

## MATERIALS LICENSE

Amendment No. 52

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, 39, 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. Beth Israel Hospital</p> <p>2. 70 Parker Avenue Passaic, New Jersey 07055</p>	<p>In accordance with letter dated June 20, 1990, 3. License number 29-03047-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date January 31, 1990 (extended)</p> <p>5. Docket or Reference No 030-02465</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 Group VI of Schedule A, Section 35.100 of 10 CFR 35</p> <p>F. 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. Any sealed source listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35</p> <p>F. 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. 2 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. 1000 millicuries total for sources authorized in Subitem 6.E.</p> <p>F. 10 millicuries of each byproduct material authorized in Subitem 6.F.</p>

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MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License number

29-03047-01

Docket or Reference number

030-02465

Amendment No. 52

(6., 7., and 8. Continued)

6. Byproduct, source, and/or  
special nuclear material7. Chemical and/or physical  
form8. 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 In-  
vestigational Exemption  
for a New Drug" (IND)  
that has been accepted  
by FDA

G. 200 millicuries

H. Palladium 103

H. Sealed source  
(Theragenics Corporation  
Model 100)

H. 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.
- H. For interstitial treatment of cancer.

## CONDITIONS

- 10. Licensed material shall be used only at 70 Parker Avenue, Passaic, New Jersey.
- 11. Radiation Safety Officer: Sreenivarsa Murthy, M.S.

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License number

29-03047-01

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(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:

Sam I. Brown, M.D.

Groups I, II, III, IV, V and VI

In vitro studies

Xenon 133

Palladium 103 for interstitial treatment  
of cancer

Arthur L. Siegel, M.D.

Groups I, II, III and VI

Xenon 133

Iodine 131 for treatment of hyperthyroidism and  
cardiac dysfunction

Palladium 103 for interstitial treatment  
of cancer

Sehedon Lang, M.D.

Iodine 125 or iodine 131 as iodinated human  
serum albumin for blood volume determination

Michael L. Mund, M.D.

Strontium 90 for treatment of  
superficial eye conditions

Michael D. Green, M.D.

Groups I, II and III

Glenn Ross, M.D.

Groups I and II

Xenon 133

Sung Il Lee, M.D.

Groups IV, V and VI

Palladium 103 for interstitial treatment  
of cancer

Surekha D. Khedekar, M.D.

Groups I, II and III

Xenon 133

13. 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. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall 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.

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(Continued)

## CONDITIONS

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 Radiation Safety Committee, and
- B. Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and
- C. Performs only those procedures which the physician is specifically authorized to perform pursuant to a license issued by the Nuclear Regulatory Commission.

The licensee shall maintain for inspection by the Commission copies of the written permission specified in A. above and of the license(s) specified in B. and C. above for a period of 5 years from the date permission is granted under 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. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from detector cells by the licensee.
17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated September 24, 1984, containing ALARA Program
  - B. Letter dated January 7, 1985
  - C. Letter dated March 5, 1985
  - D. Letter dated September 4, 1986
  - E. Letter dated September 25, 1987
  - F. Letter dated February 24, 1988
  - G. Letter dated January 23, 1989
  - H. Letter dated April 10, 1989
  - I. Letter dated June 20, 1990

For the U.S. Nuclear Regulatory Commission

ORIGINAL SIGNED BY:  
JEAN GRESICK-SCHUGSTADate AUG 28 1990

By

Nuclear Materials Safety Branch  
Region I  
King of Prussia, Pennsylvania 19406



## MATERIALS LICENSE

Amendment No. 53

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, 39, 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

In accordance with letter dated  
December 21, 1989,3. License number 29-03047-01 is amended in  
its entirety to read as follows:

4. Expiration date May 31, 1996

5. Docket or  
Reference No 030-024656. Byproduct, source, and/or  
special nuclear material7. Chemical and/or physical  
form8. Maximum amount that licensee  
may possess at any one time  
under this licenseA. Any byproduct material  
identified in 10 CFR  
35.100A. Any radiopharmaceutical  
identified in 10 CFR  
35.100

A. As needed

B. Any byproduct material  
identified in 10 CFR  
35.200B. Any radiopharmaceutical  
identified in 10 CFR  
35.200 except generators

B. As needed

C. Any byproduct material  
identified in 10 CFR  
35.300C. Any radiopharmaceutical  
identified in 10 CFR  
35.300

C. As needed

D. Any byproduct material  
identified in 10 CFR  
35.400D. Any brachytherapy source  
identified in 10 CFR  
35.400

D. As needed

E. Any byproduct material  
identified in 10 CFR  
35.500E. Any diagnostic source  
identified in 10 CFR  
35.500

E. As needed

F. Any byproduct material  
identified in 10 CFR  
31.11

F. Prepackaged Kits

F. As needed

G. Iodine 125

G. See's

G. As needed

## 9. Authorized use

- A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100.  
B. Any imaging and localization procedure approved in 10 CFR 35.200.  
C. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300.  
D. Any brachytherapy procedure approved in 10 CFR 35.400.  
E. Medical use of sealed sources included in 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).  
F. In vitro studies.  
G. Treatment of superficial eye conditions.

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License number

29-03047-01

Docket or Reference number

070-02465

Amendment No. 53

(Continued)

**CONDITIONS**

10. Location of use: 70 Parker Avenue, Passaic, New Jersey

11. Radiation Safety Officer: Sreenivasa Murthy, M.S.

12. Authorized Users:

Material and Use:

Sam I. Brown, M.D.

35.100; 35.200; 35.300; 35.400; 35.500

In vitro studies

Arthur L. Siegel, M.D.

35.100; 35.200; 35.400; 35.500

Iodine 131 for treatment of hyperthyroidism  
and cardiac dysfunction

Sheldon Lang, M.D.

35.100; 35.500

Iodine 125 or iodine 131 as iodinated human  
serum albumin for blood volume determination

Michael L. Mund, M.D.

35.400; 35.500

Michael D. Green, M.D.

35.100; 35.200; 35.500

Glenn Ross, M.D.

35.100; 35.200; 35.500

Sung IL Lee, M.D.

35.300; 35.400; 35.500

Surekha D. Khedekar, M.D.

35.100; 35.200; 35.500

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material so that at no time is a quantity of radioactive material possessed in excess of a quantity which requires decommissioning funding in accordance with 10 CFR 30.35(d), 10 CFR 40.36(b) or 10 CFR 70.25(d).

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated December 21, 1989

B. Letter dated November 13, 1990

C. Letter dated May 2, 1991

**MAY 17 1991**

Date

For the U.S. Nuclear Regulatory Commission

Original Signed By:

By

Steven R. Courtemanche

Nuclear Materials Safety Branch  
Region I

King of Prussia, Pennsylvania 19406

07/21/89

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U.S. NUCLEAR REGULATORY COMMISSION  
REGION I  
OPEN ITEMS CHECKING ONE IN

DOCKET NUMBER: 30-02465

REPORT NUMBER	STATUS	DATE OPEN	DATE CLOSED	REVIEWER NAME	CLOSING OPTION	REFER
89-001	OPEN	07/27/89		SENSEN	VIOL	
ITEM: FAILURE TO PERFORM A SURVEY OF A PATIENT AND ROOM AT CONCLUSION OF BRACHYTHERAPY						

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