

MATERIALS LICENSE

Amendment No. 10

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. Winona Memorial Hospital Limited Partnership

2. 3232 N. Meridian Street
Indianapolis, IN 46208In accordance with letter dated
June 26, 19853. License number 13-16404-01 is amended in
its entirety to read as follows:

4. Expiration date September 30, 1990

5. Docket or
Reference No. 030-109666. 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
listed in Groups I
and II of Schedule A,
Section 35.100 of
10 CFR 35A. Any radiopharmaceutical
listed in Groups I
and II of Schedule A,
Section 35.100 of
10 CFR 35A. As necessary for
uses authorized
in Subitem 9.AB. Any byproduct material
listed in Group III of
Schedule A, Section
35.100 of 10 CFR 35B. Any form listed in
Group III of Schedule A,
Section 35.100 of
10 CFR 35B. 5 curies
of each byproduct
material authorized
in Subitem 6.BC. Any byproduct material
listed in Group IV of
Schedule A, Section
35.100 of 10 CFR 35C. Any radiopharmaceutical
listed in Group IV of
Schedule A, Section
35.100 of 10 CFR 35C. As necessary for
uses authorized
in Subitem 9.CD. Any byproduct material
listed in Group V of
Schedule A, Section
35.100 of 10 CFR 35D. Any radiopharmaceutical
listed in Group V of
Schedule A, Section
35.100 of 10 CFR 35D. As necessary for
uses authorized
in Subitem 9.DE. Any byproduct material
listed in Section
31.11(a) of 10 CFR 31

E. Prepackaged kits

E. 3 millicuries
of each byproduct
material authorized
in Subitem 6.E8509110496 850903
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13-16404-01 PDR

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Docket or Reference number

030-10966

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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. 1 curie

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. In vitro studies.
- F. Blood flow studies. Pulmonary function studies.

CONDITIONS

10. A. Licensed material shall be used only at the licensee's facilities located at 3232 North Meridian Street, Indianapolis, Indiana.
- B. Licensed material listed in Subitems 6.A. and 6.B. (except molybdenum 99/technetium-99m generators) may also be used at 3171 North Meridian Street, Indianapolis, Indiana.
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."

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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:

Norman D. Gardner, M.D.

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

James D. Schroering, M.D.

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

Ronald I. Veatch, M.D.

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

David B. Goldenburg, 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. 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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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. Individuals who work in or whose duties may require them to work in restricted areas or in the vicinity of licensed materials, shall be instructed in the items specified in 10 CFR 19.12 at the time of initial employment and at least annually thereafter.
17. The licensee shall establish a bioassay program for individuals handling millicurie amounts of iodine-131 in accordance with frequencies and procedures contained in Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."
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 26, 1980; letters dated May 27, 1980, November 17, 1980, June 4, 1985 and June 26, 1985; and ALARA Program dated November 12, 1980. 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 Evelyn R. Matson

Materials Licensing Section, Region III

Date September 3, 1985

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