

MATERIALS LICENSE

Amendment No. 29

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 and hereafter in effect and to any conditions specified below.

"OFFICIAL RECORD COPY"

Licensee

In accordance with letter dated
June 25, 1987,3. License number 20-10621-01 is amended in
its entirety to read as follows:

4. Expiration date August 31, 1989

5. Docket or
Reference No. 030-019316. Byproduct, source, and/or
special nuclear material7. Chemical and/or physical
form8. Maximum amount that licensee
may possess at any one time
under this license

- 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

- 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 the manufacturer by an
Agreement State pursuant
to equivalent State
regulations

- A. As necessary for uses
authorized in
Subitem 9.A.
- B. 3 curies of each
byproduct material
authorized in
Subitem 6.B.
- C. 250 millicuries

D. Gadolinium 153

D. Sealed Source (Lunar
Model GD series)D. Not to exceed
1.5 curies each,
3 curies total

- E. Iodine 131
- F. Iodine 125
- G. Sulfur 35
- H. Technetium 99m
- I. Chromium 51
- J. Phosphorus 32
- K. Calcium 45
- L. Hydrogen 3
- M. Carbon 14

- E. Any
- F. Any
- G. Any
- H. Any
- I. Any
- J. Any
- K. Any
- L. Any
- M. Any

- E. 6 millicuries
- F. 36 millicuries
- G. 1 millicurie
- H. 100 millicuries
- I. 1 millicurie
- J. 50 millicuries
- K. 10 millicuries
- L. 3 millicuries
- M. 5 millicuries

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SUPPLEMENTARY SHEET

License number

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9. Authorized use

- A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100, 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. For use in Lunar Model DP3 or DP4 Bone Mineral Analyzer for diagnosis of patients.
- E. through M. In vitro studies, animal studies.

CONDITIONS

10. Licensed material shall be used only at 115 Lincoln Street, Framingham, Massachusetts.

11. 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:

Luke G. Tedeschi, M.D.

Groups I, II and III
Subitems 6.D. through 6.M.

Leonard H. Inker, M.D.

Groups I, II and III
Subitems 6.C. through 6.M.

Herbert Weintraub, M.D.

Groups I, II and III
Subitems 6.D. through 6.M.

Timothy H. Eisaman, M.D.

Groups I, II and III
Subitems 6.C. through 6.M.

Maurice H. Fainsinger, M.D.

Groups I, II and III
Gadolinium 153 sealed sources for diagnosing
bone maladies

Neil A. Grossman, M.D.

Groups I, II and III
Gadolinium 153 sealed sources for diagnosing
bone maladies

Stuart L. Fuld, M.D.

Groups I, II and III
Gadolinium 153 sealed sources for diagnosing
bone maladies

Isadore N. Rosenberg, M.D.

In vitro studies; animal Studies
Iodine 131 for treatment of hyperthyroidism,
cardiac dysfunction and thyroid carcinoma
Iodine 125 for In vitro studies; animal studies
Phosphorus 32 for In vitro studies; animal studies
Technetium 99m for In vitro studies, animal studies
Chromium 51 for In vitro studies; animal studies
Calcium 45 for In vitro studies; animal studies

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(11. continued)

CONDITIONS

Garry Goldstein, M.D.

Groups I and II
In vitro studies; animal studies
Iodine 131 for treatment of hyperthyroidism,
cardiac dysfunction and thyroid carcinoma
Gadolinium 153 sealed sources for diagnosing
bone maladies

Madeline S. Crivello, M.D.

Groups I, II and III
Subitems 6.E through 6.M.

Raymond S. Koff, M.D.

Subitems 6.L. and 6.M.

Hiroko Kadowaki, M.D.

Subitems 6.L. and 6.M.

12. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.

13. 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 10 half-lives.
- B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall 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.

14. For a period not to exceed 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 Radiation Safety Committee, and
- B. Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and
- C. Performs only those procedures which the physician is specifically authorized to perform pursuant to a license issued by the Nuclear Regulatory Commission.

The licensee shall maintain for inspection by the Commission copies of the written permission specified in A. above and of the license(s) specified in B. and C. above for a period of 5 years from the date permission is granted under A. above.

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CONDITIONS

15. The licensee may use the Calicheck device for doing linearity tests of its dose calibrator provided it follows the procedures in the Calcorp, Inc., Manual dated March 2, 1982.
16. 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.
17. A. The sealed sources or detector cells specified in Item 7.D. shall be tested for leakage and/or contamination at intervals not to exceed one year. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.
B. Any sealed source or detector cell in storage and not being used need not be tested. When the source or detector cell is removed from storage for use or transfer to another person, it shall be tested before use or transfer.
C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source or detector cell shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety and Safeguards Branch, 631 Park Avenue, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.
D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.
18. Replacement-exchange of the source/source-holder combination may be performed by the licensee in accordance with the instructions contained in the manufacturer's manual. The source will not be removed from the source/source-holder combination by the licensee.

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CONDITIONS

19. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated April 23, 1984
- B. Letter dated July 27, 1984
- C. Letter dated October 29, 1985
- D. Letter dated April 28, 1987



For the U.S. Nuclear Regulatory Commission

Original Signed By:

John E. Glenn

Date

12 AUG 1987

By

Nuclear Materials Safety and
Safeguards Branch, Region I
King of Prussia, Pennsylvania 19406