



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

March 17, 2005

Docket Nos. 03036878
03035837
Control Nos. 136513
136351

License Nos. 32-31021-01
29-32349-01

Jim Dittmann
Manager, Quality Compliance & Standards
Siemens Medical Solutions USA, Inc.
110 MacAlyson Court
Cary, NC 27511

SUBJECT: SIEMENS MEDICAL SOLUTIONS USA, INC., ISSUANCE OF NEW LICENSE,
CONTROL NOS. 136513 AND 136351

Dear Mr. Dittmann:

This refers to your license amendment request to change the Radiation Safety Officer to Mr. Haddock and change the mailing address. Please note that NRC License Numbers are coded specifically to the State. Since you changed your mailing address from New Jersey to North Carolina, we had to terminate NRC License No. 29-32349-01 and issue you NRC License No. 32-31021-01. Please note that your expiration date has not changed. Your license is due to expire on August 31, 2005. Please follow the guidance in NUREG-1556, Volume 18 when preparing your application. Please find enclosed with this letter the terminated and new licenses.

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 available at the NRC Web sites listed below 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).

J. Dittmann
Siemens Medical Solutions USA, Inc.

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Thank you for your cooperation.

Sincerely,

Original signed by Kathy Dolce Modes

Kathy Dolce Modes
Health Physicist
Security and Industrial Branch
Division of Nuclear Materials Safety

Enclosures:

1. License No. 31-31021-01
2. Amendment No. 1, License No. 29-32349-01

The following documents may be found on our NRC Web site:

NRC regulations

<http://www.nrc.gov/reading-rm/doc-collections/cfr/>

Licensing guidance

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>

General Policy and Procedure for NRC Enforcement Actions

<http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf>

206 of the Energy Reorganization Act of 1974

<http://www.nrc.gov/who-we-are/governing-laws.html>

cc w/encl:

Stephen J. Haddock, Radiation Safety Officer

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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 Medical Solutions USA, Inc.	3. License number 32-31021-01
2. 110 MacAlyson Court Cary, North Carolina, 27511	4. Expiration date August 31, 2005
	5. Docket No. 03036878 Reference No. 030-35837/29-32349-01 & 030-18535/12-00369-02

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. Barium 133	A. Sealed sources registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.	A. 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
B. Americium 241	B. Sealed sources registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.	B. 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
C. Americium 241	C. Sealed sources registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.	C. 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

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

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9. Authorized use:

- A. and B. To be used incident to the testing, calibration, repair, and demonstration of nuclear medicine analytical and imaging systems.
- C. For installation in Siemens Medical Systems Model M μ SIC line source holder/attenuation correction device and for installation verification and testing.

CONDITIONS

10. Licensed material may be used or stored at the Siemen's Medical Systems, Inc. field offices in accordance with procedures contained in application dated October 30, 1989 and letter dated December 9, 1994. Americium-241 sealed sources may also be stored in accordance with the letters dated September 15, 1995 and November 2, 1995. Licensed materials may also be used at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States.

If the jurisdiction status of a Federal facility within an Agreement State is unknown, the licensee should contact the Federal agency controlling the job site in question to determine whether the proposed job site is an area of exclusive Federal jurisdiction. Authorization for use of radioactive materials at job sites in Agreement States not under exclusive Federal jurisdiction shall be obtained from the appropriate state regulatory agency.

11. A. Licensed material shall be used by, or under the supervision and in the physical presence of, individuals who have successfully completed the licensee's training program as described in application dated October 30, 1989 and letter dated December 29, 1989 and have been designated by the licensee's Radiation Safety Officer. The licensee shall maintain records of these individuals who have been designated as authorized users.
- B. The Radiation Safety Officer for this license is Stephen J. Haddock.
12. 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) for establishing decommissioning financial assurance.

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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. 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.
- C. 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.
- D. 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.
- E. 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.
- F. 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.
- G. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.

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15. Sealed sources containing licensed material shall not be opened.
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 October 30, 1989
 - B. Letter dated December 29, 1989
 - C. Letter dated December 9, 1994
 - D. Letter dated September 15, 1995
 - E. Letter dated November 2, 1995
 - F. Letter dated July 31, 2001 (ML012780444)
 - G. Letter dated October 4, 2001

For the U.S. Nuclear Regulatory Commission

Date March 17, 2005

By ***Original signed by Kathy Dolce Modes***

Kathy Dolce Modes
Security and Industrial Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406