Harper Hospital
3990 John R Street
Detroit, MI 48201
313-745-2560 Telephone
313-745-2314 Fax

Gershenson Radiation Oncology Center

Fax

To: U.S. NRC Materials Licensing From: Joe Rakowski

Fax: 630-515-1078 Pages: 7 including cover

Phone: 630-829-9848 Date: 6/12/08

Re: Amendment Request CC:

☐ Urgent ☑ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

• Comments:

BARBARA ANN
KARMANOS
CANCER INSTITUTE

June 12, 2008

U.S. Nuclear Regulatory Commission, Region III
Materials Licensing Branch
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: Request for Authorized User Status for License #21-04127-06

Dear Sir or Madame,

This letter is a request to grant Authorized User Status to Elaine Arterbery, M.D., for 35.600 limited to Iridium-192 in a High Dose Rate Remote Afterloading Brachytherapy device, and Co-60 in a Leksell Gamma Knife System radiation therapy unit. We have attached the following NRC licenses that name Dr. Arterbery as an authorized user for these devices:

Co-60 Gamma Knife: NRC License # 21-04127-06
Ir-192 High Dose Rate Remote Afterloading: NRC License # 21-13562-01

If you require further assistance please feel free to contact our RSO Joe Rakowski at (313)745-1435.

Thank you.

Sincerely,

Mara Jelich
Manager Ambulatory Operations
Karmanos Cancer Center

4100 John R
Detroit, Michigan 48201
(800) KARMANOS (1-800-527-6266)
info@karmanos.org | www.karmanos.org

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Amendment No. 55

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 letter received **March 16, 2006, and letter dated March 16, 2006,**
1. Crittenton Hospital	3. License number 21-13562-01 is amended in its entirety to read as follows:
2. 1101 W. University Drive Rochester, MI 48307-1831	4. Expiration date January 31, 2011
	5. Docket No. 030-02157 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. As needed (not to exceed 1 curie of iodine-131)
D. Any byproduct material permitted by 10 CFR 35.400	D. **Sealed sources (iridium-192 [redacted] Model [redacted] iodine-125, Medi[redacted]cs, Inc. Model 6711 OncoSeed; iodine-125, Bard Brachytherapy, Inc. Model STM 1251 and palladium-103, North American Scientific, Inc., Model MED3633)**	D. **Not to exceed 1 curie total**
E. Any byproduct material permitted by 10 CFR 31.11	E. Prepackaged kit	E. As needed
F. Gadolinium-153	F. Sealed source (North American Scientific, Inc., Model 3601 or Isotope Products Laboratories, Inc., Model A3410)	F. Four sources, not to exceed 300 millicuries each

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MATERIALS LICENSE **SUPPLEMENTARY SHEET**		License Number 21-13562-01 Docket or Reference Number 030-02157 Amendment No. 55

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
G. Iodine-131	G. Sodium iodide	G. 50 millicuries
H. Gadolinium-153	H. Sealed source (Isotope Products Labs Models NES-8426 and AEA Technology Model GD.LIN2)	H. **32 sources not to exceed 14 sources per tray and not to exceed 120 millicuries per source tray and not to exceed 320 millicuries total.**
I. **Iridium-192 permitted by 10 CFR 35.600**	I. **Sealed source (Nucletron Model 105.002, Mallinckrodt Medical B.V., Westerduinweg 3, NL-1755 LE Petten, The Netherlands or AEA Technology 40 [illegible] Avenue, Burlington**	I. **One not to exceed 12 curies and one source not to exceed 13 curies.**

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. Two sources to be used in ADAC Laboratories Transmission Line Source Housing VANTAGE devices for medical radiography in humans. Two sources in shipping containers for replacement of sources.

G. For imaging and localization studies that require a written directive in accordance with 10 CFR 35.40.

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H. For use in Siemen's Transmission Attenuation Correction (Profile) source holder, **14 sources in each of 2 source trays and 4 sources in storage for source exchange.**

I. **For use in a Nucletron B.V. Model 105.980 Remote Afterloading Brachytherapy Unit for radiotherapy in humans permitted by 10 CFR 35.600. The source activity may not exceed 12 Ci at the time of installation. One source (not to exceed 13 curies while stored pending installation) in its shipping container for source replacement.**

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1101 W. University Drive, Rochester, Michigan.

11. A. Radiation Safety Officer: Kanak Varde, M.D.

B. Brachytherapy Radiation Safety Officer: Elayne Arterbery, M.D.

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

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

B. The following individuals are authorized users or medical physicists as indicated:

Authorized Users	Materials and Uses
Kanak Varde, M.D.	10 CFR 35.100, 35.200, 35.300 (except iodine-131 in quantities greater than 33 millicuries), 31.11 and gadolinium-153 in VANTAGE and Siemen's devices for medical radiography.
Arthur Porter, M.D.	10 CFR 35.400.
G. V. Vaishampayan, M.D.	10 CFR 35.400.
V. Elayne Arterbery, M.D.	10 CFR 35.400 **and 35.600 only iridium-192 in remote afterloading brachytherapy unit.**
N. G. Vaishampayan, M.D.	10 CFR 35.400.
Manijeh Hakimi, M.D.	10 CFR 31.11.
Kenneth Levin, M.D.	**10 CFR 35.300, 35.400 and 10 CFR 35.600 only iridium-192 in remote afterloading brachytherapy unit.**

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Amendment No. 32

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 January 31, 2003,
1. Harper Hospital Division Gershenson Radiation Oncology Center 2. 990 John R Detroit, MI 48201	3. License number 21-04127-06 is amended in its entirety to read as follows: 4. Expiration date June 30, 2005 5. Docket No. 030-09376 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. Cobalt-60, as permitted by 10 CFR 35.600	A. Sealed source (AECL Models C-146 or C-151)	A. 7,500 curies per source
B. Uranium, depleted in uranium-235	B. Cadmium plated metal [redacted]	B. As needed
C. Cobalt-60, as permitted by 10 CFR 35.600	C. Sealed sources (General Electric Company AB Elekta Model 43047)	C. 7250 curies (201 sources of not more than 36 curies each)
D. Cobalt-60, as permitted by 10 CFR 35.600	**D. Sealed sources (General Electric Company AB Elekta Model 43047 or MDS Nordion-Elekta Models 43047 or 43685)**	**D. 7250 curies (201 sources of not more than 36 curies each)**

9. Authorized Use:

A. Medical use permitted by 10 CFR 35.600 in an AECL Theratron 780-19 Total Body Irradiator, as described in letters dated May 17, 1991, January 9, 1992, May 8, 1992, and December 18, 1994.

B. Shielding in a teletherapy unit.

C. For medical use permitted by 10 CFR 35.600, installation, source replacement and temporary storage of a Leksell Gamma System Model 23016 (a.k.a. Gamma Knife or Cerebral Stereotactic Radiosurgical Unit) radiation therapy unit for the treatment of humans, human research and nonhuman research as described in letter dated July 19, 1995.

D. **For medical use permitted by 10 CFR 35.600, installation, operational testing, calibration**

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MATERIALS LICENSE **SUPPLEMENTARY SHEET**	License Number 21-04127-06 Docket or Reference Number 030-09376 **Amendment No. 32**

and temporary storage in a Leksell Gamma System Model 24001 Type C (a.k.a. Gamma Knife or Cerebral Stereotactic Radiosurgical Unit) radiation therapy device.

CONDITIONS

10. A. Licensed material in Subitems 6.A. and 6.B. shall be used at the licensee's facilities located in the Radiation Oncology Department, Harper Grace Hospital, Room 1031, 3990 John R Street, Detroit, Michigan.

B. Licensed material in Subitem 6.C. shall be used only at the licensee's facilities located in the sub-basement room, adjacent to the cyclotron in the Gershenson Radiation Oncology Center of Harper Hospital, Detroit, Michigan.

C. **Licensed material in Subitem 6.D. shall be used and stored only at the licensee's facilities located in the basement of the Gershenson Radiation Oncology Center of Harper Hospital, Room No. 379, Detroit, Michigan.**

11. Radiation Safety Officer: Azucena Garzon, 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
(1)	Jeffrey Forman, M.D.	10 CFR 35.600 and uranium, depleted in uranium-235.
(2)	Arthur Porter, M.D.	10 CFR 35.600 and uranium, depleted in uranium-235.
(3)	**Elaine Arterbery, M.D.**	**10 CFR 35.600, limited to Leksell Gamma System radiation therapy unit and uranium, depleted in uranium-235.**
(4)	**Edgar Ben-Josef, M.D.**	**10 CFR 35.600, limited to Leksell Gamma System radiation therapy unit and uranium, depleted in uranium-235.**
(5)	Kenneth Levin, M.D.	10 CFR 35.600, limited to Leksell Gamma System radiation therapy unit and uranium, depleted in uranium-235.