



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

February 9, 2005

Docket No. 03033876
Control No. 136350

License No. 37-30228-01

Ronald Martone
Radiation Safety Officer
Philips Medical Systems (Cleveland) Inc.
3611 Market Street
Philadelphia, PA 19104

SUBJECT: PHILIPS MEDICAL SYSTEMS (CLEVELAND) INC., ISSUANCE OF LICENSE
AMENDMENT, CONTROL NO. 136350

Dear Mr. Martone:

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).

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

Thank you for your cooperation.

Sincerely,

Original signed by Todd J. Jackson, CHP

Todd J. Jackson, CHP
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

R. Martone
Philips Medical Systems (Cleveland) Inc.

2

Enclosure:
Amendment No. 7

R. Martone
Philips Medical Systems (Cleveland) Inc.

3

DOCUMENT NAME: E:\Filenet\ML050400484.wpd

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OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	TJackson/TJJ							
DATE	2/9/2005							

OFFICIAL RECORD COPY

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. Philips Medical Systems (Cleveland) Inc.</p> <p>2. 3611 Market Street Philadelphia, Pennsylvania 19104</p>	<p>In accordance with the letter dated January 14, 2005,</p> <p>3. License number 37-30228-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date January 31, 2011</p> <hr/> <p>5. Docket No. 030-33876 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Cesium 137</p>	<p>7. Chemical and/or physical form</p> <p>A. Sealed sources (Isotope Products Laboratories Models HEG-137 Series; GF-137 Type R Series; and RV-137 Series)</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. Not to exceed 20 millicuries per source and 100 millicuries total</p>
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9. Authorized use:

A. For calibration of Positron Emission Tomography scanners.

CONDITIONS

- 10. Licensed material may be used or stored at the licensee's facilities located at 3611 Market Street, Philadelphia, Pennsylvania.
- 11. Licensed material shall only be used by, or under the supervision of, Gerd Muehllehner; Behrouz Khanvali; or Ronald J. Martone.
- 12. The Radiation Safety Officer for this license is Ronald J. Martone.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
37-30228-01Docket or Reference Number
030-33876

Amendment No. 7

13. 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 by 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 by an Agreement State prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- C. 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.
- D. 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.
- E. Tests for leakage and/or contamination shall be performed by the licensee or other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. In addition, the licensee is authorized to collect leak test samples for analysis by persons specifically licensed by the Commission or an Agreement State to perform such services.
- F. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
14. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.
15. 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.
16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
37-30228-01

Docket or Reference Number
030-33876

Amendment No. 7

17. 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 May 2, 1995
- B. Letter dated October 15, 1995
- C. Letter dated November 7, 1995
- D. Letter dated October 17, 2000
- E. Letter dated January 12, 2001
- F. Letter dated December 4, 2003
- G. Letter dated January 14, 2005



For the U.S. Nuclear Regulatory Commission

Date February 9, 2005
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By ***Original signed by Todd J. Jackson, CHP***

Todd J. Jackson, CHP
 Commercial and R&D Branch
 Division of Nuclear Materials Safety
 Region I
 King of Prussia, Pennsylvania 19406