



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 13, 2005

Docket No. 03014680
Control No. 134555

License No. 29-00117-06

Thomas Salzmann, Ph.D.
Executive Vice President
Merck & Company, Inc.
RY8OHP
P. O. Box 2000
Rahway, NJ 07065

SUBJECT: MERCK & COMPANY, INC., APPLICATION FOR LICENSING ACTION,
CONTROL NO. 134555

Dear Dr. Salzmann:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

In accordance with the provisions of 10 CFR 30.11, "the Commission may, upon application by an interested person or upon its own initiative, grant such exemptions from the requirements of the regulations as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest." To the extent that the material authorized for disposal in this 10 CFR 20.2002 authorization is otherwise licensable, the staff concludes that the material is exempt from the Atomic Energy Act and NRC licensing requirements. The staff also evaluated the environmental impacts of the exemption and determined that granting the exemption would not result in any significant impacts. For this action, an Environmental Assessment and Finding of No Significant Impact were prepared and published in the Federal Register (June 13, 2005, Volume 70, Number 112, pages 34166-34167 [70 FR 34166]). Accordingly, pursuant to 10 CFR 30.11, the exemption is granted and effective immediately.

Current NRC regulations and guidance are available at the NRC web site at <http://www.nrc.gov/materials/miau/mat-toolkits.html> and <http://www.nrc.gov/who-we-are/governing-laws.html> or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

T. Salzmann
Merck & Company, Inc.

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Thank you for your cooperation.

Sincerely,

Original signed by Elizabeth Ullrich

Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 41

cc:
Vincent Williams, Radiation Safety Officer

DOCUMENT NAME: E:\Filenet\ML051690112.wpd

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NAME	EUllrich <i>/BU/</i>		JDwyer <i>/JPD/</i>					
DATE	6/13/05		6/13/05					

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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 style="text-align: center;">Licensee</p> <p>1. Merck & Co., Inc.</p> <p>2. RY80HP P.O. Box 2000 Rahway, New Jersey 07065</p>	<p>In accordance with the letter dated February 23, 2004,</p> <p>3. License number 29-00117-06 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date May 31, 2011</p> <hr/> <p>5. Docket No. 030-14680 Reference No.</p>
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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	A. Any	A. 100 millicuries per radionuclide and 2 curie total
B. Hydrogen 3	B. Any	B. 2,000 curies
C. Carbon 14	C. Any	C. 100 curies
D. Phosphorus 32	D. Any	D. 500 millicuries
E. Phosphorus 33	E. Any	E. 500 millicuries
F. Sulfur 35	F. Any	F. 10 curies
G. Calcium 45	G. Any	G. 100 millicuries
H. Chromium 51	H. Any	H. 100 millicuries
I. Nickel 63	I. Any	I. 250 millicuries
J. Rubidium 86	J. Any	J. 100 millicuries
K. Technetium 99	K. Any	K. 100 millicuries
L. Iodine 125	L. Any	L. 2 curies
M. Iodine 131	M. Any	M. 200 millicuries
N. Xenon 133	N. Any	N. 500 millicuries
O. Cesium 137	O. Any	O. 1 curie

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|---|---|--|
| 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 |
| P. Molybdenum 99/
Technetium 99m | P. Generators | P. 2 curies |
| Q. Americium 241 | Q. Any | Q. 1 millicurie |
| R. Hydrogen 3 | R. Foil or plated sources registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State. | R. No single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State |
| S. Nickel 63 | S. Foil or plated sources registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State. | S. No single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State |
| T. Cesium 137 | T. Sealed Sources (AECL Model C-161) | T. Not to exceed 2,100 curies per source and 4,200 curies total |
| U. Cesium 137 | U. Sealed Sources (Isomedix Model ISO-1000) | U. Not to exceed 720 curies per source and 3,264 curies total |
| V. Cesium 137 | V. Sealed Sources (MDS Nordion Model C440) | V. Not to exceed 2,100 curies per source and 4,200 curies total |

9. Authorized use:

- A. through Q. Research and development as defined in 10 CFR 30.4; animal studies; and calibration of the licensee's instruments.
- R. and S. To be used for sample analysis in compatible gas chromatography devices that have been registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess, and use the devices.

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T. through V. For irradiation of materials in self-shielded irradiator devices that have been registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and which have been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess, and use the devices.

CONDITIONS

10. Licensed material may be used at the licensee's facilities at 126 East Lincoln Avenue, Rahway, New Jersey; and Branchburg Farm, 203 River Road, Somerville, New Jersey.
11. A. Licensed material in Items 6.A. through 6.S. shall only be used by, or under the supervision of, individuals designated, in writing, by the Radiation Safety Committee.
B. Licensed material shall be used by, or under the supervision of, individuals who have received the training described in the application dated March 28, 1995 and letter dated August 23, 1995 and have been designated, in writing, by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.
C. The Radiation Safety Officer for this license is Vincent Williams.
12. The licensee shall not use licensed material in or on human beings.
13. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
14. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
15. This license does not authorize commercial distribution of licensed material.
16. This license does not authorize distribution to persons licensed pursuant to 10 CFR 32.72 or 32.74; to persons exempt from licensing; or to general licensees.
17. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

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- C. 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.
- D. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- E. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
- F. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred 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 shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- G. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
- H. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
18. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
19. The licensee shall conduct a physical inventory every six months, or at other interval approved by the U.S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license.
20. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
21. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.

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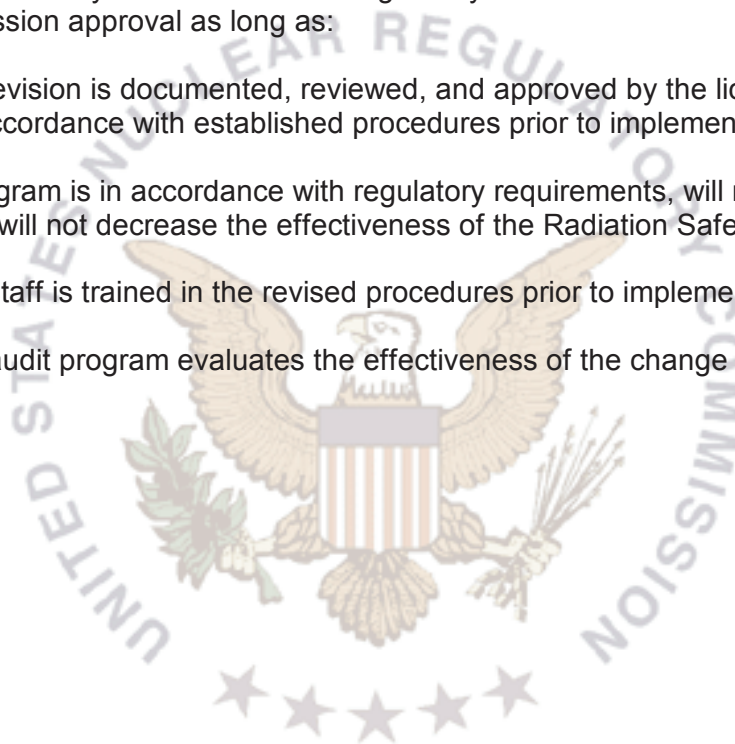
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- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
22. The licensee shall not repair, remove, replace, or alter any of the following: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, or any component that may affect safe operation of the irradiator. These activities shall be performed by a person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
23. The procedures contained in the manufacturer's instruction manual for the irradiator authorized by this license, shall be followed, and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.
24. Pursuant to 10 CFR 20.1302(c) and 10 CFR 20.2002, the licensee is authorized to dispose of licensed material by incineration, provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR Part 20.
25. Pursuant to 10 CFR 20.2002, the licensee may dispose of incinerator ash containing radioactive materials with atomic numbers 1 through 83, except as identified below, as ordinary waste in a landfill provided that the concentration of radionuclides (in microcuries per gram of ash) at the time of disposal are no greater than the values of Table II, Column 2, 10 CFR Part 20, Appendix B. For hydrogen-3, carbon-14, aluminum-26, chlorine-36, silver-108m, niobium-94, iodine-129, technetium-99, and thallium-204, the concentration can be no greater than one-tenth of the value in Table II, Column 2, 10 CFR Part 20, Appendix B. If more than one radionuclide is present in the ash, then the sum of fractions rule applies.
26. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
- A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding.
 - B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.
 - C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
27. Pursuant to 10 CFR 20.2002, the licensee may dispose of solid materials (80 cubic yards of soils) containing 756 microcuries of hydrogen-3 (H-3 or tritium) as ordinary waste in a landfill. Pursuant to 10 CFR 30.11, this material is exempt from the requirements of licensing.

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28. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
29. Notwithstanding the requirements of License Condition 28, the licensee is authorized to make program changes and changes to procedures specifically identified in the letter dated September 25, 2000, which were previously approved by the U.S. Nuclear Regulatory Commission and incorporated into the license without prior Commission approval as long as:
- A. The proposed revision is documented, reviewed, and approved by the licensee's Radiation Safety Committee in accordance with established procedures prior to implementation.
 - B. The revised program is in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program.
 - C. The licensee's staff is trained in the revised procedures prior to implementation.
 - D. The licensee's audit program evaluates the effectiveness of the change and its implementation.



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30. 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 U.S. 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 March 28, 1995
- B. Letter dated August 23, 1995
- C. Application dated June 27, 2000 [ML003731575]
- D. Letter dated September 25, 2000 [ML003754064]
- E. Letter dated January 12, 2001 [ML010220469]
- F. Letter dated May 23, 2001 [ML011450049]
- G. Letter dated September 20, 2002 [ML022800631]
- H. Letter dated February 23, 2004 [ML040711197]
- H. Letter dated November 3, 2004 [ML043220324]



For the U.S. Nuclear Regulatory Commission

Original signed by Elizabeth Ullrich

Date June 13, 2005
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By _____
Elizabeth Ullrich
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406