MATERIALS LICENSE

Amendment No. 38

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. The Hospital Center at Orange Department of Nuclear Medicine	In accordance with application dated April 4, 1985 3. License number 29-03038-01 is amended in its entirety to read as follows:
2. 188 South Essex Avenue Orange, New Jersey 07051	4. Expiration date July 31, 1990
	5. Docket or Reference No. 030-02464

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 reagent kit listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. Any form, except generators, listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. As necessary for uses authorized in Subitem 9.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 sources authorized in Subitem 6.E.
F. Any byproduct material listed in Section 31.11(a) of 10 CFR 31	F. Prepackaged kits	F. 3 millicuries of each byproduct material authorized in Subitem 6.F.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
29-03038-01

Docket or Reference number
030-02464

Amendment No. 38

(continued)

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
G. Xenon 133	G. 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	G. 300 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. Any procedure listed in Group VI of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
F. In vitro studies.
G. Blood flow and pulmonary function studies.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities, 188 South Essex Avenue, Orange, New Jersey.

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."

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 29-03038-01
Docket or Reference number: 030-02464
Amendment No. 38

(continued) CONDITIONS

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:

Wade N. Miller, M.D.	Groups I, II, III, IV and V In vitro studies Xenon 133
Arnold I. Brenner, D.O.	Groups I, II and III In vitro studies Xenon 133 Phosphorus 32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases Iodine 131 for treatment of hyperthyroidism, cardiac dysfunction and thyroid carcinoma
Mary Natrella, M.D.	Groups I, II, III, IV and V In vitro studies Xenon 133
Thomas Borok, M.D.	Group VI Phosphorus 32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases

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 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 the 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.

15. Sealed sources containing licensed material shall not be opened.

16. Patients containing Iodine 131 for the treatment of thyroid carcinoma shall remain hospitalized until the residual activity is 30 millicuries or less.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 29-03038-01
Docket or Reference number: 030-02464
Amendment No. 38

(continued) CONDITIONS

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. 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 24, 1979, June 14, 1982, and April 4, 1985, and letters dated May 27, 1980, May 24, 1982, and June 25, 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 07 1985

By Original Signed By:
John E. Glenn
Nuclear Materials Safety and
Safeguards Branch, Region I
King of Prussia, Pennsylvania 19406