NRC FORM 374



U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 18

# 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 June 03, 2019. | 4. Expiration Date: December 31, 2019 |
|---|---|---|
| 1. Endocyte, Inc.<br><br>2. 3000 Kent Ave.<br>West Lafayette, IN 47906 | 3. License number: 13-32212-01 is amended in its entirety to read as follows: | 5. Docket No.: 030-35228<br>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. Hydrogen-3 | A. Any non-volatile | A. 100 millicuries total | A. For research and development as defined in 10 CFR 30.4, including animal studies. |
| B. Carbon-14 | B. Any non-volatile | B. 10 millicuries total | B. Same as Subitem No. 9.A. |
| C. Phosphorus-32 | C. Any non-volatile | C. 20 millicuries total | C. Same as Subitem No. 9.A. |
| D. Phosphorus-33 | D. Any non-volatile | D. 10 millicuries total | D. Same as Subitem No. 9.A. |
| E. Sulfur-35 | E. Any non-volatile | E. 20 millicuries total | E. Same as Subitem No. 9.A. |
| F. Technetium-99 | F. Any | F. 1 millicurie total | F. Same as Subitem No. 9.A. |
| G. Technetium-99m | G. Any non-volatile | G. 500 millicuries total | G. Same as Subitem No. 9.A. |
| H. Iodine-125 | H. Any non-volatile | H. 10 millicuries total | H. Same as Subitem No. 9.A. |
| I. Iodine-125 | I. Liquid | I. 10 millicuries total | I. Same as Subitem No. 9.A. |

**MATERIALS LICENSE SUPPLEMENTARY SHEET**

License Number 13-32212-01

Amendment No. 18

Docket or Reference Number 030-35228

| 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 |
|---|---|---|---|
| J. Gallium-67 | J. Liquid | J. 60 millicuries total | J. Same as Subitem No. 9.A. |
| K. Gallium-68 | K. Liquid | K. 80 millicuries total | K. Same as Subitem No. 9.A. |
| L. Indium-111 | L. Liquid | L. 40 millicuries total | L. Same as Subitem No. 9.A. |
| M. Astatine-211 | M. Liquid | M. 100 millicuries total | M. Same as Subitem No. 9.A. |
| N. Radium-223 | N. Liquid | N. 10 millicuries total | N. Same as Subitem No. 9.A. |
| O. Actinium-225 | O. Any | O. 60 millicuries total | O. Same as Subitem No. 9.A. |
| P. Yttrium-90 | P. Liquid | P. 20 millicuries total | P. Same as Subitem No. 9.A. |
| Q. Lutetium-177 | Q. Liquid | Q. 500 millicuries total | Q. Same as Subitem No. 9.A. |
| R. Iodine-131 | R. Sodium Iodide I-131, Liquid | R. 30 millicuries total | R. Same as Subitem No. 9.A. |
| S. Copper-67 | S. Liquid | S. 50 millicuries total | S. Same as Subitem No. 9.A. |
| T. Thorium-227 | T. Solid or Liquid | T. 50 millicuries total | T. Same as Subitem No. 9.A. |
| U. Tungsten-188 | U. Any | U. 350 millicuries total | U. For use in a tungsten-188/rhenium-188 generator for research and development as defined in 10 CFR 30.4, including animal studies. |
| V. Rhenium-188 | V. Any | V. 350 millicuries total | V. Same as Subitem No. 9.U. |
| W. Rhenium-186 | W. Liquid | W. 200 millicuries total | W. Same as Subitem No. 9.A. |
| X. Copper-64 | X. Any | X. 100 millicuries total | X. Same as Subitem No. 9.A. |

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CONDITIONS

10. A. Licensed material listed in Subitem Nos. 6.A. through 6.X. may be used or stored at the licensee's facilities located at 3000 Kent Ave., West Lafayette, Indiana, 47906.
    B. Licensed material listed in Subitem Nos. 6.C. through 6.X. may be used or stored at the licensee's facilities located at 190 S Russell St., West Lafayette, Indiana, 47907. Use at this location is limited to radionuclides with a half-life of 120 days or less.

11. The Radiation Safety Officer (RSO) for this license is Le-Cun Xu, Ph.D.

12. Licensed material shall be used by, or under the supervision of, the following individuals for the materials and uses indicated:

| Authorized Users | Material and Use |
|---|---|
| Christopher P. Leamon, Ph.D. | For research and development use of hydrogen-3, carbon-14, phosphorus-32, phosphorus-33, sulfur-35, technetium-99, technetium-99m, and iodine-125 as permitted under this license |
| Melissa Nelson | For research and development use of all radionuclides permitted under this license |
| Nikki Parker | For research and development use of all radionuclides permitted under this license |
| Joseph A. Reddy, Ph.D. | For research and development use of hydrogen-3, technetium-99m, and iodine-125 as permitted under this license |
| Elaine Westrick | For research and development use of all radionuclides permitted under this license |
| Le-Cun Xu, Ph.D. | For research and development use of all radionuclides permitted under this license |

13. 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.

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14. 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.

15. The licensee shall not use the licensed material in or on humans.

16. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

17. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

18. 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 September 25, 2009 (ML092740759)

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B. Letter dated February 14, 2013 (ML13050A724)
C. Letter dated April 29, 2013 (ML13120A637)
D. Letter dated July 23, 2015 (ML15205A331)
E. Letter dated December 12, 2016 (ML16348A276)
F. Letter dated August 7, 2017 (ML17221A166)
G. Letter dated June 21, 2018 (ML18198A185)
H. Letter dated October 8, 2018 (ML18282A032)
I. Letter dated November 28, 2018 (ML18333A248)
J. Letter dated January 13, 2019 (ML19037A111)
K. Letter dated June 3, 2019 (ML19155A183)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: August 13, 2019

By: Sara A. Forster

Sara A. Forster
Region 3