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

May 25, 2001

Docket No. 03014680 License No. 29-00117-06
Control No. 128332

Edwin Wurtz, Ph.D.
Director, Health Physics, Biosafety
& Environmental Services
Merck & Co., Inc.
RY80M-190
P.O. Box 2000
Rahway, NJ 07065

SUBJECT: MERCK & CO., INC., ISSUANCE OF LICENSE RENEWAL, CONTROL NO. 128332

Dear Dr. Wurtz:

This refers to your request for renewal of your NRC license. Enclosed with this letter is the renewed license. Please review the enclosed document carefully and be sure that you understand all conditions. 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.

Your request concerning release of individual laboratories for unrestricted use was approved. You agreed to use site specific release criteria based on MARSSIM and the use of D&D screening code, version 1 to obtain DCGLs corresponding to surface concentrations of radionuclide contamination that would result in a TEDE of 1 millirem per year, to the average member of the critical group. The approval was granted under the following provisions. Notwithstanding the DCGLs that you calculate, you must decontaminate to release levels are ALARA and maintain records of the actions and methods you used to achieve ALARA goals. In addition, to demonstrate compliance at the time of license termination or request for removal of an entire site from your license, you must: (1) submit records of release surveys of building surfaces maintained in compliance with 10 CFR 30.35(g) including surveys of pipes, ductwork, underground tanks, mobile equipment, etc.; and (2) submit data supporting that building surfaces and pipes, ductwork, underground tanks, mobile equipment, etc. were not recontaminated (or submit additional release surveys). Since the description of your authorized locations of use in condition 10 of your license encompass sites which include multiple buildings, you are permitted to use licensed material in individual laboratories or buildings after you have released them. If licensed material is used again in the released areas of a laboratory or building in the future, further decommissioning actions will be necessary as discussed above.

The NRC is required to have your Taxpayer Identification Number in order to make payments (refunds). The self-addressed, stamped NRC Form 531, "Request for Taxpayer Identification Number," is enclosed.

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The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify the NRC in writing of any change in mailing address.

3. In accordance with 10 CFR 30.36(d), notify the NRC, promptly, in writing, and request termination of the license

   a) when you decide to terminate all activities involving materials authorized under the license; or

   b) if you decide not to acquire or possess and use authorized material.

4. Request and obtain a license Amendment before you:

   a) change Radiation Safety Officers;

   b) order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license; or

   c) add or change the areas of use, or addresses of use identified in the license application or on the license; or

   d) change the name or ownership of your organization.

5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or a certifying official of the licensee rather than a consultant.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in NUREG 1600, "General Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy).

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at http://www.nrc.gov/NRC/ADAMS/index.html.

Thank you for your cooperation.

Sincerely,

Original signed by Pamela J. Henderson

Pamela J. Henderson
Senior Health Physicist
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

Enclosures:
1. Amendment No. 38
2. 10 CFR Parts 19, 20, 21, 30, 33, 71, 170, and171
3. NRC Forms 3, 313, and 531
4. Section 206 of the Energy Reorganization Act of 1974
5. NUREG 1600, General Policy and Procedure for NRC Enforcement Actions (Enforcement Policy)

cc:
Glenn M. Sturchio, M.S., C.H.P., Radiation Safety Officer

DOCUMENT NAME: C:\I29-00117-06.128332.05252001.wpd

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Amendment No. 38

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.

Licensee	In accordance with the application dated June 27, 2000,
1. Merck & Co., Inc.	3. License number 29-00117-06 is amended in its entirety to read as follows:
2. RY80M-190 P.O. Box 2000 Rahway, New Jersey 07065	4. Expiration date May 31, 2011 5. Docket No. 030-14680 Reference No.

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

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.

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.

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11. A. Licensed material shall only be used by, or under the supervision of, individuals designated, in writing, by the Radiation Safety Committee.

    B. The Radiation Safety Officer for this license is Glenn Sturchio, M.S., CHP.

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 37.72 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.

    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.

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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.

B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

22. 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.

23. 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.

24. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:

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A. Waste to be disposed of in this manner shall be held for decay a minimum of 10 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 3 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.

D. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

25. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

26. Notwithstanding the requirements of License Condition 27, 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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27. 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 June 27, 2000
B. Letter dated September 25, 2000
C. Letter dated January 12, 2001
D. Letter dated May 23, 2001

For the U.S. Nuclear Regulatory Commission

Date May 25, 2001

By *Original signed by Pamela J. Henderson*

Pamela J. Henderson
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406