



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

March 21, 2007

Docket No. 03037353
Control No. 140230

License No. 41-31193-01

Roger Moroney, C.H.P.
Manager, Radiological Compliance & Corporate RSO
Siemens Molecular Imaging, Inc.
810 Innovation Drive
Knoxville, TN 37932

SUBJECT: SIEMENS MOLECULAR IMAGING, INC., LICENSE AMENDMENT, CONTROL
NO. 140230

Dear Dr. Moroney:

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.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by Dennis R. Lawyer

Dennis R. Lawyer
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 1

cc:

R. Moroney
Siemens Molecular Imaging, Inc.

2

Thomas Lee Collier, Ph.D., Radiation Safety Officer

R. Moroney
Siemens Molecular Imaging, Inc.

3

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SUNSI Review Complete: DLawyer

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NAME	DLawyer /DRL1/							
DATE	3/21/2007							

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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.

Licensee 1. Siemens Molecular Imaging, Inc. 2. 810 Innovation Drive Knoxville, Tennessee 37932		In accordance with the letter dated March 7, 2007, 3. License number 41-31193-01 is amended in its entirety to read as follows: 4. Expiration date November 30, 2016 5. Docket No. 030 - 37353 Reference No.	
6. Byproduct, source, and/or special nuclear material A. Cobalt 60 B. Iodine 129 C. Cesium 137	7. Chemical and/or physical form A. Sealed Sources (IPL Models GF-XXX Type M Series and GF-XXX Type R Series) B. Sealed Sources (IPL Model GF-XXX Type R Series) C. Sealed Sources (IPL Models GF-XXX Type M Series, GF-XXX Type R Series and RV-XXX)	8. Maximum amount that licensee may possess at any one time under this license A. Not to exceed 100 microcuries per source and 10 millicuries total B. 1 microcurie per source and 100 microcuries total C. 200 microcuries per source and 10 millicuries total	
9. Authorized use: A. through C. Calibration and checking of the licensee's instruments.			

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 406 Industrial Drive, North Wales, Pennsylvania.
11. Licensed material shall be used by, or under the supervision of, Thomas Lee Collier, Ph.D., Tigran Sinanian, R.Ph., Henry Padgett, Ph.D., and Zhihong Zhu, Ph.D.
12. The Radiation Safety Officer for this license is Thomas Lee Collier, Ph.D.

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13. The licensee shall not use licensed material in or on human beings.
14. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at 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. 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.
- D. 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.
- E. 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.
- F. 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.
- G. 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.
- H. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

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16. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
17. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
18. 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 September 22, 2006 [ML062850491]



For the U.S. Nuclear Regulatory Commission

Date March 21, 2007

By

Original signed by Dennis R. Lawyer

Dennis R. Lawyer
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406