

MATERIALS LICENSE

Amendment No. 39

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); 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.

"OFFICIAL RECORD COPY"

Licensee

1. St. Joseph Hospital
2. 128 Strawberry Hill Avenue
Stamford, Connecticut 06904-1222

In accordance with letter dated
April 2, 1985,

3. License number 06-06922-02 is amended in its
entirety to read as follows:

4. Expiration date September 30, 1990

5. Docket or
Reference No. 030-01266

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
- B. Any byproduct material
listed in Group III of
Schedule A, Section
35.100 of 10 CFR 35
- C. Any byproduct material
listed in Group IV of
Schedule A, Section
35.100 of 10 CFR 35
- D. Any byproduct material
listed in Group V of
Schedule A, Section
35.100 of 10 CFR 35
- E. Any byproduct material
listed in Group VI of
Schedule A, Section
35.100 of 10 CFR 35
- F. Any byproduct material
listed in Section 31.11(a)
of 10 CFR 31

- A. Any radiopharmaceutical
listed in Groups I and
II 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
- C. Any radiopharmaceutical
listed in Group IV 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
- E. Any sealed source listed
in Group VI of Schedule
A, Section 35.100 of
10 CFR 35
- F. Prepackaged kits

- A. As necessary for uses
authorized in Subitem
9.A.
- B. 2 curies of each
byproduct material
authorized in Subitem 6.B.
- C. As necessary for uses
authorized in Subitem 9.C.
- D. As necessary for uses
authorized in Subitem 9.D.
- E. 1000 millicuries total for
sources authorized in
Subitem 6.E.
- F. 3 millicuries of each
byproduct material
authorized in Subitem 6.F.

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

06-06922-02

Docket or Reference number

030-01266

Amendment No. 39

(Continued)

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. 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. 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, 128 Strawberry Hill Avenue, Stamford, Connecticut.
- 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; Inspection," 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:

James J. McSweeney, M.D.

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

James M. Rini, M.D.

Groups I, II and III
In vitro studies
Xenon 133
Iodine 131 for treatment of hyperthyroidism and cardiac dysfunction

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(Continued)

William J. Caragol, M.D.

Groups I, II and III

In vitro studies

Xenon 133

Iodine 131 for treatment of hyperthyroidism and
cardiac dysfunction

Frank A. Masino, M.D.

Group VI

12. 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. 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 ventilation systems in areas where xenon-133 is used and stored shall be tested at least semi-annually to determine that system performance meets the specifications submitted in application dated November 21, 1978 and letter dated March 28, 1980.
17. The xenon-133 charcoal trap shall be tested weekly in accordance with the procedures specified in letter dated February 20, 1980, to assure that the device is functioning properly and that filter saturation has not occurred.

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SUPPLEMENTARY SHEET

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Amendment No. 29

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18. The licensee is authorized to hold radioactive material with a physical half-life of less than 60 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.
19. 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 November 21, 1978; letter dated October 1, 1979; Items 1 through 5 of letter dated February 20, 1980 and letters dated March 28, 1980, August 5, 1980, November 7, 1980, August 3, 1981, March 15, 1983 and April 2, 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

Original Signed By:

Jenny M. [illegible]

By

Nuclear Materials Safety and
Safeguards Branch, Region 1
King of Prussia, Pennsylvania 19406

Date

SEP 21 1981