

STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH SERVICES
RADIOLOGICAL HEALTH SECTION
RADIOACTIVE MATERIAL LICENSE

Pursuant to the State of New Hampshire, Department of Health and Human Services' Radiological Health Section regulations and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Department of Health and Human Services' Radiological Health Section now or hereafter in effect and to any conditions specified below.

LICENSEE		3. LICENSE NO. 418R AMENDMENT NO. 19
1. NAME	Metabolic Solutions, Inc.	4. EXPIRATION DATE January 31, 2011
2. ADDRESS	460 Amherst Street Nashua, New Hampshire 03063	5. CATEGORY Research and/or Development
		In accordance with letter dated March 15, 2010, signed by David A. Wagner, Ph.D., President, New Hampshire Radioactive Material License No. 418R is hereby amended as noted herein. <i>PREVIOUS AMENDMENTS ARE VOID.</i>
6. RADIOACTIVE MATERIAL (ELEMENT AND MASS NUMBER)	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM AMOUNT OF RADIOACTIVITY WHICH LICENSEE MAY POSSESS AT ONE TIME
A. Carbon 14	A. Any	A. 75 millicuries (mCi)
B. Carbon 14	B. Carbon Dioxide Gas	B. 100 microcuries
C. Hydrogen 3	C. Liquid or solid	C. 25 mCi

9. AUTHORIZED USE

- A. For use in research, development, processing, manufacturing, and distribution of the Erythromycin Breath Test Dose (ERMBT™ Dose) kit to persons authorized to possess the licensed material pursuant to a specific license issued by the Department of Health and Human Services' Radiological Health Section ("Agency") or under an equivalent license issued by the United States Nuclear Regulatory Commission (NRC) or an Agreement State.
- B. Activity incident to the receipt, possession, and analysis of breath bag samples from customers for carbon-14 activity in the form of CO₂.
- C. For analysis of blood and urine samples from basic biochemical scientific research projects.

CONDITIONS

10. The licensee shall comply with the provisions of Parts He-P 4019, 4020, 4021, 4022, and 4023, New Hampshire Rules for the Control of Radiation (NHRCR).
11. This license is subject to an annual fee in accordance with Part He-P 4070, NHRCR, for the applicable amount specified in Table 4070.1 of that Part.
12. Radioactive material shall be used only at, and distributed in accordance with this license only from, the licensee's facility located at 460 Amherst Street, Nashua, New Hampshire. Records pertaining to activities authorized by this license shall be maintained at the licensee's authorized facility.
13. Radioactive material shall be used only by, or under the supervision of, David A. Wagner, Ph.D., Thomas E. Chapman, Ph.D., Keith J. Goodman, Ph.D., or Knut M. Greulich.

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Supplementary Sheet

14. The individual designated to perform the duties and functions of Radiation Safety Officer (RSO) for the activities covered by this license is David A. Wagner, Ph.D.
15. Any proposed changes in packaging, labeling, shielding, or the instructions for use and storage of the ERMBT Dose kit shall be submitted to the Agency for review and approval.
16. Proposed changes in or additions to the licensee's radiation protection program manual shall be submitted to and approved by the Agency, before being incorporated into this document.
17. The licensee shall not use licensed material in or on human beings.
18. The licensee is authorized to distribute licensed material as a research tool for use by sponsors of clinical investigations of human drugs. The distribution shall be only to licensees authorized to possess and use the radioactive material and who are also authorized by the United States Food and Drug Administration (FDA) to conduct the clinical investigations under a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or other FDA provisions allowing use of investigational drugs in radiopharmaceutical and/or animal research.
19. A. This license does not authorize the distribution of exempt quantities of licensed material pursuant to Section 30.18, Part 30, Title 10, Code of Federal Regulations (CFR), Section 32.18 of 10 CFR Part 32, or pursuant to He-P 4030.03 and He-P 4032, NHRCR.
B. This license does not authorize the distribution of licensed material to persons generally licensed.
20. The licensee shall maintain a copy of the radioactive material license and FDA approvals for each customer for inspection by the Agency. The licensee shall verify that the customer is authorized to possess, receive, and use the radioactive material prior to dispensing, distributing, or transferring.
21. The licensee shall maintain a record, for inspection by the Agency, of all radioactive materials dispensed, distributed or transferred.
22. Radiopharmaceuticals that are procured shall be from a licensed nuclear pharmacy or from a supplier who distributes the radiopharmaceuticals with FDA approval.
23. A. In addition to the requirements of NHRCR He-P 4020.04, "Radiation Protection Programs", so as to implement the ALARA requirements of He-P 4020.04(b), and notwithstanding the requirements in He-P 4020.13, a "constraint" (as defined in Part B of this condition) on air emissions of radioactive material to the environment, (excluding Radon-222 and its daughters), shall be established by the licensee such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions.
B. For the purposes of this condition, "Constraint" (dose constraint) means a value above which specified licensee actions are required.
C. If the dose constraint specified in Part A of this condition is exceeded, the licensee shall report the exceedance as specified in Part D below, and promptly take appropriate corrective action to ensure against recurrence.

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Condition 23 (cont'd from previous page)

- D. In addition to the reporting requirements of NHRCR He-P 4021.14, "Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits", the licensee shall submit a written report within 30 days after learning of doses in excess of the ALARA constraints for air emissions established under Part A of this condition. The content of the report shall comply with the requirements set out in He-P 4021.14(b), and shall include the corrective steps taken or planned to ensure against a recurrence, the schedule for achieving conformance with the ALARA constraint, and the specified information for each individual exposed.
24. Except as specifically provided otherwise by this license, the licensee shall possess and use the radioactive material authorized by this license in accordance with statements, representations, and procedures contained in the documents, including any enclosures, listed below:

application dated July 31, 1996
letters dated November 22, 1996
December 24, 1996
January 9, 1997
November 6, 1998
December 4, 1998
December 5, 2003
March 31, 2004
January 9, 2006
March 16, 2006
June 9, 2006
March 15, 2010

The New Hampshire Rules for the Control of Radiation shall prevail over the statements contained in the above documents unless such statements are more restrictive than the regulations.

For the Department of Health and Human Services
Division of Public Health Services



Dennis P. O'Dowd, Administrator
Radiological Health Section

DATE OF ISSUANCE April 28, 2010