

MATERIALS LICENSE

Amendment No. 05

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. Humana Hospital-Hoffman Estates</p> <p>2. 1555 N. Barrington Road Hoffman Estates, IL 60194</p>		<p>In accordance with letter dated January 31, 1985</p> <p>3. License number 12-18742-01 is amended in its entirety to read as follows:</p>
		<p>4. Expiration date May 31, 1990</p>
		<p>5. Docket or Reference No. 030-14116</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 IV of Schedule A, Section 35.100 of 10 CFR 35</p> <p>D. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35</p> <p>E. Any byproduct material listed in Section 31.11(a) of 10 CFR 31</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 radiopharmaceutical listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35</p> <p>D. Any radiopharmaceutical listed in Group V of Schedule A, Section 35.100 of 10 CFR 35</p> <p>E. Prepackaged kits</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. 4 curies of each byproduct material authorized in Subitem 6.B</p> <p>C. As necessary for uses authorized in Subitem 9.C</p> <p>D. As necessary for uses authorized in Subitem 9.D</p> <p>E. 3 millicuries of each byproduct material authorized in Subitem 6.E</p>

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

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Docket or Reference number

030-14116

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6. Byproduct, source,
and/or special nuclear
material

F. Xenon-133

7. Chemical and/or
physical form

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

8. Maximum amount that
licensee may possess
at any one time
under this license

F. 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. Any therapeutic procedure listed in Group V of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- E. In vitro studies.
- F. Blood flow studies. Pulmonary function studies.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1555 North Barrington Road, Hoffman Estates, Illinois.
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:

Timothy E. Tully, M.D.

Groups I, II, III, IV and V

Xenon-133

In vitro studies

Daniel E. Horan, M.D.

Groups I, II and III

Xenon-133

Donald Waxler, M.D.

Groups I, II and III

Xenon-133

Iodine-131 for treatment of

hyperthyroidism, cardiac

dysfunction and thyroid carcinoma

Margaret Schorsch Boyle, M.D.

Groups I, II and III

Xenon-133

In vitro studies

Iodine-131 for treatment of

hyperthyroidism, cardiac

dysfunction and thyroid carcinoma

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 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. 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."
17. Airflow rates in the ventilation system in areas where xenon-133 is used or stored shall be measured at least semi-annually to determine that system performance meets the specifications submitted in letter dated January 31, 1985 (with attached application).
18. The licensee may use the Calicheck device for doing linearity tests of his dose calibrator provided he follows the procedures in the Calcorp, Inc., Manual dated March 2, 1982.
19. The licensee may use the Lineator device for doing linearity tests of his dose calibrator provided he follows the procedures in the Atomic Products Corporation Lineator Instructions Manual dated June 20, 1983.
20. 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 letter dated January 31, 1985 (with attached application). 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 J. R. Madera

Materials Licensing Section, Region III

Date May 10, 1985

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