

**U. S. NUCLEAR REGULATORY COMMISSION
MATERIALS LICENSE**

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Amendment No. 06

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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 1, Parts 30, 31, 32, 33, 34, 35, 36, 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); and to import such byproduct and source material. 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 align="center">Licensee</p> <p>1. Veterans Administration Medical Center</p> <p>2. New Castle Road Butler, Pennsylvania 16001</p>		<p>In accordance with application dated January 22, 1979</p> <p>3. License number 37-16034-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date February 28, 1985</p> <p>5. Docket or Reference No.</p>
<p>6. product, 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 IV of Schedule A, Section 35.100 of 10 CFR 35</p>	<p>7. Chemical and/or physical form</p> <p>A. Any radio-pharmaceutical 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 radio-pharmaceutical listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35</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 curies of each byproduct material authorized in Subitem 6.B.</p> <p>C. As necessary for uses authorized in Subitem 9.C.</p>

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|--|---|--|
| 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 |
| D. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35 | D. Any radio-pharmaceutical 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 Section 31.11(a) of 10 CFR 31 | E. Any | E. 10 millicuries of each byproduct material authorized in Subitem 6.E. |
| 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. 500 millicuries |

9. Authorized use

- A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100 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. In vitro studies.
Blood flow and pulmonary function studies.

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10. Licensed material shall be used only at the licensee's address stated in Item 2 above.

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:

Anna Polizio, M.D.

Groups I, II and III

In vitro studies

Xenon 133

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

Carl Bean, M.D.

Groups I, II and III

In vitro studies

Xenon 133

Phosphorus 32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions

Gold 198 as colloid for intracavitary treatment of malignant effusions

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.

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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 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.
16.
 - A. Technetium-99m separated from molybdenum-99 either by elution of a molybdenum-99/technetium-99m generator or by an extraction process shall be tested to detect and quantify molybdenum-99 activity prior to administration to patients.
 - B. The licensee shall not administer to patients technetium-99m containing more than one (1) microcurie of molybdenum-99 per millicurie of technetium-99m or more than five (5) microcuries of molybdenum-99 per dose of technetium-99m at time of administration. The limits for molybdenum-99 contamination represent maximum values and molybdenum-99 contamination should be kept as low as reasonably achievable below these limits.
 - C. The licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum-99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of molybdenum-99 in excess of the limits specified in Subitem B. above are detected.
 - D. Personnel performing tests to detect and quantify molybdenum-99 contamination shall be given specific training in performing these tests prior to conducting such tests.
 - E.
 1. The licensee shall maintain for inspection by the Nuclear Regulatory Commission records of the results of each test performed to detect and quantify molybdenum-99 contamination and records of training given to personnel performing these tests.
 2. Records described in Subitem E.1. above shall be maintained for two (2) years following the performance of the tests and the training of personnel.

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17. 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 22, 1979 and letter dated January 17, 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.

Date FEB 26 1980

For the U. S. Nuclear Regulatory Commission

Michael E. Smith
by Material Licensing Branch

Division of Fuel Cycle and
Material Safety
Washington, D.C. 20555