MATERIALS LICENSE

Amendment No. 13

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.

Licensee	
1. Columbia Regional Hospital 2. 404 Keene Street Columbia, MO 65201	In accordance with letter received January 28, 1985 3. License number 24-16281-01 is amended in its entirety to read as follows:
	4. Expiration date: May 31, 1990
	5. Docket or Reference No.: 030-10721

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
A. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. Any radiopharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. As necessary for uses authorized in Subitem 9.A
B. Any byproduct material listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. Any form listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. 2 curies of each byproduct material authorized in Subitem 6.B
C. Any byproduct material listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. Any radiopharmaceutical listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. As necessary for uses authorized in Subitem 9.C
D. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. Any radiopharmaceutical listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. As necessary for uses authorized in Subitem 9.D
E. Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. Any sealed source listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. 1 curie total for all sources authorized in Subitem 6.E

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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. 300 millicuries
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 therapeutic procedure listed in Group IV of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

D. Any therapeutic procedure listed in Group V of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

E. Any procedure listed in Group VI of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

F. Blood flow studies. Pulmonary function studies.

G. In vitro studies

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 404 Keene Street, Columbia, 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."

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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:

George A. Wilson, M.D.	Groups I, II, III, IV, V and VI Xenon-133 In vitro studies
Lewis J. Garrotto, M.D.	Groups I, II, III and VI Iodine-131 for therapy Soluble phosphorus-32 for therapy Xenon-133 In vitro studies
Joseph Soha, M.D.	Groups I, II and III Iodine-131 for therapy Soluble phosphorus-32 for therapy Xenon-133 In vitro studies
Nestor Canoy, M.D.	Group VI
Hemlata K. Lepkowski, M.D.	Groups I, II and III Xenon-133 In vitro studies
Murray Boles, M.D.	Group VI

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.

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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.

    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) of Title 10, Code of Federal Regulations, the licensee is authorized to receive Group VI sealed sources from Regional Radiation Therapy Center, NRC License Number 24-20475-01 in accordance with application dated September 27, 1979 and letters dated February 7, 1984 and April 27, 1984.

19. Notwithstanding the provisions of Section 35.14(b) of Title 10, Code of Federal Regulations, the licensee is authorized to receive licensed material from NRC License Number 24-01565-01 issued to Boone Hospital Center in accordance with procedures outlined in letter dated February 2, 1982 (with attached letters dated February 9, 1982 and November 8, 1981, signed by A. H. Emmons).

20. The licensee shall maintain at their facility records required by 10 CFR 35.14(b)(5).

21. When using the Calicheck kit, the licensee shall follow the procedures contained in the manufacturer's instruction manual dated November 25, 1981, revised March 2, 1982.

22. The licensee shall follow procedures contained in Appendix F, "Procedures for Safely Opening Packages Containing Radioactive Material" of Regulatory Guide 10.8, October 1980.

23. The licensee shall follow procedures contained in Appendix I, "Area Survey Procedures" of Regulatory Guide 10.8, October 1980.

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24. 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."

25. 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 applications dated September 27, 1979 and August 7, 1980; application received July 16, 1982; letters dated January 17, 1980, February 2, 1982 (with attached letters dated February 9, 1982, November 8, 1981, signed by A. H. Emmons); February 7, 1984, agreement dated January 20, 1984 signed by David Finkel, letters dated April 10, 1984, April 27, 1984 and letter received Janaury 28, 1985 and ALARA Program as contained in Appendix O of Regulatory Guide 10.8, October, 1980. 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

Date May 15, 1985

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