

MATERIALS LICENSE

Amendment No. 52

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. Mercy Hospital Medical Center
Administrative Director
Radiology Department
2. Sixth and University
Des Moines, IA 50314

In accordance with application dated
February 1, 1985

3. License number 14-01137-01 is amended in
its entirety to read as follows:

4. Expiration date June 30, 1990

5. Docket or
Reference No. 030-01683

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

D. Iodine-131

E. Iodine-125

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. Prepackaged kits

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 of a
specific license issued to
a manufacturer by an
Agreement State pursuant to
equivalent State regulations

E. Sealed source(s)
(AECL Model C-324
enclosed within source
holder AECL Model C-236)

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

C. 3 millicuries
of each byproduct
material authorized
in Subitem 6.C

D. 200 millicuries

E. 2 sources not
to exceed 200
millicuries each

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number
14-01137-01

Docket or Reference number
030-01683

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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. 600 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. In vitro studies.
- D. For treatment of hyperthyroidism, cardiac dysfunction or thyroid carcinoma.
- E. One source to be used in a Nuclear Data Model 1100 Bone Densitometer Scanner for bone mineral analysis on humans. One source in its shipping container to be in possession of the licensee as necessary to the replacement of the source holder AECL Model C-236 in the Nuclear Data Model 1100 Bone Densitometer Scanner.
- F. Blood flow studies. Pulmonary function studies.

CONDITIONS

10. Licensed material shall be used at Mercy Hospital, Sixth and University, Des Moines, Iowa. Licensed material for diagnosis may also be used at any hospital located in the State of Iowa provided: (a) The hospital does not have a byproduct material license under Section 35.11 of 10 CFR Part 35, (b) The licensee has the prior written permission from the hospital's administrator, (c) The licensee performs a daily contamination survey in all areas where radioactive materials are used, (d) The licensee removes all byproduct material when he departs other than the amount remaining in the patient, and (e) The licensee maintains a list of all hospital's serviced in the State of Iowa in any calendar year and submits the list to the Nuclear Regulatory Commission, Region III, Office of Inspection and Enforcement, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, by March 1, of each year. The Nuclear Data 1100 Bone Densitometer Scanner shall be used at Mercy Medical Plaza, 421 Laurel Street, Suite 410, Des Moines, Iowa.

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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:

Julio Acebey, M.D.

Groups I, II and III
Xenon-133

Harrison W. Pratt, D.O.

Group I
In vitro studies

Stephan M. Cooper, M.D.

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

John Henderson, M.D.

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

Michael A. Disbro, M.D.

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

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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.
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 February 1, 1985; and letters dated December 26, 1984 and April 5, 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

Original Signed

By John R. Madera

Materials Licensing Section, Region III

Date May 17, 1985

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