Main Line Health
Lankenau Hospital

NMSB1

Main Line Health
Bryn Mawr Hospital
Lankenau Hospital
Paoli Hospital
Riddle Memorial Hospital
Bryn Mawr Rehab Hospital
The Home Care Network
Lankenau Institute for Medical Research
Main Line HealthCare
Main Line Health Centers
Main Line Health Laboratories
Mid County Senior Services
Wayne Center

January 18, 2008

Radiation Oncology Department

Sandra Gabriel
Senior Health Physicist, Medical Branch
Division of Nuclear Materials Safety
US NRC, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

03003098

SUBJECT: License Amendment for Lankenau Hospital and Lankenau Institute for Medical Research, License #37-07905-04

Dear Ms. Gabriel:

Please consider this letter as notification under 10CFR 35.14, that we are permitting a new Authorized Medical Physicists (AMP) for HDR Iridium-192, under 10CFR 35.13(b)(4). Duan Qiang (David) Wang, Ph.D., is currently listed as an AMP on NRC license 13-06009-01 (Community Hospitals of Indiana, Inc.) for HDR Ir-192, and has received the necessary training for the Nucletron Corporation Model 105.999 remote afterloader unit for which we are licensed.

If you require any further information regarding this amendment request, please feel free to contact our Radiation Oncology physicist, Anne Thompson, at 610-645-2581.

Sincerely,

Scott McKinnon
Vice President of Operations
Lankenau Hospital
100 Lancaster Ave
Wynnewood, PA 19096

RECEIVED
REGION 1
2008 JAN 23 AM 10: 58

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NMSS/RGN1 MATERIALS-002

NRC FORM 374 U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 72

MATERIALS LICENSE

Corrected Copy

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 June 28, 2006 and Facsimiles dated August 2, 2006, October 18, 2006, and October 24, 2006**
1. Community Hospitals of Indiana, Inc.	3. License number 13-06009-01 is amended in its entirety to read as follows:
2. 1500 N. Ritter Avenue Indianapolis, IN 46219	4. Expiration date January 31, 2014
	5. Docket No. 030-01625 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. 900 millicuries
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed sources (reference model numbers described in letter dated January 8, 2004, and Bard Brachytherapy, Inc., Model STM 1251; Isotope Products Laboratory, Storz Surgical Instruments Model B-450-12)	D. 3.2 curies
E. Any byproduct material permitted by 10 CFR 31.11	E. Prepackaged Kits	E. As needed

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		Docket or Reference Number 030-01625
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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
F. Iridium-192 as permitted by 10 CFR 35.600	F. Sealed sources (Nucletron Model No. 105.002, manufactured by Mallinckrodt Medical BV or AEA Technology, Inc.)	F. 2 sources not to exceed 12 curies each
G. Cesium-137	G. Sealed sources (AECL Model ORNL RAMCO-50 or ISO-1000)	G. 650 curies
H. Uranium depleted in uranium-235	H. Solid Metal	H. Not to exceed 999 kilograms total possession limit
I. Iridium-192, as permitted by 10 CFR 35.600	I. Sealed sources (Mallinckrodt Model Nos. 096.001, formerly DRN-07735, CIL BV, or MS-HDR and AlphaOmega Services, Inc. Model CSN-0010-192)	I. 2 sources; 1 source not to exceed 12 curies, and 1 source not to exceed 10 curies
J. Americium-241	J. Sealed source (Amersham Model AMC-24)	J. 14 millicuries
K. Iodine-125, as permitted by 10 CFR 35.1000	K. Liquid as Iotrex™	K. 8.0 curies
L. Yttrium-90 permitted by 10 CFR 35.1000	L. Sealed sources as SIR-Spheres (AEA Technology QSA GmbH)	L. 1350 millicuries
M. Yttrium-90 permitted by 10 CFR 35.1000	M. Glass microspheres as TheraSpheres (MDS Nordion)	M. 1350 millicuries

9. Authorized Use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.

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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, as permitted by 10 CFR 35.600, in a Nucletron MicroSelectron-HDR Model 105.999 remote afterloading brachytherapy device. One source (not to exceed 12 curies while stored pending installation) in a shipping container for source replacement.

G. To be used in a Nordion International, Inc. (AECL) Gamma cell 1000, Model A irradiator for irradiation of blood or blood components (excluding the irradiation of explosives and flammable materials).

H. For storage only incident to disposal.

I. One source for medical use, as permitted by 10 CFR 35.600, in a Nucletron MicroSelectron-"Classic" HDR remote afterloading brachytherapy device. The source activity may not exceed 10 curies at the time of installation. One source in a shipping container for source replacement.

J. For use as an anatomical marker.

K. For medical use permitted by 10 CFR 35.1000 in the Proxima Therapeutics' GliaSite® Radiotherapy System.

L. For medical use, as permitted by 10 CFR 35.1000, in a Sirtex Medical Limited brachytherapy afterloader delivery system.

M. For medical use as permitted by 10 CFR 35.1000 in a TheraSphere dose delivery system.

CONDITIONS

10. Locations of Use:

A. Material listed in Subitems 6.A. through 6.M. may be used at Community Hospital East - 1500 N. Ritter Avenue, Indianapolis, Indiana.

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B. Material listed in Subitems 6.A. through 6.M. may be used at Community Hospital North - 7150 Clearvista Drive, Indianapolis, Indiana.

C. Material listed in Subitems 6.B. may be used at Breast Diagnostic Center North - 7250 Clearvista Drive, Suite 199, Indianapolis, Indiana, as described in letter dated February 18, 1999.

D. Material listed in Subitems 6.A. through 6.E. may be used at Community Hospital South - 1402 E. County Line Road South, Indianapolis, Indiana.

11. A. Primary Radiation Safety Officer: Andrea D. Browne, Ph.D.

B. Assistant Radiation Safety Officer: Eric D. Slessinger, M.S.

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

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

B. The following individuals are authorized users for medical uses:

Authorized Users	Material and Use
William J. Elliott, M.D.	10 CFR 35.100, 35.200 and 35.300.
Mark Fox, M.D.	10 CFR 35.100, 35.200 and 35.300.
Nini Bermudez, M.D.	10 CFR 35.300, 35.400 and iridium-192 for use in High Dose Rate Remote Afterloader Units.
James R. Bognanno, M.D.	10 CFR 35.100 and 35.200.
Arve Gillette, M.D.	10 CFR 35.300, 35.400, iridium-192 for uses in High Dose Rate Remote Afterloader Units and iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System.
Morgan E. Tharp II, M.D.	10 CFR 35.300, 35.400, iridium-192 for uses in High Dose Rate Remote Afterloader Units and yttrium-90 as SIR-Spheres and TheraSpheres.

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Thomas G. Belt, M.D.	10 CFR 35.100, 35.200 and iridium-192 for uses in High Dose Rate Remote Afterloader Units.
John Paul Jacobs, M.D.	10 CFR 35.300, 35.400 and iridium-192 for uses in High Dose Rate Remote Afterloader Units.
David Kurlander, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
Franklin W. Sequeria, M.D.	10 CFR 35.100, 35.200, and 35.300.
Richard L. Scales, M.D.	10 CFR 35.100 and 35.200.
Deovrat Singh, M.D.	10 CFR 35.200.
Habib Komari, M.D.	10 CFR 35.200.
Ramachandra Reddy, M.D.	10 CFR 35.100 and 35.200.
Paul W. Sheets, M.D.	10 CFR 35.100 and 35.200.
John T. Mail, M.D.	10 CFR 35.100 and 35.200.
Gregory A. Merchun, M.D.	10 CFR 35.100, 35.200 and 35.300.
Orrin W. Perkins, M.D.	10 CFR 35.100, 35.200 and 35.300.
Richard J. Gordon, M.D.	10 CFR 35.200.
Mary Ellen Below, M.D.	10 CFR 35.100 and 35.200.
Daniel Lips, M.D.	10 CFR 35.200.
Colleen Marie Madden, M.D.	10 CFR 35.100 and 35.200.
Perry E. Wethington, M.D.	10 CFR 35.100 and 35.200.
Mark Joseph Paluszny, M.D.	10 CFR 35.100, 35.200 and 31.11.
Thomas N. Murphy, M.D.	10 CFR 35.100, 35.200 and 31.11.

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Vincent M. Bournique, M.D.	10 CFR 35.200.
Ibad U. Ansari, M.D.	10 CFR 35.100 and 35.200.
Seyed Mohsen Sharifi Takieh, M.D.	10 CFR 35.100 and 35.200.
Joseph A. Aronovitz, M.D.	10 CFR 35.300, 35.400 and iridium-192 for uses in High Dose Rate Remote Afterloader Units.
James Blahunka, M.D.	10 CFR 35.100, 35.200, and 35.300.
Stephan M. Stockberger, Jr., M.D.	10 CFR 35.100, 35.200, and 35.300 (limited to iodine-131 for treatment of hyperthyroidism).
Jianan C. Graybill, M.D.	10 CFR 35.300, 35.400, iridium-192 for uses in High Dose Rate Remote Afterloader Units, iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System and yttrium-90 as SIR-Spheres and TheraSpheres.
Daniel C. Han, M.D.	10 CFR 35.300, 35.400, iridium-192 for uses in High Dose Rate Remote Afterloader Units, iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System and yttrium-90 as SIR-Spheres and TheraSpheres.
James E. Currier, M.D.	10 CFR 35.300, 35.400, iridium-192 for uses in High Dose Rate Remote Afterloader Units, iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System and yttrium-90 as SIR-Spheres and TheraSpheres.
John E. Marvel, M.D.	10 CFR 35.300, 35.400, iridium-192 for uses in High Dose Rate Remote Afterloader Units, iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System and yttrium-90 as SIR-Spheres and TheraSpheres.
David B. Ross, M.D.	10 CFR 35.300, 35.400, iridium-192 for uses in High Dose Rate Remote Afterloader Units, iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System and yttrium-90 as SIR-Spheres and TheraSpheres.

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Edwin B. Watkins, M.D.	10 CFR 35.300, 35.400, iridium-192 for uses in High Dose Rate Remote Afterloader Units, iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System and yttrium-90 as SIR-Spheres and TheraSpheres.
Thomas C. Dugan, M.D.	10 CFR 35.300, 35.400, iridium-192 for uses in High Dose Rate Remote Afterloader Units, iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System and yttrium-90 as SIR-Spheres and TheraSpheres.
Rahul Dewan, D.O.	10 CFR 35.300, 35.400, iridium-192 for uses in High Dose Rate Remote Afterloader Units, iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System and yttrium-90 as SIR-Spheres and TheraSpheres.
Newell Pugh, M.D.	10 CFR 35.300, 35.400, iridium-192 for uses in High Dose Rate Remote Afterloader Units, iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System and yttrium-90 as SIR-Spheres and TheraSpheres.
Kenyon K. Kopecky, M.D.	10 CFR 35.100, 35.200, and 35.300.
Daniel W. Weed, M.D.	10 CFR 35.300, 35.400, iridium-192 for uses in High Dose Rate Remote Afterloader Units and yttrium-90 as SIR-Spheres and TheraSpheres.
Kenneth R. Stookey, M.D.	10 CFR 35.100 and 35.200.
Michael L. Swack, M.D.	10 CFR 35.100 and 35.200.
Scott L. Ackley, M.D.	10 CFR 35.300 and 35.400.
Peter G. Garrett, M.D.	10 CFR 35.400.
Alexander M. Yeh, M.D.	10 CFR 35.400.
Anwar Ahmad, M.D.	10 CFR 35.400.
Shih Jack Wei, M.D.	**10 CFR 35.400 and iridium-192 for uses in High Dose Rate Remote Afterloader Units.**

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C. The following individual is an authorized user for non-medical uses:

Authorized User	Material and Use
Andrea D. Browne, Ph.D.	Cesium-137 for use in irradiator in Subitem No. 6.G.

D. The following individuals are Authorized Medical Physicists:

Michael D. Loyd, M.S.	Strontium-90 ophthalmic sources permitted by 10 CFR 35.400; iridium-192 in High Dose Rate Remote Afterloading Brachytherapy device; iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System; for calibration, spot checks and training.
Eric Slessinger, M.S.	Strontium-90 ophthalmic sources permitted by 10 CFR 35.400; iridium-192 in High Dose Rate Remote Afterloading Brachytherapy device; iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System; for calibration, spot checks and training.
Andrea Browne, Ph.D.	Strontium-90 ophthalmic sources permitted by 10 CFR 35.400; iridium-192 in High Dose Rate Remote Afterloading Brachytherapy device; iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System; for calibration, spot checks and training.
A. Carl Warner, M.S.	Strontium-90 ophthalmic sources permitted by 10 CFR 35.400; iridium-192 in High Dose Rate Remote Afterloading Brachytherapy device; iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System for calibration, spot checks and training.
Yun Wang, Ph.D.	Strontium-90 ophthalmic sources permitted by 10 CFR 35.400; iridium-192 in High Dose Rate Remote Afterloading Brachytherapy device; for calibration, spot checks and training.
Danny Y. Dickow, M.S.	Strontium-90 ophthalmic sources permitted by 10 CFR

35.400; iridium-192 in High Dose Rate Remote Afterloading Brachytherapy device; iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System for calibration, spot checks and training.

Ana Mihail, M.S. — Iridium-192 in a High Dose Rate Remote Afterloading device for calibrations, spot-checks, and training.

Duan Qiang (David) Wang, Ph.D. — Iridium-192 in a High Dose Rate Remote Afterloading device for calibrations, spot-checks, and training.

13. 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 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.

B. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

C. Sealed sources need not be leak tested if:

(i) they contain not more than 100 microcuries of beta and/or gamma emitting material;

(ii) 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 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 or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

(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

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(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 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 or detector cell 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 shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

14. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.

15. The procedures contained in Nordion International's instruction manual for the Model Gammacell 1000 Model A device shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.

16. Sealed sources containing licensed material shall not be opened or removed from the irradiator by the licensee.

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

18. 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) for establishing decommissioning financial assurance.

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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. 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. Application dated July 15, 2003; and

B. Facsimiles dated January 8, 2004 (with attachments), February 12, 2004, February 23, 2004, June 24, 2004, and September 6, 2006; and

C. Letters dated April 1, 2005, July 7, 2005, November 17, 2005, and second letter also dated November 17, 2005, May 23, 2006, June 5, 2006; and

D. Email dated May 24, 2005.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date NOV 16 2006

NOV 16 2006

By _____
Cassandra F. Frazier
Materials Licensing Branch
Region III

This is to acknowledge the receipt of your letter/application dated

1/18/2008, and to inform you that the initial processing which includes an administrative review has been performed.

☑ AMEND. 37-07905-04
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

_____.

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 141657.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader