

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 19

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.

Licensee

1. **EMD Millipore**
2. 15 Research Park Drive
St. Charles, MO 63304

In accordance with the letter dated **July 15, 2010**,

3. License number 24-26445-01 is amended in its entirety to read as follows:

4. Expiration date July 31, 2013

5. Docket No. 030-32903/030-36554
Reference No.

- | | | |
|---|---|--|
| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Iodine-125</p> <p>B. Carbon-14</p> <p>C. Hydrogen-3</p> <p>D. Phosphorus-32</p> <p>E. Phosphorus- 33</p> <p>F. Sulfur-35</p> | <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> <p>F. Any</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 500 millicuries</p> <p>B. 10 millicuries</p> <p>C. 10 millicuries</p> <p>D. 10 millicuries</p> <p>E. 10 millicuries</p> <p>F. 10 millicuries</p> |
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9. Authorized Use:

- A. To be used in the manufacture of radiolabeled peptides and proteins for distribution to persons authorized to receive the licensed material under the terms and conditions of a specific license issued by the Commission or an Agreement State. Also to be used for research and development, as defined in 10 CFR 30.4.
- B. through F. For use in research and development, as defined in 10 CFR 30.4.

CONDITIONS

10. Licensed material listed in item A shall be used only at the licensee's facilities located at 6 Research Park Drive, 14 Research Park Drive, and 15 Research Park Drive, St. Charles, Missouri. Licensed material listed in items B through F may only be used at 15 Research Park Drive, St. Charles, Missouri.

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11. A. Licensed material for manufacturing and distribution purposes shall be used by, or under the supervision of, John Nichols.
- B. Licensed material for research and development purposes shall be used by, or under the supervision of, Nann Green, Ph.D. Licensed material listed in items B through F shall only be used by, or under the supervision of Jacob Bode for research and development purposes.
12. The Radiation Safety Officer for this license is James C. Hatten.
13. 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 30.18.
14. This license does not authorize distribution to persons licensed pursuant to 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.500, or 10 CFR 35.600
15. 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, 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, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
16. Licensed material shall not be used in or on humans
17. The licensee shall not use licensed material in field applications.
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."

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19. 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 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. Applications dated January 20, 2003 (with attachments) and March 25, 2004; and
 - B. Facsimile letters dated April 23, 2004, April 25, 2004 and February 23, 2007 and May 14, 2007; and
 - C. Letters dated April 22, 2004, May 7, 2004, June 7, 2004, January 26, 2005, November 2, 2006, December 18, 2006 (excluding name and ownership change request), December 27, 2006 (excluding name and ownership change request), and February 1, 2007, July 18, 2008, (limited to use of pre-labeled RIA kits), February 8, 2010 and **July 15, 2010; and**
 - D. Letter received October 9, 2003.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date SEP 14 2010

By

William P. Reichhold
Materials Licensing Branch
Region III