



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

June 30, 2006

Docket No. 03037299  
Control No. 139038

License No. 34-31170-01

Peter Cempellin  
General Manager  
Philips Medical Systems (Cleveland) Inc.  
Nuclear Medicine, PET/CT  
595 Miner Road  
Cleveland, OH 44143

SUBJECT: PHILIPS MEDICAL SYSTEMS (CLEVELAND) INC., NEW LICENSE, CONTROL  
NO. 139038

Dear Mr. Cempellin:

This refers to your request for an NRC license. Enclosed with this letter is the 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.

When submitting future license amendments, please have the document signed by a management representative rather than the Radiation Safety Officer. The NRC views a letter signed by a management representative as indication that management has reviewed the application and concurs in the statements and representations contained therein. 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.

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.

The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of safety and 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.

You will be periodically inspected by the NRC. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and the 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, imposition of a civil penalty, or an order suspending, modifying or revoking your license.

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](http://www.nrc.gov); select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Toolkit Index Page**. Or you may 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).

P. Cempellin  
Philips Medical Systems (Cleveland) Inc.

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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:

1. NRC Form 531
2. License No. 34-31170-01

cc:

Gregory M. Breznai, Radiation Safety Officer  
Ronald J. Martone, Previous RSO

P. Cempellin  
Philips Medical Systems (Cleveland) Inc.

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**SUNSI Review Complete: DLawyer**

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NAME	DLawyer/DRL						
DATE	06/30/2006						

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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. Philips Medical Systems (Cleveland) Inc.	3. License number 34-31170-01
2. 595 Miner Road Cleveland, Ohio 44143	4. Expiration date January 31, 2011
	5. Docket No. 030-37299 Reference No. 37-30228-01, 030-33876

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. Cesium 137	A. Sealed Sources (Isotope Products Laboratories Models HEG-137 Series; GF-137 Type R Series; and RV-137 Series)	A. 20 millicuries per source and 100 millicuries total

9. Authorized use:

A. For calibration of Positron Emission Tomography Scanners.

**CONDITIONS**

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

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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.
13. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
14. 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.
15. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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16. 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 [ML003762252]
  - E. Letter dated January 12, 2001 [ML010180590]
  - F. Letter dated December 4, 2003 [ML033450543]
  - G. Letter dated January 14, 2005 [ML050390033]



For the U.S. Nuclear Regulatory Commission

Date June 30, 2006

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