



GE Healthcare

3520 Progress Drive  
Bensalem, PA 19020  
USA

T 215 245 7805  
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June 27, 2006

*MS16*

*J-6*

U. S. Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19406

Re: License No. 37-27830-02MD  
Mail Control Number 138937

*03031990*

Dear Sir,

Enclosed please find Mallinckrodt Medical's radioactive material license naming Elio Gould as an authorized user. Please add Elio Gould to our license as requested in the May 30, 2006 correspondence.

Thank you for your assistance. I can be reached at (215)245-7805 to answer any questions you may have.

Sincerely,

Michael Hess R.Ph.  
Facility RSO

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NMSS/RCNI MATERIALS-002

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Amendment No. 14

**MATERIALS LICENSE**

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.

<p>Licensee</p> <p>1. Mallinckrodt, Inc.</p> <p>2. 675 McDonnell Boulevard P.O. Box 5840 St. Louis, Missouri 63134</p>	<p>In accordance with the letter dated June 27, 2002,</p> <p>3. License number 24-04206-01MD is amended in its entirety to read as follows:</p> <p>4. Expiration date March 31, 2003</p> <p>5. Docket No. 03062995 Reference No.</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with atomic numbers 1 through 83, except molybdenum 99, technetium 99m, iodine 131 and xenon 133</p> <p>B. Molybdenum 99</p> <p>C. Technetium 99m</p> <p>D. Iodine 131</p> <p>E. Xenon 133</p> <p>F. Any byproduct material listed in 10 CFR 31.11(a)</p> <p>G. Any byproduct material authorized under 10 CFR 35.57(a)</p> <p>H. Depleted Uranium</p> <p>I. Iodine 125</p> <p>J. Yttrium 90</p>	<p>7. Chemical and/or physical form</p> <p>A. Any, except sealed sources</p> <p>B. Any, except sealed sources</p> <p>C. Any, except sealed sources</p> <p>D. Any, except sealed sources</p> <p>E. Any, except sealed sources</p> <p>F. Prepackaged units for <u>in vitro</u> diagnostic tests</p> <p>G. Sealed sources</p> <p>H. Metal</p> <p>I. Any brachytherapy source identified in 10 CFR 35.400</p> <p>J. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. Not to exceed 100 millicuries per radionuclide and 1 curie total</p> <p>B. 200 curies</p> <p>C. 200 curies</p> <p>D. 5 curies</p> <p>E. 4 curies</p> <p>F. 20 millicuries</p> <p>G. 300 millicuries</p> <p>H. 999 kilograms</p> <p>I. 4 curies</p> <p>J. 1 curie</p>

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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 labeling 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.
- H. Shielding for molybdenum 99/technetium 99m generators.
- I. Distribution of sealed sources pursuant to 10 CFR 32.74 to persons licensed pursuant to 10 CFR 35.400 or under equivalent licenses of any Agreement State.
- J. Preparation and distribution of radioactive drugs in accordance with 10 CFR 32.72.

10. Licensed material may be used only at the licensee's facilities located at 4400 Lewis Road, Suite A, Harrisburg, 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(a)(2)(i) or (4), pharmacists working as authorized nuclear pharmacists.

## B. Authorized Nuclear Pharmacists:

Steven Alvey  
Margaret Anderson  
Brian Auger  
Terry Austin  
Christine Basilone  
Wendy Lou Baumering  
Quent Besing  
Amy Bettie  
Thomas Brady  
John Briggs  
Barry Brown  
Nancy Cahill  
Robert Chandler

Bonnie Gindling  
Margaret Glennon  
Christine Goetting (Surerus)  
Elio Gould  
Kelly Hall  
David Hart  
David Hartter  
Elaine Haynes  
Michael Hess  
Richard Hyllinski  
Henry Jahn  
Homan Jarrar  
Lucie Kawaguchi

Neal Patel  
Craig Petzold  
Karen Pieszala  
David Poydence  
Charles Reed  
Debra Ross  
Michael Rossi  
Warren Salomon  
Barbara Scavullo  
Richard Schafer  
David Schmitt  
Steven Schultz  
David Senko

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Padmesh Chhita  
Harold Cleveland  
Matthew Cocco  
Daniel Coffman  
Cheryl Cordum  
Brian Cox  
William Crawford  
Dennis Davis  
Vincent DiSpigno  
Grag Edquist  
Vicky Davis  
Rodney Detrow  
Kenneth DeTurk  
Oliver Emberger  
Allen Fazekas  
Joseph Fery  
Thomas Firman  
James Flynn  
Lori Follis (DeVos)  
Joseph Gatton  
Rudolph Gilliam

John Keenan  
Michael Klug  
Scott Knishka  
Raymond Komosinski  
Lisa Koss (Leonard)  
Timothy Layne  
Sam Shan-Shan Ling  
Paul Lukas  
David Lutes  
Thomas Mabis  
John Manzi  
Brad Martin  
John Martin  
Deborah McDowell  
(Cassbaugh)  
Thomas McKean  
Barry Means  
John W. Miller  
Barbara Miesel  
Richard Nicks  
Michael Palmer  
Amit Pankh

Aly Sharaf  
William Short III  
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  
Randal Watt  
Larry Weidner  
Henry Weilgosz  
Jeff Williams  
Jason Willman  
Brian Wong  
Richard Wride

12. The Radiation Safety Officer for this license is Brad Martin, 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.

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- 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
  - (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 microcuries 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 Alleghene 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.

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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.
  - 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. This license does not authorize distribution to persons exempt from licensing.
23. Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from the U.S. Nuclear Regulatory Commission before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective Registration Certificates issued either by the Commission pursuant to 10 CFR 32.210 or by an Agreement State.

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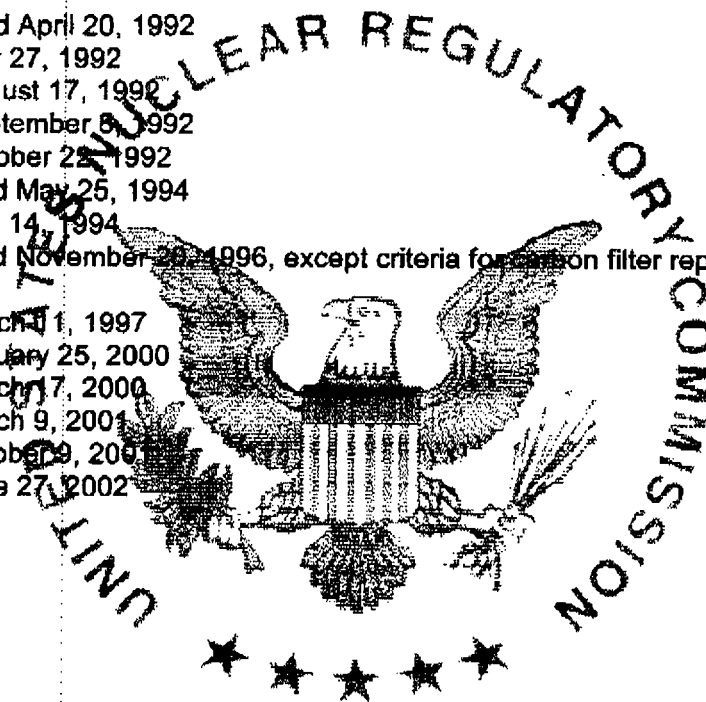
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24. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear 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 20, 1992
- B. Letter dated July 27, 1992
- C. Letter dated August 17, 1992
- D. Letter dated September 8, 1992
- E. Letter dated October 22, 1992
- F. Application dated May 25, 1994
- G. Letter dated July 14, 1994
- H. Application dated November 20, 1996, except criteria for carbon filter replacement, in item 10.10, B on page 4.
- I. Letter dated March 1, 1997
- J. Letter dated January 25, 2000
- K. Letter dated March 17, 2000
- L. Letter dated March 9, 2001
- M. Letter dated October 9, 2001
- N. Letter dated June 27, 2002



For the U.S. Nuclear Regulatory Commission

Date August 29, 2002

By

James P. Dwyer  
Nuclear Materials Safety Branch 1  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406

9039324