

CORRECTED COPY

MATERIALS LICENSE

Amendment No. 02

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, 36, 39, 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.

OFFICIAL RECORD COPY

Licensee 1. Mallinckrodt Medical, Inc. Nuclear Medicine Division 2. 2703 Wagner Place Maryland Heights, Missouri 63043		In accordance with the letter dated November 21, 1996, 3. License Number 24-04206-17MD is amended in its entirety to read as follows:	
		4. Expiration Date August 31, 2003	
		5. Docket or Reference No. 030-33157	
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. Any byproduct material with atomic numbers 1 through 83, except molybdenum 99, technetium 99m, iodine 131 and xenon 133	A. Any, except sealed sources	A. Not to exceed 100 millicuries per radionuclide and 1 curie total	
B. Molybdenum 99	B. Any, except sealed sources	B. 200 curies	
C. Technetium 99m	C. Any, except sealed sources	C. 200 curies	
D. Iodine 131	D. Any, except sealed sources	D. 5 curies	
E. Xenon 133	E. Any, except sealed sources	E. 2 curies	
F. Any byproduct material listed in 10 CFR 31.11(a)	F. Prepackaged units for <u>in vitro</u> diagnostic tests	F. 20 millicuries	
G. Any byproduct material authorized under 10 CFR 35.57(a)	G. Sealed sources	G. 100 millicuries	
H. Depleted Uranium	H. Metal	H. 600 kilograms	
I. Cesium 137	I. Sealed sources (Tech/Ops Model 77302)	I. Not to exceed 165 millicuries per source and 330 millicuries total	

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9. Authorized use

- A. through E. Preparation and distribution of radioactive drugs, production of technetium 99m pertechnetate, compounding of iodine 131 and distribution of unused molybdenum 99/technetium 99m generators to authorized recipients in accordance with 10 CFR 32.72 and to authorized recipients for non-medical use.
- F. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labelling remain unchanged.
- G. Calibration and checking of the licensee's instruments. Distribution of sealed sources to authorized recipients in accordance with 10 CFR 32.74 and to authorized recipients for non-medical use.

ML 10



MATERIALS LICENSE
SUPPLEMENTARY SHEET

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License Number

24-04206-17MD

Docket or Reference Number

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Amendment No. 02

- H. Shielding for molybdenum 99/technetium 99m generators.
I. For use in a Tech/Ops Model 773 device for calibrations and checking of the licensee's survey instruments.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 2299 Brodhead Road, Suite H and I, Bethlehem, Pennsylvania.
11. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:
- A. In accordance with 10 CFR 32.72(b)(2)(i) or (4), pharmacists working as authorized nuclear pharmacists.
- B. Authorized Nuclear Pharmacists:
- | | | |
|---------------------|------------------------------|------------------------------|
| Steven Alvey | Allen Fazekas | Thomas Mabis |
| Margaret Anderson | Joseph Fery | John Manzi |
| Brian Auger | Thomas Firman | Brad Martin |
| Terry Austin | James Flynn | John Martin |
| | Lori Follis (DeVos) | Deborah McDowell (Cashbaugh) |
| Christine Basilone | | Thomas McKean |
| Wendy Lou Baumering | Joseph Gatton | John Minella |
| Quent Besing | Rudolph Gilliam | Barbara Missal |
| Amy Bettle | Bonnie Gindling | |
| Thomas Brady | Margaret Glennon | Richard Nickel |
| John Briggs | Christine Goetting (Surerus) | |
| Barry Brown | | Michael Palmer |
| | Kelly Hall | Amit Parikh |
| Nancy Cahill | David Hart | Neal Patel |
| Robert Chandler | David Hartter | Craig Petzold |
| Padmesh Chhita | Elaine Haynes | Karen Pieszala |
| Harold Cleveland | Michael Hess | David Poydenre |
| Matthew Coccaro | Richard Hylinski | |
| Daniel Coffman | | Charles Reed |
| Cheryl Cordum | Henry Jahn | Debra Ross |
| Brian Cox | Homan Jarrar | Michael Rossi |
| William Crawford | | |
| | Lucie Kawaguchi | |
| Dennis Davis | John Keenan | |
| Vicky Davis | Michael Klug | |
| Rodney Detrow | Scott Knishka | |
| Kenneth DeTurk | Raymond Komosinski | |
| Vincent DiSpigno | Lisa Koss (Leonard) | |
| | | |
| Greg Edquist | Timothy Layne | |
| Oliver Emberger | Sam Shen-Shin Ling | |
| | Paul Lukas | |
| | David Lutes | |

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License Number 24-04206-17MD

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Amendment No. 02

Warren Salomon
Barbara Scavullo
Richard Schafer
David Schmitt
Steven Schultz
David Senko
Aly Sharaf
Mary Sue Shrum
James Sorensen
Gary Spence
Michael Stipanovich

Wayne Toal
Sally DuAnn Vanderslice
Deborah Vanerka (Wierzba)
Thomas Viering
Tracey Villa

Donald Warner
Todd Warren
Genevieve Watanabe
Randall Watt
Larry Weidner
Henry Weilgosz
Jeff Williams
Jason Willman
Brian Wong
Richard Wride

12. The Radiation Safety Officer for this license is Timothy Layne, R.Ph.
13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.
14. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources and detector cells need not be leak tested if:
- (i) they contain only hydrogen-3; or
 - (ii) they contain only a radioactive gas; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

**MATERIALS LICENSE
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Amendment No. 02

(v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. 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, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.

G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

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

16. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

17. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.

18. Reagent kits may be redistributed to persons licensed pursuant to 10 CFR 35.200 or under equivalent licenses of Agreement States.

19. 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. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

24-04206-17MD

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Amendment No. 02

- C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
20. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the statements, representations and procedures in the application dated November 20, 1996.
21. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
22. 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 21, 1993
 - B. Letter dated July 13, 1993
 - C. Letter dated March 1, 1994
 - D. Letter dated March 30, 1994
 - E. Application dated November 20, 1996, except criteria for carbon filter replacement, in item 10.10, B on page 4.

Date

FEB 24 1997

For the U.S. Nuclear Regulatory Commission

Original Signed By:

John D. Kinneman

By

Division of Nuclear Materials Safety
Region I

King of Prussia, Pennsylvania 19406