NRC Form 374
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 12

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. Mallinckrodt, Inc. Diagnostic Imaging Services	In accordance with letter dated May 14, 1987, 3. License number 37-21345-01MD is amended in its entirety to read as follows:
2. #19 Independence Court Folcroft, Pennsylvania 19032	4. Expiration date August 31, 1988
	5. Docket or Reference No. 030-20537

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
A. Molybdenum 99	A. Any Molybdenum 99/ Technetium 99m generator manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.73 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	A. 60 curies
B. Any byproduct material authorized under Section 35.14(d)(4) of 10 CFR Part 35	B. Any sealed source listed in Section 35.14(d)(4) of 10 CFR Part 35	B. 5 millicuries total for all sources authorized under Subitem 6.B
C. Xenon 133	C. Unit dose containers of Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA	C. 2 curies

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 37-21345-01MD
Docket or Reference number: 030-20537
Amendment No. 12

(Items 6., 7., and 8. continued)

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 form listed in Groups I through V of Schedule A, Section 35.100 of 10 CFR 35	D. 500 millicuries
E. Technetium 99m	E. Any form listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	E. 60 curies
F. Any byproduct material, except Iodine 131 or Technetium 99m, listed in Group I of Schedule A, Section 35.100 of 10 CFR Part 35	F. Any form listed in Group I of Schedule A, Section 35.100 of 10 CFR 35	F. 50 millicuries total possession limit
G. Any byproduct material, except Iodine 131 or Technetium 99m, listed in Group II of Schedule A, Section 35.100 of 10 CFR Part 35	G. Any form listed in Group II of Schedule A, Section 35.100 of 10 CFR 35	G. 400 millicuries total possession limit
H. Any byproduct material, except Iodine 131, listed in Group IV of Schedule A, Section 35.100 of 10 CFR Part 35	H. Any form listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	H. 100 millicuries total possession limit

9. Authorized use

A. Production of technetium 99m pertechnetate. Redistribution of unopened generators, as received from the manufacturer in the manufacturer's original packaging and shielding and accompanied by the manufacturer's approved package insert, to authorized recipients.
B. Instrument calibration.
C. Distribution to authorized recipients.
D. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.
E. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Use of technetium 99m pertechnetate for processing with reagent kits in the preparation of radiopharmaceuticals.
F. through H. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.

Pursuant to Section 32.72 and 32.73, 10 CFR 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 of this license to persons licensed pursuant to Section 35.14 and Section 35.100, 10 CFR Part, or under equivalent licensees of Agreement States, for the Groups indicated below:

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 37-21345-01MD

Docket or Reference number: 030-20537

Amendment No. 12

(9. continued)

A. Molybdenum 99/technetium 99m generators may be redistributed to persons licensed pursuant to Group III.

D. through H. Any form listed in each Group, Groups I, II, IV or V of Schedule A, Section 35.100 of 10 CFR 35, may be distributed to persons licensed pursuant to that Group.

CONDITIONS

10. Licensed material shall be used only at Independence Court, Bay #20, Folcroft, Pennsylvania and at #19 Independence Court, Folcroft, Pennsylvania.

11. Licensed material shall be used by, or under the supervision of,

Gregory Brooks
Daniel J. Casey
Robert P. Chandler
Alice Worthen
Rudolph V. Gilliam
Frank M. Gwynn
Stuart B. Herrick
Isaac Khalil
Rebecca S. Kubic
Mitchell W. Mandich
John Manzi
John C. Martin
William R. Martin
Craig Minami
John P. Minella
Richard A. Nickel
Dennis Davis
Amit S. Parikh
Monique Piontek
Greg Stolinski
Barbara D. Scavullo
Mark K. Scheffler
Todd Schmidt
Janna Millenbine
Mary Ellen Dominik
Gary L. Spence
Wayne Toal
Todd A. Warren
Randal Watt
Michael Whyte
William C. Wilson
Carl E. Wood
Denise Horner
Joseph J. Nacchio

12. At least one individual named in Condition 11 shall be physically present at the authorized place of use whenever licensed material is being used.

13. A(1) The source or detector cell specified in Item(s) 7.B. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source or detector cell 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.

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

B. Any 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.

(13. continued) CONDITIONS

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.

14. Sealed sources containing licensed material shall not be opened.

15. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 2 years from the date of each inventory.

16. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material".

17. A. Radiopharmaceuticals dispensed and/or distributed for human use shall be either:

(i) Repackaged from prepared radiopharmaceuticals that are the subject of an FDA-approved "New Drug Application" (NDA) or for which FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or

(ii) Prepared from generators and reagent kits that are the subject of an FDA-approved NDA or for which FDA has accepted an IND.

B. Prepared radiopharmaceuticals for which FDA has accepted an IND and radiopharmaceuticals prepared from generators or reagent kits for which FDA has accepted an IND shall be dispensed and/or distributed:

(i) In accordance with the directions provided by the sponsor of the IND, and

(ii) Only to physicians who have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 37-21345-01MD
Docket or Reference number: 030-20537
Amendment No. 12

(17. continued) CONDITIONS

The licensee shall inform in writing each physician who participates in an IND evaluation that the physician is responsible to the sponsor of the IND for use of the drug in accordance with protocols established by the sponsor and for reporting to the sponsor the clinical information obtained through use of the drug.

18. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.

19. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements and representations in application dated April 8, 1983.

20. 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.

21. 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.

22. The licensee may use the Lineator device for doing linearity tests of its dose calibrator provided it follows the procedures in the Atomic Products Corporation Lineator Instructions Manual dated June 20, 1983.

23. 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 8, 1983
    B. Letter dated June 30, 1983
    C. Letter dated July 19, 1983
    D. Letter dated August 4, 1983
    E. Letter dated December 19, 1983
    F. Letter dated May 23, 1984

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
37-21345-01MD

Docket or Reference number
030-20537

Amendment No. 12

(23. continued) CONDITIONS

G. Letter dated August 9, 1984
H. Letter dated October 15, 1984
I. Letter dated December 18, 1984
J. Letter dated January 15, 1985
K. Letter dated February 27, 1985
L. Letter dated April 9, 1985
M. Letter dated April 16, 1986 (12A. and 12C. only)
N. Letter dated May 27, 1986
O. Letter dated July 2, 1986
P. Letter dated August 6, 1986
Q. Letter dated March 25, 1987
R. Letter dated April 20, 1987
S. Letter dated May 14, 1987

For the U.S. Nuclear Regulatory Commission

Date 26 AUG 1987

By Original Signed By:
Jenny M. Johansen
Nuclear Materials Safety and
Safeguards Branch, Region I
King of Prussia, Pennsylvania 19406