

## MATERIALS LICENSE

Amendment No. 43

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 Hospital and Health Center  
Department of Radiology

2. 2222 Philadelphia Drive  
Dayton, OH 45406

In accordance with application dated  
January 21, 1985

3. License number 34-01311-01 is amended in  
its entirety to read as follows:

4. Expiration date July 31, 1990

5. Docket or  
Reference No. 030-20674

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 byproduct material  
listed in Group III 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

B. 5 curies  
of each byproduct  
material authorized  
in Subitem 6.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. 1500 millicuries  
total for all  
sources authorized  
in Subitem 6.E

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License number

34-01311-01

Docket or Reference number

030-20674

Amendment No. 43

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. 1500 millicuries

G. Uranium (depleted in  
U-235)

G. Cadmium plated metal

G. 182 kilograms

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

H. Prepackaged kits

H. 6 millicuries  
of each byproduct  
material authorized  
in Subitem 6.H

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. Any procedure listed in Group VI of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

F. Blood flow studies. Pulmonary function studies.

G. To be used as shielding in a medical linear accelerator.

H. In vitro studies.

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SUPPLEMENTARY SHEET**

License number

34-01311-01

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Amendment No. 43

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 2222 Philadelphia Drive, Dayton, Ohio.
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:

G. W. Bretz, M.D.

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

Dudley K. Campbell, M.D.

Groups I, II, III, IV, V and VI,  
except gold-198 and colloidal  
phosphorus-32 for therapy  
Xenon-133  
In vitro studies

Roger H. Cook, M.D.

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

Tomas S. Garnica, M.D.

Groups I, II, III, IV and V,  
except gold-198 for therapy  
Xenon-133  
In vitro studies

H. R. Hittner, M.D.

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

Donald Marger, M.D.

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

Thomas C. Mick, M.D.

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

L. H. van der Hoeven, M.D.

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

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License number

34-01311-01

Docket or Reference number

030-20674

Amendment No. 43

Theodore K. Payne, M.D.

Groups I, II, III, IV, V and VI  
Xenon-133

In vitro studies

Stuart J. Sorkin, M.D.

Groups I, II, III, IV and V  
Xenon-133

In vitro studies

W. P. Kirchner, M.D.

Groups I, II, III, IV and V  
Xenon-133

In vitro studies

B. Must, Jr., M.D.

Groups II, III and VI  
Xenon-133

In vitro studies

Joel E. Janousek, M.D.

Groups I, II and III  
Xenon-133

In vitro studies

Iodine-131 for therapy

Michael R. Carroll, M.D.

Groups I, II and III  
Xenon-133

In vitro studies

Iodine-131 for therapy

Robert L. Antonelli, M.D.

Groups I, II, III, IV and V  
Xenon-133

In vitro studies

Michael J. Cohen

Groups I, II and III  
Xenon-133

In vitro studies

Gregory MacNealy

Groups I, II and III  
Xenon-133

In vitro studies

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

**MATERIALS LICENSE**  
**SUPPLEMENTARY SHEET**

License number 34-01311-01  
Docket or Reference number 030-20674  
Amendment No. 43

- (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 Cobalt 60, Cesium 137 or Iridium 192 implants shall remain hospitalized until a source count and surveys made with an appropriate radiation detection instrument indicate that all implants have been removed. The results of these surveys shall be recorded and maintained for inspection by the Commission for five (5) years from the time the implants are removed.
16. 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.
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 application dated January 21, 1985; xenon procedures in letters dated February 3, 1983 and June 19, 1984; and ALARA Program dated January 21, 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 July 9, 1985

Original Signed  
By Evelyn R. Matson  
Materials Licensing Section, Region III

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