

Amendment No. 08

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.

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| Licensee | | In accordance with letter dated June 27, 1985 | |
| 1. St. Luke's Hospital | | 3. License number 40-18000-01 is amended in its entirety to read as follows: | |
| 2. 305 S. State Street Aberdeen, South Dakota 57401 | | 4. Expiration date August 31, 1988 | |
| | | 5. Docket or Reference No. 030-13778 | |
| 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 Section 31.11(a) of 10 CFR 31 | D. Any | D. 3 millicuries of each byproduct material author- ized in Subitem 6.D. | |

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E. Xenon-133

E. 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

E. 200 millicuries

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. In vitro studies.
- E. Blood flow or pulmonary function studies.

CONDITIONS

- 10. Licensed material shall be used only at St. Luke's Hospital, 305 South State Street, Aberdeen, South Dakota.
- 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:

Paul R. Leon, M.D.

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

John R. Hastings, M.D.

In vitro studies

W. T. Sweeney, M.D.

In vitro studies

Roy G. Burt, M.D.

In vitro studies

Calvin F. Andersen, M.D.

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

James R. Alexander, M.D.

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

Douglas R. Peterson, M.D.

Groups I, II, and III
Xenon-133
In vitro studies
Iodine-131 as iodide for treatment of
hyperthyroidism, cardiac
dysfunction, and thyroid carcinoma

13. 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.
14. For a period not to exceed 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 Radiation Safety Committee, and

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14. (continued)

- 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 5 years from the time the licensee grants its permission under Subitem A above.

15. 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 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.

16. 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 January 10, 1983; and letters dated December 22, 1982, August 22, 1984, and June 27, 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

Date AUG 26 1985

Original Signed By
By Jack E. Whitten
Nuclear Materials Safety Section
Region IV
Arlington, Texas 76011

Official Record Copy

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