

Amendment No. 14

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, 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>Licensee</p> <p>1. Liberty Hospital</p> <p>2. 2525 Glenn W. Hendren Drive Liberty, MO 64068</p>		<p>In accordance with application dated April 4, 1985</p> <p>3. License number 24-16178-01 is amended in its entirety to read as follows:</p>	
		<p>4. Expiration date</p>	<p>May 31, 1990</p>
		<p>5. Docket or Reference No.</p>	<p>030-10532</p>
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35</p> <p>B. Any byproduct material listed in Group III of Schedule A, Section 35.100 of 10 CFR 35</p> <p>C. Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35</p> <p>D. Iodine-131</p>	<p>7. Chemical and/or physical form</p> <p>A. Any radiopharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35</p> <p>B. Any form listed in Group III of Schedule A, Section 35.100 of 10 CFR 35</p> <p>C. Any sealed source listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35</p> <p>D. Any iodide that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations.</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As necessary for uses authorized in Subitem 9.A</p> <p>B. 2.5 curies of each byproduct material authorized in Subitem 6.B</p> <p>C. 450 millicuries total for all sources authorized in Subitem 6.C</p> <p>D. 300 millicuries</p>	

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**MATERIALS LICENSE  
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Amendment No. 14

E. Phosphorus-32

E. Soluable phosphate that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations.

E. 50 millicuries

F. Xenon-133

F. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA

F. 1 curie

G. Any byproduct material listed in Section 31.11(a) of 10 CFR 31

G. Prepackaged kits

G. 3 millicuries of each byproduct material authorized in Subitem 6.G

**9. Authorized Use**

- A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- B. Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- C. Any procedure listed in Group VI of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- D. For treatment of hyperthyroidism, cardiac dysfunction and/or thyroid carcinoma.
- E. For treatment of polycythemia vera, leukemia, and/or bone metastases. For detection of intraocular tumors.
- F. Blood flow studies. Pulmonary function studies.
- G. In vitro studies

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CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 2525 Glenn W. Hendren Drive, Liberty, Missouri.
11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."
12. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Primall Gukhool, M.D.

Groups I, II and III  
In vitro studies  
Xenon-133

John Deligeorges, M.D.

Phosphorus-32 for diagnosis

John Hagen, M.D.

Phosphorus-32 for diagnosis

Eashwar K. Reddy, M.D.

Iodine-125 seeds for therapy

Patrick T. Hunt, M.D.

Groups I, II and III  
Iodine-131 for treatment of  
hyperthyroidism, cardiac  
dysfunction, and thyroid  
carcinoma  
Phosphorus-32 (soluable) for  
treatment of polycythemia vera,  
leukemia and bone metastases  
Xenon-133

Emmett K. Burk, M.D.

Groups I, II and III  
Xenon-133

Robert A. MacNaughton, II, M.D.

Groups I, II and III  
Xenon-133  
Iodine-131 for treatment of  
hyperthyroidism, cardiac  
dysfunction, and thyroid  
carcinoma  
Phosphorus-32 (soluable) for  
treatment of polycythemia vera,  
leukemia and bone metastases

Richard A. Morrison, M.D.

Group VI

Nasser Nakissa, M.D.

Group VI

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Larry Nussbaum, M.D.

Groups I, II and III

Iodine-131 for treatment of  
hyperthyroidism, cardiac  
dysfunction, and thyroid  
carcinoma

Phosphorus-32 (soluble) for  
treatment of polycythemia vera,  
leukemia and bone metastases

13. For a period not to exceed sixty (60) days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:

- (a) Has the prior written permission of the hospital's Administrator and its Medical Isotopes Committee, and
- (b) Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and
- (c) Performs only those procedures for which he is specifically authorized by a Nuclear Regulatory Commission license.

The licensee shall maintain for inspection by the Commission, copies of the written permission specified in Subitem (a) above and of the license(s) specified in Subitems (b) and (c) above. These records shall be maintained for five (5) years from the time the licensee grants its permission under Subitem (a) above.

- 14. Licensed material shall be used in accordance with the provisions of Section 35.14(b)(c)(e) and (f) of Title 10, Code of Federal Regulations.
- 15. Patients containing Cobalt 60, Cesium 137 or Iridium 192 implants shall remain hospitalized until a source count and surveys made with an appropriate radiation detection instrument indicate that all implants have been removed. The results of these surveys shall be recorded and maintained for inspection by the Commission for five (5) years from the time the implants are removed.
- 16. Patients containing Iodine 131 for the treatment of thyroid carcinoma (or patients containing therapeutic quantities of Gold 198) shall remain hospitalized until the residual activity is 30 millicuries or less.
- 17. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:
  - A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of ten (10) half-lives.
  - B. Prior to disposal as normal waste, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background with typical low-level laboratory survey instruments. All radiation labels will be removed or obliterated.

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C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

18. Notwithstanding the provisions of Section 35.14(b)(3) of Title 10, Code of Federal Regulations, the licensee is authorized to receive Group VI sealed sources from NRC License Number 24-19486-02 issued to Richard A. Morrison, M.D. in accordance with procedures outlined in application dated April 4, 1985.
19. The licensee shall designate an individual responsible for overseeing inventory control of Group VI sealed sources.
20. The licensee shall maintain at their facility records required by 10 CFR 35.14(b)(5).
21. The licensee shall establish a bioassay program for individuals handling millicurie amounts of iodine-131 in accordance with frequencies and procedures contained in Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."
22. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated April 4, 1985 and Model ALARA Program dated February 1, 1985. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

For the U.S. Nuclear Regulatory Commission

Original Signed

By James R. Mullauer

Materials Licensing Section, Region III

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Date May 10, 1985