

MATERIALS LICENSE

Amendment No. 05

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. Research Medical Center

2. 2316 E. Meyer Blvd.
Kansas City, MO 64132In accordance with applications dated
August 1, 1984 and January 24, 19853. License number 24-18625-01 is amended in
its entirety to read as follows:

4. Expiration date June 30, 1990

5. Docket or
Reference No. 030-139596. 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. 2 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 Group VI of
Schedule A, Section
35.100 of 10 CFR 35E. Any sealed source
listed in Group VI of
Schedule A, Section
35.100 of 10 CFR 35E. 1.5 curies
total for all
sources authorized
in Subitem 6.E8506060629 850517
REG3 LIC30
24-18625-01 PDR11 ML30 Br COPY 2
MAY 17 1985

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

24-18625-01

Docket or Reference number

030-13959

Amendment No. 05

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. 500 millicuries

G. Gadolinium-153

G. Sealed sources
(Gulf Nuclear Model
GD-1 contained in a
Lunar Radiation Corp.
lead-lined brass source
holder)

G. 2 curies
(2 sources not
to exceed 1
curie each)

H. Cesium-137

H. Sealed source

H. 110 millicuries

I. Uranium (depleted in
Uranium-235)

I. Cadmium plated metal

I. 182 kilograms

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

J. Prepackaged kits

J. 5 millicuries
of each byproduct
material authorized
in Subitem 6.J

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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

24-18625-01

Docket or Reference number

030-13959

Amendment No. 05

9. Authorized Use (cont'd)

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. One source to be used in a Lunar Radiation Corporation Model DP3 Spine/Femur Scanner for determining human bone mineral content. One source in its shipping container to be in possession of the licensee as necessary for replacement in the scanner.

H. For use in an Eon Corporation Survey Instrument Calibrator Model No. 64-764.

I. For use as shielding in a medical linear accelerator.

J. In vitro studies.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 2316 E. Meyer Blvd., Kansas City, 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:

Walter G. Dukstein, M.D.

Groups I, II, III, IV and V

Xenon-133

Gadolinium-153

In vitro studies

William E. White, M.D.

Groups I, II, III, IV and V

Xenon-133

Gadolinium-153

In vitro studies

Ben J. Throne, M.D.

Groups IV, V and VI

George A. Cowan, M.D.

Groups IV, V and VI

Jorge C. Paradelo, M.D.

Group VI

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

24-18625-01

Docket or Reference number

030-13959

Amendment No. 05

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.

16. Patients containing Cobalt 60, Cesium 137 or Iridium 192 implants shall remain hospitalized until a source count and surveys made with an appropriate radiation detection instrument indicate that all implants have been removed. The results of these surveys shall be recorded and maintained for inspection by the Commission for five (5) years from the time the implants are removed.

17. A. (1) Sealed sources listed in Subitems 6.G. and 6.H. shall be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

(3) The periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

24-18625-01

Docket or Reference number

030-13959

Amendment No. 05

- B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.
- C. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within five (5) days of the test with the U. S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, describing the equipment involved, the test results, and the corrective action taken.
- D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically authorized by the Commission or an Agreement State to perform such services.
18. 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.
19. Sealed sources listed in Subitems 6.G. and 6.H. shall not be opened or removed from their respective source holders by the licensee.
20. 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 applications dated August 1, 1984 and January 24, 1985; and ALARA Program dated July 31, 1984. 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 B.J. Holt

Materials Licensing Section, Region III

Date May 17, 1985

COPY