

MATERIALS LICENSE

Amendment No. 15

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. Heartland Hospital West
2. Seventh to Ninth on Faraon
St. Joseph, MO 64501

In accordance with application dated
May 16, 1985

3. License number 24-13246-01 is amended in
its entirety to read as follows:

4. Expiration date October 31, 1990

5. Docket or
Reference No. 030-02378

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. 2 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. 2 curies
total for all
sources authorized
in Subitem 6.E

8512050106 851025
REG3 LIC30 PDR
24-13246-01

COPY

me39
85 10/25/85

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

24-13246-01

Docket or Reference number

030-02378

Amendment No. 15

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. 150 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

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. In vitro studies.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

24-13246-01

Docket or Reference number

030-02378

Amendment No. 15

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at Seventh to Ninth on Faraon, St. Joseph, Missouri.
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:
- | | |
|-------------------------|--|
| Edward M. Stevens, M.D. | Groups I, II, III, IV, V and VI
Xenon-133
<u>In vitro</u> studies |
| Joseph L. Fisher, M.D. | Groups I, II, III, IV and V
Xenon-133
<u>In vitro</u> studies |
| R. Phillip Acuff, M.D. | Groups I, II, III, IV and V
Xenon-133
<u>In vitro</u> studies |
| Donald E. Heins, M.D. | Groups I, II and III
Xenon-133
<u>In vitro</u> studies |
| Stephen C. Tines, M.D. | Groups I, II and III
Xenon-133
<u>In vitro</u> studies
Iodine-131 For treatment of
hyperthyroidism, cardiac
dysfunction and thyroid carcinoma |
| Eshwar K. Reddy, M.D. | Group VI |
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

24-13246-01

Docket or Reference number

030-02378

Amendment No. 15

- (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. 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.
15. 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.
16. The licensee may transport licensed material or deliver licensed material to a carrier for transport in accordance with the provisions of Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions."
17. Notwithstanding the requirements of Section 35.14(b)(3) of 10 CFR Part 35, the licensee may receive Groups II and III radiopharmaceuticals from Heartland Hospital East, 5325 Faraon Street, St. Joseph, Missouri, License Number 24-18287-01.
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 May 16, 1985; letters dated July 25, 1985, August 27, 1985 and October 4, 1985; and ALARA Program contained in application dated May 16, 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

OCT 25 1985

Date _____

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

COPY