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

July 21, 2005

Docket No. 03003013 License No. 37-01893-01
Control No. 137382

Mary N. Mannix
President
Robert Packer Hospital
One Guthrie Square
Sayre, PA 18840

SUBJECT: GUTHRIE HEALTHCARE SYSTEM AND GUTHRIE CLINIC, LICENSE AMENDMENT, CONTROL NO. 137382

Dear Ms. Mannix:

This refers to your license amendment request. Enclosed with this letter is the amended license restoring William F. Kendall, Ph.D. as Authorized Medical Physicist. Because you stated that Timothy Kensora will not participate in high dose rate remote afterloading procedures, it is not necessary to add his name to your 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 available at the NRC web site at http://www.nrc.gov/materials/miau/mat-toolkits.html and http://www.nrc.gov/who-we-are/governing-laws.html 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 Sandra Gabriel

Sandra Gabriel
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 69

C-3

cc:
Asaf Durakovic, M.D., Radiation Safety Officer

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NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

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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	
	In accordance with the letter dated July 21, 2005,
1. Guthrie Healthcare System and Guthrie Clinic	3. License number 37-01893-01 is amended in its entirety to read as follows:
2. Guthrie Square Sayre, Pennsylvania 18840	4. Expiration date September 30, 2011
	5. Docket No. 030-03013 Reference No.

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. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As needed
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 1000 millicuries
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed Sources	D. 2500 millicuries
E. Any byproduct material permitted by 10 CFR 31.11	E. Prepackaged Kits	E. 0.5 millicuries
F. Iridium 192 permitted by 10 CFR 35.600	F. Sealed Sources (Nucletron Model No. 105.002 [manufactured by Mallinckrodt Medical B.V. or AEA Technology])	F. [redacted]
G. Americium 241	G. Sealed source (Amersham Model No. AMC-24)	G. 14 millicuries
H. Depleted Uranium	H. Metal	H. 160 kilograms

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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
I. Strontium 90	I. Sealed Source (Nuclear Enterprises Model 2503)	I. 10 millicuries
J. Hydrogen 3	J. Any	J. 90 millicuries
K. Carbon 14	K. Any	K. 40 millicuries
L. Phosphorus 32	L. Any	L. 200 millicuries
M. Phosphorus 33	M. Any	M. 200 millicuries
N. Sulfur 35	N. Any	N. 200 millicuries
O. Calcium 45	O. Any	O. 5 millicuries
P. Chromium 51	P. Any	P. 200 millicuries
Q. Iodine 125	Q. Any	Q. 150 millicuries
R. Yttrium 90	R. Any	R. 20 millicuries

9. Authorized use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
B. Any imaging and localization study permitted by 10 CFR 35.200.
C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300.
D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
E. In vitro studies.
F. One source for medical use permitted by 10 CFR 35.600 in a Nucletron Corporation MicroSelectron Model 105.999 remote afterloader unit. The source may not exceed 10 curies at the time of installation. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.
G. For storage only.
H. Shielding in a linear accelerator.
I. Non-human use. For calibrations and checking of licensee's survey instruments.
J. through R. Research and development as defined in 10 CFR 30.4.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Robert Packer Hospital, Guthrie Clinic, and Guthrie Foundation for Medical Research, 1 Guthrie Square, Sayre, Pennsylvania.

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11. The Radiation Safety Officer for this license is Asaf Durakovic, M.D.

12. Licensed material is only authorized for use by, or under the supervision of:

A. Individuals permitted to work as an authorized user, authorized nuclear pharmacist, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

B. The following individuals are authorized users for medical use as indicated:

Authorized Users	Material and Use
John M. Antos, M.D.	35.100; 35.200; 35.300; In vitro studies
Richard Foster, M.D.	35.100; 35.200; In vitro studies
Ralph D. Zehr, M.D.	35.100; 35.200; 35.300; 35.400; In vitro studies
Christopher Joy, M.D.	35.100; 35.200; Oral administration of sodium iodide Iodine 131 for imaging and localization studies and treatment of hyperthyroidism and cardiac dysfunction
Thomas Gergel, M.D.	Iridium 192 for use in a high dose rate remote afterloading device; depleted uranium
Gary Proulx, M.D.	35.400; Iridium 192 for use in a high dose rate remote afterloading device; depleted uranium
Asaf Durakovic, M.D.	35.100; 35.200; 35.300; In vitro studies
Duk K. Choi, M.D.	35.100; 35.200
Richard A. Kostick, D.O.	35.100; 35.200; In vitro studies

C. The following individuals are authorized medical physicists as indicated:

Authorized Medical Physicists	Material and Use
Jian (Jason) H. Chen, Ph.D.	Iridium-192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training
William F. Kendall, Ph.D.	Iridium-192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training

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D. The following individuals are authorized users for non-medical uses as indicated:

Authorized Users	Materials
Nan-Shang Chang, Ph.D.	Hydrogen 3, Carbon 14, Phosphorus 32, Phosphorus 33, Sulfur 35, Calcium 45, Chromium 51, Iodine 125
John D. Noti, Ph.D.	Hydrogen 3, Carbon 14, Phosphorus 32, Phosphorus 33, Sulfur 35, Calcium 45, Chromium 51, Iodine 125
Carol L. Williams, Ph.D.	Hydrogen 3, Carbon 14, Phosphorus 32, Phosphorus 33, Sulfur 35, Calcium 45, Chromium 51, Iodine 125
Sydney Welt, M.D.	Chromium 51, Iodine 125, Yttrium 90
Asaf Durakovic, M.D.	Americium 241 (storage), Strontium 90 (calibration)

13. 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), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.

14. The licensee shall not use licensed material in or on human beings except as provided otherwise by specific condition of this license.

15. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

16. The licensee is authorized to hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if it:

    A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

    B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

    C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

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."

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18. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:

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 under equivalent regulations of an Agreement State.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. 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.

D. 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.

E. 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.

F. 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.

G. 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.

H. 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. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.

19. 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.

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20. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. 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 December 18, 1990
B. Letter dated August 17, 1995
C. Letter dated November 30, 1995
D. Letter dated March 16, 2001 except Quality Management Program (QMP)
E. Letter dated August 28, 2001 except QMP
F. Letters dated August 30, 2001
G. Letter dated September 14, 2001
H. Letter dated September 12, 2001
I. Letter dated February 14, 2002
J. Letter dated March 27, 2002
K. Letter dated December 15, 2003
L. Letter dated October 18, 2004

For the U.S. Nuclear Regulatory Commission

Date July 21, 2005

By *Original signed by Sandra Gabriel*

Sandra Gabriel
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406