

## MATERIALS LICENSE

Amendment No. 07

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. Tolfree Memorial Hospital
2. 335 East Houghton Avenue  
West Branch, MI 48661

In accordance with application dated  
March 12, 1985

3. License number 21-18892-01 is amended in  
its entirety to read as follows:

4. Expiration date June 30, 1990

5. Docket or  
Reference No. 030-17321

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. Iodine-131

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 iodide that has  
been manufactured,  
labeled, packaged, and  
distributed in accordance  
with a specific license  
issued pursuant to Section  
32.72 of 10 CFR Part 32 or  
a specific license issued  
to a manufacturer by an  
Agreement State pursuant  
to equivalent State  
regulations.

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. 2 curies  
of each byproduct  
material authorized  
in Subitem 6.B

C. 250 millicuries

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License number

21-18892-01

Docket or Reference number

030-17321

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

D. Xenon-133

7. Chemical and/or  
physical form

D. 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

D. 300 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. For treatment of hyperthyroidism, cardiac dysfunction, or thyroid carcinoma.
- D. Blood flow studies. Pulmonary function studies.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 335 East Houghton Avenue, West Branch, Michigan.
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:

Paul W. Rowe, M.D.

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

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Harold Blumenstein, M.D.

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

James Fenton, M.D.

Groups I, II and III  
Iodine-131 for the treatment of  
hyperthyroidism  
Xenon-133

Paul J. Hettle, M.D.

Groups I, II and III  
Iodine-131 for the treatment of  
hyperthyroidism  
Xenon-133

Tyre K. Jones, III, M.D.

Groups I, II and III  
Xenon-133

George F. Ascherl, M.D.

Groups I, II and III  
Xenon-133

Stephen M. Ascherl, M.D.

Groups I, II and III  
Xenon-133

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.

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16. 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 12, 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 May 17, 1985

Original Signed  
By John R. Madera  
Materials Licensing Section, Region III  
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