



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

May 30, 2008

Docket No. 03034196
Control No. 142318

License No. 07-30325-01

William Bedzyk, Ph.D.
Head of Glasgow Predevelopment
Siemens Healthcare Diagnostics Inc.
P.O. Box 6101
Newark, DE 19714-6101

SUBJECT: SIEMENS HEALTHCARE DIAGNOSTICS INC., LICENSE AMENDMENT,
CONTROL NO. 142318

Dear Dr. Bedzyk:

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 1-866-512-1800. 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. 8

W. Bedzyk
Siemens Healthcare Diagnostics Inc.

2

cc:
Roger Jamieson, Radiation Safety Officer

DOCUMENT NAME: C:\FileNet\ML081540412.wpd

SUNSI Review Complete: DLawyer

After declaring this document "An Official Agency Record" it will be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	<input checked="" type="checkbox"/> N	DNMS/RI	<input type="checkbox"/>	DNMS/RI	<input type="checkbox"/>	<input type="checkbox"/>
NAME	DLawyer /DC9/						
DATE	5/30/2008						

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. Siemens Healthcare Diagnostics Inc.</p> <p>2. P.O. Box 6101 Newark, Delaware 19714-6101</p>	<p>In accordance with the letter dated April 9, 2008,</p> <p>3. License number 07-30325-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date October 31, 2011</p> <hr/> <p>5. Docket No. 030-34196 Reference No.</p>
---	---

<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with atomic numbers 3 through 83</p> <p>B. Hydrogen 3</p> <p>C. Carbon 14</p> <p>D. Phosphorus 32</p> <p>E. Sulfur 35</p> <p>F. Chromium 51</p> <p>G. Iodine 125</p> <p>H. Nickel 63</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> <p>F. Any</p> <p>G. Any</p> <p>H. Plated sources and foils</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 10 millicuries per radionuclide and 100 millicuries total</p> <p>B. 5 curies</p> <p>C. 5 curies</p> <p>D. 100 millicuries</p> <p>E. 100 millicuries</p> <p>F. 200 millicuries</p> <p>G. 300 millicuries</p> <p>H. 15 millicuries per foil and 180 millicuries total</p>
--	--	---

9. Authorized use:

- A. through G. Research and development as defined in 10 CFR 30.4
- H. For use in gas chromatographs.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
07-30325-01Docket or Reference Number
030-34196

Amendment No. 08

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at Route 896, Glasgow, Delaware.
11. A. Licensed material shall only be used by, or under the supervision of, individuals designated, in writing, by the Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.
- B. The Radiation Safety Officer for this license is Roger Jamieson.
12. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. 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.
- E. Sealed sources and detector cells need not be leak tested if:
- (i) they contain only hydrogen-3; or
 - (ii) they contain only a radioactive gas; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
 - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer 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 or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
07-30325-01Docket or Reference Number
030-34196

Amendment No. 08

- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the appropriate U. S. Nuclear Regulatory Commission, Regional Office referenced in Appendix D of 10 CFR Part 20. The report shall specify the source or detector cell involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
13. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.
14. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.
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."
16. 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:
- A. Waste to be disposed of in this manner shall be held for decay a minimum of ten 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 three 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.
17. The licensee shall not use licensed material in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
07-30325-01

Docket or Reference Number
030-34196

Amendment No. 08

18. In addition to the possession limits in Item 8, the licensee shall further restrict possession of unsealed byproduct material of half-life greater than 120 days in the following manner. If only one such isotope is possessed, the quantity possessed will be maintained at a quantity less than or equal to 100,000 times the applicable quantity in Appendix C to 10 CFR 20. For a combination of such isotopes, R, defined as the sum of the ratios of the quantity of each isotope possessed to the applicable quantity in Appendix C to 10 CFR 20, divided by 100,000 will be less than or equal to one.
19. 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 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, 2001 [ML012070091]
 B. Letter dated October 1, 2001 [ML012900023]
 C. Letter dated April 9, 2008 [ML081160495]



For the U.S. Nuclear Regulatory Commission

Date May 30, 2008

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