

March 27, 2006

U.S. Nuclear Regulatory Commission
Region I
Nuclear Materials Safety Branch
475 Allendale Road
King of Prussia, PA 19406-1415

NMSB 2

03032951

RECEIVED
REGION I
2006 MAR 30 AM 10:30

RE: Material License #24-04206-14MD

Please Expedite Licensing Action

Dear License Reviewer:

Due to recent personnel changes at our Pine Brook, NJ nuclear pharmacy, please amend the above referenced material license to reflect the following modifications:

1. Effectively immediately, amend to name **Yogesh Patel., R.Ph.** as Radiation Safety Officer. Mr. Patel shall replace Mark Marinock, R.Ph. in this capacity, as Mr. Marinock is no longer with Mallinckrodt Inc. Mr. Patel is also the Nuclear Pharmacy Manager at this facility.

Mr. Patel is currently listed as an Authorized Nuclear Pharmacist on Illinois Emergency Management Agency radioactive materials license number IL-01117-01, included for your convenience as Attachment A, and therefore satisfies the training and experience requirements listed in 10 CFR 35.900 for Radiation Safety Officers.

2. Please amend to update the facility diagram, included as Attachment B.

138631

NMSS/RONI MATERIALS-002

All other items relating to our radioactive material license and established Radiation Safety Program remain unchanged at this time. Please contact April Chance, Manager, Radiological Affairs (314-654-7960) for further information regarding this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Kay M. Yoder". The signature is written in a cursive style with a large initial "K".

Kay M. Yoder,
Director, Radiation, Environment, Health, & Safety – Mallinckrodt Inc.

Attachments

cc: Y. Patel, R.Ph., Radiation Safety Officer (Pine Brook, NJ)
A. Chance, Manager, Radiological Affairs (Hazelwood, MO)
C. Patton, Interim Manager, EHS, Pharmacy Operations (Hazelwood, MO)

ATTACHMENT A
ILLINOIS LICENSE IL-01117-01

August 31, 2004

Radioactive Material License
IL-01117-01

Dale Simpson
Director of Manufacturing
Mallinckrodt, Inc.
Diagnostic Imaging Services
675 McDonnell Boulevard
St. Louis, MO 63134

Dear Mr. Simpson:

Enclosed is amendment number 32 to your License Number IL-01117-01. For your convenience, the changes are boldfaced on this license amendment.

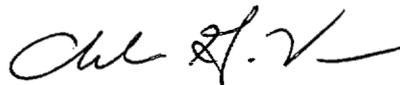
Please review the enclosed document carefully and be sure that you understand all conditions. You must conduct your program involving radioactive material in accordance with the conditions of your Illinois license, representations made in your license application, and Illinois regulations.

You must request and obtain an appropriate amendment if you plan to make any changes in your facility or program. Certain amendments require that a fee be assessed and paid to the Agency. If applicable, you will be billed in accordance with the requirements of 32 Ill. Adm. Code Part 331.120.

You will be inspected periodically by this agency. Failure to conduct your program in accordance with IEMA regulations and your license will result in enforcement action.

Thank you for your cooperation in this matter. When corresponding with this office, please refer to your License Number and ensure that all items are submitted in duplicate. If you have any questions, please contact Radioactive Materials Licensing at (217) 785-9947.

Sincerely,



Charles G. Vinson, Supervisor
Radioactive Materials Licensing

CGV:MEB:kjc

Enclosure

STATE OF ILLINOIS
IEMA DIVISION OF NUCLEAR SAFETY
RADIOACTIVE MATERIAL LICENSE

LICENSEE	LICENSE NUMBER	AMENDMENT NUMBER	EXPIRATION DATE
Mallinckrodt, Inc.	IL-01117-01	32	March 31, 2008

ITEM	RADIONUCLIDE	CHEMICAL and/or PHYSICAL FORM	MAXIMUM ACTIVITY* PER SOURCE	MAXIMUM POSSESSION LIMIT
E.	Any radionuclide identified in 32 Ill. Adm. Code 335.2040	Any calibration or reference source identified in 32 Ill. Adm. Code 335.2040	25 mCi	300 mCi
F.	Uranium Depleted	Metal encased in stainless steel		600 kg
G.	Mo-99	Any Mo-99/Tc-99m generator		200 Ci
H.	Tc-99m	Any radiopharmaceutical identified in 32 Ill. Adm. Code 335.3010 and 335.4010		200 Ci
I.	Xe-133	Unit dose containers of gas or gas in solution		5 Ci
J.	I-131	Any radiopharmaceutical identified in 32 Ill. Adm. Code 335.3010, 335.4010 or 335.5010		5 Ci
K.	Tl-201	Any radiopharmaceutical identified in 32 Ill. Adm. Code 335.3010 or 335.4010		1 Ci
L.	Y-90	Calibration and Reference Standard or radiopharmaceutical identified in 32 Ill. Adm. Code 335.5010.		1 Ci

μCi-microcurie; mCi-millicurie; Ci-Curie; MBq-Megabecquerel; GBq-Gigabecquerel; TBq-Terabecquerel; g-gram; μg-microgram; kg-kilogram

APPROVED BY:

DATE

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Charles G. Vinson, Supervisor of Materials Licensing
IL 473-0059

August 31, 2004

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STATE OF ILLINOIS
IEMA DIVISION OF NUCLEAR SAFETY
RADIOACTIVE MATERIAL LICENSE

<u>LICENSEE</u>	<u>LICENSE NUMBER</u>	<u>AMENDMENT NUMBER</u>	<u>EXPIRATION DATE</u>
Wallinckrodt, Inc.	IL-01117-01	32	March 31, 2008

AUTHORIZED USE:

- A., B. C., H., J., K. and M. For processing, mixing or compounding and distribution of prepared radiopharmaceuticals to specifically licensed recipients.
- D. For redistribution to general and specifically licensed recipients.
- E. and M. For instrument calibration or redistribution to specifically licensed recipients.
- F. For use as shielding in Mo-99/Tc-99m generators.
- G. For production of Tc-99m pertechnetate production or redistribution of unused generators to specifically licensed recipients.
- I. For redistribution to specifically licensed recipients.
- L. Redistribution of sealed sources, including repackaged sealed sources, to specifically licensed recipients in accordance with the statements, representations and procedures listed in other conditions of this license.

CONDITIONS

1. Radioactive material shall be used only at the licensee's facilities located at 601-F Busse Road, Elk Grove, Illinois, and at 4749-4751 West 135th Street, Crestwood, Illinois, in accordance with statements, representations and procedures listed in other conditions of this license.
2.
 - A. The use of radioactive material shall be by or under the direct supervision and in the physical presence of a State of Illinois Registered Pharmacist who meets the training and experience requirements specified in the application dated February 27, 2003. The licensee shall maintain for Agency inspection training records, the Corporate Radiation Safety Officer's written approval and a valid Illinois Board of Pharmacy License for each pharmacist authorized under this condition.
 - B. If an authorized user specified in Condition 2.A. is not a State of Illinois registered pharmacist, then a State of Illinois registered pharmacist must also be physically present in order for radiopharmaceuticals to be dispensed. Radiopharmaceuticals shall only be dispensed by a State of Illinois registered pharmacist.

μCi-microcurie; mCi-millicurie; Ci-Curie; MBq-Megabecquerel; GBq-Gigabecquerel; TBq-Terabecquerel; g-gram; μg-microgram; kg-kilogram

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IL 473-0059

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STATE OF ILLINOIS
IEMA DIVISION OF NUCLEAR SAFETY
RADIOACTIVE MATERIAL LICENSE

<u>CENSEE</u>	<u>LICENSE NUMBER</u>	<u>AMENDMENT NUMBER</u>	<u>EXPIRATION DATE</u>
Mallinckrodt, Inc.	IL-01117-01	32	March 31, 2008

3.
 - A. The Radiation Safety Officer for the Elk Grove facility is **Yogesh Patel, R.Ph.**
 - B. The Radiation Safety Officer for the Crestwood facilities is **Deborah Vanerka, R.Ph.**
4.
 - A. Each sealed source possessed under this license shall be tested for leakage and/or contamination as specified in 32 Ill. Adm. Code 340.410. Tests for leakage and/or contamination shall be performed by persons specifically licensed to provide such services.
 - B. This license does not authorize analysis of leak test samples. However, the licensee is authorized to collect leak test samples for analysis by persons specifically authorized by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.
 - C. The records of tests for leakage and/or contamination shall contain the manufacturer, model and serial number, if assigned, of each source tested, the identity of each source radionuclide and its calculated activity as of the date of the test or the activity and activity assay date, the measured activity of each test sample expressed in Bq or μCi , the date the sample was collected, the date the sample was analyzed, the identity of the individual who collected the sample(s) and the identity of the individual who analyzed the sample(s).
5. The licensee shall conduct a physical inventory at intervals not to exceed six months to account for each sealed source received and possessed under the license and shall maintain a record of such inventories. The inventory records shall include the radionuclide, activity, activity assay date, manufacturer, model and serial number, the location of the sealed source, date of the inventory and the identity of the individual(s) performing the inventory. Records of inventories shall be maintained for five years from the date of each inventory.
6. The licensee shall elute generators and process radioactive material in reagent kit preparations in accordance with the manufacturer-supplied package insert. Otherwise, the radiopharmaceutical shall be prepared and compounded following the directions of an authorized user physician or in accordance with the regulations of the Illinois Department of Professional Regulation. This does not relieve the licensee from compliance with other applicable federal, State and local requirements governing preparation and use of radioactive material.
7.
 - A. Radioactive drugs shall be dispensed only under the prescription of a specifically licensed physician who is authorized to possess and use the radioactive drugs or of a physician authorized under the provisions of a broad radioactive material license.

* μCi -microcurie; mCi-millicurie; Ci-Curie; MBq-Megabecquerel; GBq-Gigabecquerel; TBq-Terabecquerel; g-gram; μg -microgram; kg-kilogram

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IL 473-0059

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STATE OF ILLINOIS
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 RADIOACTIVE MATERIAL LICENSE

<u>CENSEE</u>	<u>LICENSE NUMBER</u>	<u>AMENDMENT NUMBER</u>	<u>EXPIRATION DATE</u>
Mallinckrodt, Inc.	IL-01117-01	32	March 31, 2008

(Condition 7. continued)

- B. The licensee shall maintain a copy of the radioactive material license of each customer physician and shall verify that the physician is authorized to receive the prescribed radiopharmaceutical prior to transferring the radiopharmaceutical.
8. The licensee shall report to the Agency, within ten days of occurrence, any irregularities pertaining to identification, labeling, quality, or assay of any radioactive drug received under the authority of this license.
9. Sealed sources containing radioactive material shall not be opened.
10. The licensee may use the Calcorp, Inc. "Calicheck" device or the Atomic Products Corp. "Lineator" device for linearity tests of their dose calibrator(s). Such tests shall be performed in strict accordance with the procedures contained in the device manufacturer's instruction manual. A copy of the appropriate device manufacturer's instruction manual shall be maintained at the licensee's facility if one of these devices is used.
11. Radioactive waste material generated by customers of the licensee may be picked up for final disposal in accordance with procedures outlined in the application dated February 27, 2003. Appropriate records of receipt and disposition shall be maintained for inspection by the Agency.
12. The licensee is authorized to store waste containing, or comprised of, radioactive material with a physical half-life of less than 90 days for "decay-in-storage" before disposal with the following provisions:
- A. Radioactive waste to be disposed of shall be held for decay a minimum of ten half-lives.
- B. Pursuant to 32 Ill. Adm. Code 340.510(a) and (b), radiation surveys shall be performed prior to disposal of the waste to ensure that the waste's radioactivity cannot be distinguished from background radiation levels. The package/container surface shall be surveyed with an appropriate radiation detection survey instrument set on its most sensitive scale, with no interposed shielding between the detector and the waste, in a low background radiation environment. Records of monitoring shall be maintained to include: date of disposal; date placed in storage; manufacturer, model and serial number of the survey instrument used; background radiation levels; measured radiation levels; and identity of the individual performing the monitoring. All radiation labels shall be removed or obliterated.
- C. Generator columns shall be segregated from their shields and other waste and monitored separately to ensure decay to background levels prior to disposal.

* μ Ci-microcurie; mCi-millicurie; Ci-Curie; MBq-Megabecquerel; GBq-Gigabecquerel; TBq-Terabecquerel; g-gram; μ g-microgram; kg-kilogram

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STATE OF ILLINOIS
IEMA DIVISION OF NUCLEAR SAFETY
RADIOACTIVE MATERIAL LICENSE

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Mallinckrodt, Inc.	IL-01117-01	32	March 31, 2008

(Condition 12. continued)

- D. Nothing in this condition relieves the licensee from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous property of these materials.
13. Any proposed change in primary packaging, product shielding, product labeling or package inserts which changes either exposure to handlers and users, or recommended uses of material, shall be submitted to the Agency. Any other change to packaging, shielding, labeling or package inserts shall be maintained by the licensee, and shall be available for inspection by representatives of this Agency.
14. Biological products labeled with radionuclides or kits used to prepare such products shall be procured from a supplier who holds an unsuspended or unrevoked license issued by the Secretary of the Department of Health and Human Services to propagate, manufacture, prepare, label, or distribute the products. The labeled biological products shall be used only for the medical indications covered by the supplier's Department of Health and Human Services license.
15. Radiometric tests for molybdenum breakthrough shall be made upon each elution of a molybdenum-99/technetium-99m generator in accordance with the requirements of 32 Ill. Adm. Code 335.4020.
16. All radioactive drugs shall be procured from a supplier who manufactures or repackages the product under appropriate pharmaceutical controls related to assay, identity, quality, purity, sterility and non-pyrogenicity.
17. Individuals who work in, or whose duties may require them to work in restricted areas, shall be instructed in the items specified in 32 Ill. Adm. Code 400.120 at the time of initial employment and at least annually thereafter. The licensee shall maintain records of initial and annual employee training for Agency inspection for 5 years from the date on which the training was given. The record shall contain a signed statement the individuals have received the information in 32 Ill. Adm. Code 400.120 and understand it, and the date(s) the training was received by the individuals.
18. The licensee shall measure airflow rates initially and semi-annually thereafter to assure proper ventilation system performance. Records of the evaluation of ventilation system performance shall be maintained for Agency inspection and shall include: the date of evaluation; results of ventilation rate measurements; manufacturer, model and serial number of the measurement instrument used; and the identity of the individual performing the measurements.

* μ Ci-microcurie; mCi-millicurie; Ci-Curie; MBq-Megabecquerel; GBq-Gigabecquerel; TBq-Terabecquerel; g-gram; μ g-microgram; kg-kilogram

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Charles G. Vinson, Supervisor of Materials Licensing

August 31, 2004

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STATE OF ILLINOIS
IEMA DIVISION OF NUCLEAR SAFETY
RADIOACTIVE MATERIAL LICENSE

LICENSEE	LICENSE NUMBER	AMENDMENT NUMBER	EXPIRATION DATE
Mallinckrodt, Inc.	IL-01117-01	32	March 31, 2008

19. Except as specifically provided otherwise by the license, the licensee shall possess and use radioactive material described in all schedules of this license in accordance with statements, representations and procedures contained in, referenced in, or enclosed with the documents listed below. The regulations contained in 32 Ill. Adm. Code: Chapter II, Subchapters b and d shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations. The most recent statements, representations and procedures listed below shall govern if they conflict with previously submitted documents.
- A. Application February 27, 2003.
 - B. Letter, with attachments, dated July 18, 2003, November 11, 2003, September 11, 2003 and February 23, 2004.
 - C. Telefacsimiles dated November 14, 2003 and November 17, 2003.
 - D. Letter dated October 9, 2003.

CGV:MEB:kje

* μ Ci-microcurie; mCi-millicurie; Ci-Curie; MBq-Megabecquerel; GBq-Gigabecquerel; TBq-Terabecquerel; g-gram; μ g-microgram; kg-kilogram

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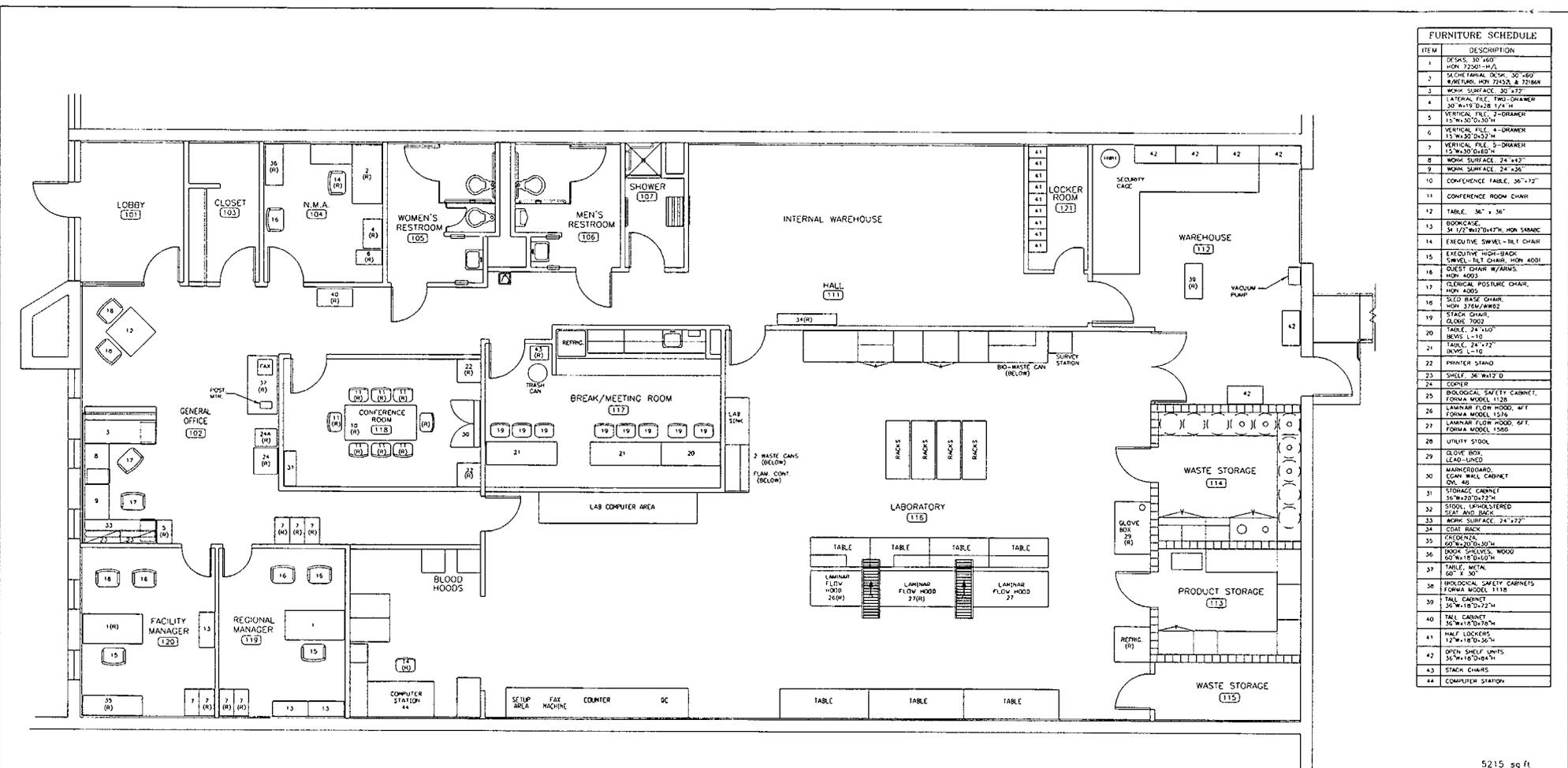
Charles G. Vinson, Supervisor of Materials Licensing

August 31, 2004

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**ATTACHMENT B
UPDATED FACILITY DIAGRAM**



ITEM	DESCRIPTION
1	SECS. 30" WIDE HOM 72501-11/A
2	SCHE TARIK DESK 30" x 60" KINETIC, HOM 72501 & 22168
3	WORK SURFACE 30" x 72"
4	LATERAL FILE, TWO-DRAWER 30" W x 15" D x 18" H / A / H
5	VERTICAL FILE, 2-DRAWER 15" W x 30" D x 30" H
6	VERTICAL FILE, 4-DRAWER 15" W x 30" D x 30" H
7	VERTICAL FILE, 5-DRAWER 15" W x 30" D x 30" H
8	WORK SURFACE 24" x 42"
9	WORK SURFACE 24" x 36"
10	CONFERENCE TABLE, 36" x 72"
11	CONFERENCE ROOM CHAIR
12	TABLE, 36" x 36"
13	BOOKCASE 34 1/2" W x 17" D x 47" H, HOM 51846
14	EXECUTIVE SWIVEL - HLT CHAIR FORMA MODEL 1128
15	EXECUTIVE HIGH-BACK SWIVEL - HLT CHAIR, HOM 4001
16	GUEST CHAIR W/ARM'S, HOM 4003
17	CLEVER POSTURE CHAIR, HOM 4005
18	SEEL BRACE CHAIR, HOM 3756/AW02
19	STACK CHAIR, GLOVE HOOD
20	TABLE, 24" x 40" BOWS L-10
21	TABLE, 24" x 72" BOWS L-10
22	PRINTER STAND
23	SHLFL, 36" W x 12" D
24	COOPER
25	BIOLOGICAL SAFETY CABINET, FORMA MODEL 1128
26	LAMINAR FLOW HOOD, 4 FT FORMA MODEL 1276
27	LAMINAR FLOW HOOD, 6 FT, FORMA MODEL 1580
28	UTILITY STOOL
29	GLOVE BOX, LEAD-LINED
30	WARRANTYBOARD, EGAN WALL CABINET ON, 40"
31	STORAGE CABINET 16" W x 20" D x 12" H
32	STOOL, UPHOLSTERED
33	WORK SURFACE, 24" x 72"
34	CD-R TRACK
35	FORMA MODEL 1201/2070
36	BOOK SHELVES, WOOD 60" W x 18" D x 36" H
37	TABLE, METAL 60" x 90"
38	BIOLOGICAL SAFETY CABINETS FORMA MODEL 1118
39	TALL CABINET 36" W x 18" D x 72" H
40	TALL CABINET 36" W x 18" D x 72" H
41	HALF LOCKERS 12" W x 18" D x 36" H
42	OPEN SHELF UNITS 36" W x 18" D x 36" H
43	STACK CHAIRS
44	COMPUTER STATION

5215 sq ft
Scale: 1/8" = 1'

Restricted
Area



REV	DATE	DESCRIPTION
1	02/10/00	ISSUE #1
2	02/10/00	ISSUE #2, REVISION #1
3	02/10/00	ISSUE #3, REVISION #1
4	02/10/00	ISSUE #4, REVISION #1
5	02/10/00	ISSUE #5, REVISION #1
6	02/10/00	ISSUE #6, REVISION #1
7	02/10/00	ISSUE #7, REVISION #1
8	02/10/00	ISSUE #8, REVISION #1
9	02/10/00	ISSUE #9, REVISION #1
10	02/10/00	ISSUE #10, REVISION #1
11	02/10/00	ISSUE #11, REVISION #1
12	02/10/00	ISSUE #12, REVISION #1
13	02/10/00	ISSUE #13, REVISION #1
14	02/10/00	ISSUE #14, REVISION #1
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21	02/10/00	ISSUE #21, REVISION #1
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46	02/10/00	ISSUE #46, REVISION #1
47	02/10/00	ISSUE #47, REVISION #1
48	02/10/00	ISSUE #48, REVISION #1
49	02/10/00	ISSUE #49, REVISION #1
50	02/10/00	ISSUE #50, REVISION #1

TYCO HEALTHCARE
 MALLINCKRODT
 2703 Water Place, Maywood Heights, MO 63045
 Pine Brook Pharmacy
 Equipment Plan
 Plan View
 DOC NO: 0001-216-001 REV NO: 2
 JOB NO: N/A PROJ NO: N/A
 SHT: P-01-01-01 DATE: 11/11/00
 DWG: 11/11/01 INT: N/A
 TITL: EQUIPMENT PLAN
 SCALE: AS SHOWN
 MATERIAL: N/A
 THIS DRAWING IS THE PROPERTY OF MALLINCKRODT AND IS NOT TO BE REPRODUCED, COPIED OR USED FOR ANY PURPOSES EXCEPT AS SPECIFIED BY MALLINCKRODT IN WRITING.

Pine Brook Pharmacy
 P.O. Box 671
 26 Chopin Road, Unit 1110
 Pinebrooke, NJ 07058

This is to acknowledge the receipt of your letter/application dated

3/27/2006, and to inform you that the initial processing which includes an administrative review has been performed.

Amend. 24-04206-14010
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 138631.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.