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

November 6, 2001

Docket No. 030-03013 License No. 37-01893-01
Control No. 130258

Mary N. Mannix
Chief Operating Officer
Guthrie Healthcare System
Guthrie Clinic
Guthrie Square
Sayre, PA 18840

SUBJECT: GUTHRIE HEALTHCARE SYSTEM, ISSUANCE OF LICENSE AMENDMENT NO. 54, CONTROL NO. 130258

Dear Ms. Mannix:

This refers to your license amendment request in the letter dated August 30, 2001 to add a medical physicist and the requested corrections to your license identified in the letter dated September 14, 2001. Enclosed with this letter is the amended which also incorporates the corrections 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.

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at http://www.nrc.gov/NRC/ADAMS/index.html.

Thank you for your cooperation.

Sincerely,

Original signed by Teresa Hall Darden

Teresa Hall Darden
Senior Health Physicist
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 54

cc:
Christopher J. Hawkins, M.S., D.A.B.R., Radiation Safety Officer

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NAME	TDarden/THD							
DATE	11/06/2001							

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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 letters dated August 30, & September 14, 2001
1. Guthrie Healthcare System and Guthrie Clinic	3. License number 37-01893-01 is amended in its entirety to read as follows:
2. 1 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 identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. 1000 millicuries
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. 2500 millicuries
E. Any byproduct material identified in 10 CFR 31.11	E. Prepackaged Kits	E. 0.5 millicuries
F. Iridium 192	F. Sealed sources (Mallinckrodt Model No. 105.002, DRN 07736)	F. 2 sources, 1 source not to exceed 12 curies and 1 source not to exceed 10 curies
G. Americium 241	G. Sealed source (Amersham Model No. AMC-24)	G. 14 millicuries
H. Depleted Uranium	H. Metal	H. 160 kilograms
I. Strontium 90	I. Sealed source (Nuclear Enterprises Model 2503)	I. 10 millicuries
J. Hydrogen 3	J. Any	J. 90 millicuries

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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
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

9. Authorized use:

A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100.
B. Any imaging and localization procedure approved in 10 CFR 35.200.
C. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300.
D. Any brachytherapy procedure approved in 10 CFR 35.400.
E. In vitro studies.
F. One source to be used in a Nucletron Corporation MicroSelectron-HDR(105.999) remote afterloading brachytherapy device for interstitial, intraluminal, and intracavitary radiotherapy in humans. The source activity may not exceed 10 curies at the time of installation. One source in its shipping container for source replacement.
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 Q. Research and development as defined in 10 CFR 30.4.

CONDITIONS

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

11. The Radiation Safety Officer for this license is Christopher J. Hawkins, M.S.

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

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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 the materials and uses indicated:

Authorized Users	Material and Use
John M. Antos, M.D.	35.100; 35.200; 35.300; In vitro studies
Mei-Chang Cheng, M.D.	35.300; 35.400 Iridium 192 in a high dose rate remote afterloading unit; Depleted uranium
Samuel K. Choi, M.D.	35.100; 35.200; In vitro studies
Richard Foster, M.D.	35.100; 35.200; In vitro studies
Philip Gottlieb, M.D.	35.100; 35.200; Iodine 131 for treatment of hyperthyroidism, cardiac dysfunction, and thyroid dysfunction
Ralph D. Zehr, M.D.	35.100; 35.200; 35.300; 35.400; In vitro studies
Robert S. Aronstam, Ph.D.	Hydrogen 3, Carbon 14, Phosphorus 32, Phosphorus 33, Sulfur 35, Calcium 45, Chromium 51, Iodine 125
Donald H. Beezhold, Ph.D.	Hydrogen 3, Carbon 14, Phosphorus 32, Phosphorus 33, Sulfur 35, Calcium 45, Chromium 51, Iodine 125
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

C. Medical Physicists: Christopher J. Hawkins, M.S. and Robert Buchanan, M.S.

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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. A. Access to the treatment room housing each high dose rate remote afterloading brachytherapy unit shall be controlled by a door at each entrance.

    B. Each entrance to the treatment room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off" control is reset at the control panel.

    C. Electrical interlocks on each entrance door to the treatment room shall be tested for proper operation at least once each day of use.

    D. In the event of malfunction of the door interlock, the unit shall be locked in the "off" position and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

15. For each high dose rate remote afterloading brachytherapy unit, prior to initiation of a treatment program, and subsequent to each source exchange, the licensee shall perform the following radiation surveys:

    A. Survey the source housing, with the source in the shielded position. The maximum radiation levels at 100 centimeters from the surface of the main source safe shall not exceed 3 millirem per hour.

    B. Survey all areas adjacent to the treatment room with the source in the “exposed” position. The survey shall clearly establish:

        (i) Radiation levels in restricted areas are not likely to cause personal exposure in excess of the limits specified in 10 CFR 20.1201(a), 20.1207 and 20.1208.

        (ii) Radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.1301(a).

16. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such service:

    A. Installation, and replacement of the sealed sources contained in each high dose rate remote afterloading brachytherapy unit.

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B. Maintenance or repair operations on any high dose rate remote afterloading brachytherapy unit and associated equipment involving work on the source safe, the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

17. In lieu of the source inventory described in 10 CFR 35.406, the licensee shall:

A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each high dose remote brachytherapy procedure.

B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.

C. Make a record of the survey including survey instrument used, dose rate, time, date and name of the individual making the survey.

D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(d).

18. In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(b).

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

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

21. Notwithstanding the requirements of 10 CFR 35.92(a), the licensee may hold any radioactive material authorized by this license with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided the licensee stores the material for decay in accordance with all other requirements of 10 CFR 35.92.

22. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

23. 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. 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

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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 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, 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.

24. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

25. The licensee shall conduct a physical inventory every six months, or at other interval approved by the U.S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license.

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26. 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, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. 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

For the U.S. Nuclear Regulatory Commission

Date November 6, 2001

By ***Original signed by Teresa Hall Darden***

Teresa Hall Darden
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406