

## 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. Good Samaritan Medical Center  
Lutheran Campus
2. 2000 W. Kilburn Avenue  
Milwaukee, WI 53233

In accordance with applications dated  
November 16, 1984, January 7, 1985, and  
and March 25, 1985

3. License number 48-00988-04 is amended in  
its entirety to read as follows:

4. Expiration date June 30, 1990

5. Docket or  
Reference No. 030-03415

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

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

7. Chemical and/or physical  
form

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

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

A. As necessary for  
uses authorized  
in Subitem 9.A

B. 4 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. 1 curie  
total for all  
sources authorized  
in Subitem 6.E

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48-00988-04 PDR

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JUN 25 1985

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License number

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Docket or Reference number

030-03415

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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

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

G. Any byproduct material  
listed in Section  
31.11(a) of 10 CFR 31

G. Prepackaged kits

G. 3 millicuries  
of each byproduct  
material authorized  
in Subitem 6.G

H. Uranium (Depleted in  
Uranium 235)

H. Cadmium plated metal

H. 160 kilograms

I. Iodine-131

I. Iodomethynorcholesterol  
manufactured by and  
received from the Nuclear  
Pharmacy of the University  
of Michigan

I. 10 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. For storage only.

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9. Authorized Use (cont'd)

F. Blood flow studies, Pulmonary function studies.

G. In vitro studies.

H. For use as shielding in a Medical Linear accelerator.

I. For adrenal imaging used in accordance with Notice of Claimed Investigational Exemption For a New Drug (IND) Number 17,757.

CONDITIONS

10. A. Licensed material shall be used only at the licensee's facilities located at Lutheran Campus, 2000 W. Kilburn Avenue, Milwaukee, Wisconsin and 620 N. 19th Street, Milwaukee, Wisconsin.

B. Licensed material listed in Subitems 6.A. through 6.D. and 6.G. only, may also be used and stored at the Edgerton Health Center, 6901 W. Edgerton Avenue, Milwaukee, Wisconsin.

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:

J. R. Kasner, M.D.

Groups I, II and III  
Iodine-131 for therapy  
Soluble phosphorus-32 for therapy  
Xenon-133

Bert D. Collier, Jr., M.D.

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

Howard H. Johnson, M.D.

Groups I, II and III  
Xenon-133  
Iodine-131 for treatment of  
hyperthyroidism, cardiac  
dysfunction, and thyroid carcinoma

George C. Bares, M.D.

Groups I, II and III  
Xenon-133

Roland C. Brown, M.D.

Groups I, II and III  
Xenon-133

William J. Pier, Jr., M.D.

Groups I, II and III  
Xenon-133

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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.

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. 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.
- B. 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.

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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 application dated March 25, 1985; and letters dated January 7, 1985, January 15, 1985, and April 3, 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 Bruce S. Mallett, Ph.D.

Materials Licensing Section, Region III

Date June 21, 1985

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