

MATERIALS LICENSE

Amendment No. 20

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. Doctors Hospital, Incorporated | In accordance with application dated April 15, 1985 |
| 2. 420 Austin Avenue Massillon, OH 44646 | 3. License number 34-13381-01 is amended in its entirety to read as follows: |
| | 4. Expiration date June 30, 1990 |
| | 5. Docket or Reference No. 030-07577 |
| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form |
| 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 |
| 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 |
| C. Xenon-133 | C. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA |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 |
| | A. As necessary for uses authorized in Subitem 9.A |
| | B. 2 curies of each byproduct material authorized in Subitem 6.B |
| | C. 500 millicuries |

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

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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

D. Iodine-131

D. 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.

D. 200 millicuries

E. 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.E

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. Blood flow studies. Pulmonary function studies.

D. For treatment of hyperthyroidism and cardiac dysfunction.

E. In vitro studies

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 420 Austin Avenue, Massillon, 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."

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

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Amendment No. 20

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:

Robert Reither, D.O.

Groups I, II and III

Xenon-133

In vitro studies

John Uslick, D.O.

Groups I, II and III

Xenon-133

In vitro studies

Hulsi Ergun, M.D.

Groups I, II and III

Iodine-131 for treatment of
hyperthyroidism and cardiac
dysfunction

Xenon-133

In vitro studies

R. Sassano, M.D.

Groups I, II and III

Iodine-131 for treatment of
hyperthyroidism and cardiac
dysfunction

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
- (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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

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34-13381-01

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Amendment No. 20

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 license is authorized to dispose of records of: dose calibrator accuracy, constancy and linearity checks; survey meter calibrations; occupational and non-occupational personnel training; and radiation safety/medical isotope committee meeting minutes provided that:
- 1. The record was examined during a routine NRC inspection;
 - 2. The record is in excess of two years from the date of generation; and
 - 3. Disposal of the record does not conflict with the requirements of other State and Federal agencies.
17. 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 April 15, 1985 and Model ALARA Program dated March 25, 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 James Mullauer
Materials Licensing Section, Region III
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