Officer for this license is Willie Regits, Ph.D.
14. Notwithstanding the requirements of 10 CFR 32.72(b)(2)(ii), the licensee may approve authorized nuclear pharmacists in accordance with application dated July 20, 2011.
15. 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. 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.
- C. 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

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shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

- D. 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.
- E. 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.
16. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
17. 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.
18. 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."
19. The licensee is authorized to hold byproduct material with a physical half-life of less than 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 meter 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. 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.
21. 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

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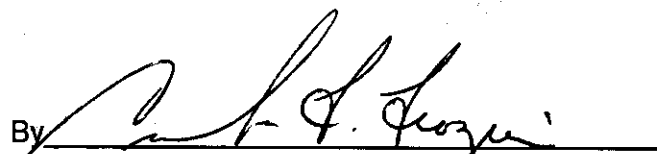
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- 22. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
- 23. 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.
- 24. This license does not authorize distribution to persons exempt from licensing.
- 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. 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 July 20, 2011; and
  - B. Letters dated August 14, 2006 (training program), December 18, 2006, February 8, 2007, July 25, 2011, and December 7, 2011.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date FEB 29 2012

By   
Cassandra F. Frazier  
Materials Licensing Branch  
Region III