

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1415

May 5, 2005

Docket No. 03033421 Control No. 136648 License No. 29-30119-01

Geoffrey M. Nichol, M.D. Senior VP Product Development Medarex, Incorporated 519 Route 173 West Bloomsbury, NJ 08804

SUBJECT: MEDAREX, INCORPORATED, ISSUANCE OF LICENSE AMENDMENT,

CONTROL NO. 136648

Dear Dr. Nichol:

This refers to your license amendment requests dated March 8, 2005, and April 27, 2005. Enclosed with this letter is the amended license with Dr. Tibor Keler listed as Radiation Safety Officer.

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).

Thank you for your cooperation.

Sincerely,

Original signed by David B. Everhart

David B. Everhart
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure: Amendment No. 10 G. Nichol Medarex, Incorporated

NRC Web site addresses

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

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206 of the Energy Reorganization Act of 1974

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

cc:

Tibor Keler, Ph.D., Radiation Safety Officer

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Amendment No. 10

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		In accordance with the letters dated				
		March 8, 2005 and April 27, 2005;				
1. Medarex, Incorporated		3. License number 29-30119-01 is amended in				
	SCLEAR A	its entirety to read as follows:				
2. 519 Route 173 West	10-	4. Expiration date March 31, 2014				
Bloomsbury, New Jersey 08804		5. Docket No. 030-33421				
6		Reference No.				
41		1				
Byproduct, source, and/or special nuclear material	7. Chemical and/or p	physical form 8. Maximum amount that licensee may possess at any one time under this license				
A. Hydrogen 3	A. Pre-labeled	A. 5 millicuries				
B. Chromium 51	B. Any	B. 10 millicuries				
C. Iodine 125	C. Pre-labeled	C. 2 millicuries				
	THE STATE OF THE S	S. S.				
9. Authorized use:	0 "	M. 44 70.				
C. Possession and stor	age only of waste ma	aterial.				

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 519 Route 173 West, Bloomsbury, New Jersey.
- 11. Licensed material in items 6.A. through 6.C. shall be used by, or under the supervision of Tibor Keler, Ph.D., Robert Graziano, Ph.D., and Joel Goldstein, Ph.D. Licensed material in Item 6.A. and 6.B. may also be used by, or under the supervision of Laura A. Vitale. Licensed material in Item 6.B. may also be used by, or under the supervision of Joseph Chiarappa.
- 12. The Radiation Safety Officer for this license is Dr. Tibor Keler.
- 13. The licensee shall not use licensed material in or on human beings.
- 14. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.

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License Number			
29-30119-01			
Docket or Reference Number 030-33421	er		
Amendment No. 10			•

- 15. 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 10 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 3 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.
- 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."
- 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. Letter dated February 6, 2004, with attached application dated February 7, 2004
 - B. E-mail dated March 18, 2004

For the U.S. Nuclear Regulatory Commission

			Original signed by David B. Everhart
Date	May 5, 2005	By	
		•	Dovid B. Everbort

David B. Everhart
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406