

## MATERIALS LICENSE

Amendment No. 03

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 1, 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.

OFFICIAL RECORD COPY

<p>Licensee</p> <p>1. Wills Eye Hospital</p> <p>2. 900 Walnut Street Philadelphia, Pennsylvania 19107-5598</p>	<p>In accordance with the letter dated April 24, 1997,</p> <p>3. License Number 37-00783-05 is amended in its entirety to read as follows:</p> <p>4. Expiration Date December 31, 2005</p> <p>5. Docket or Reference No. 030-33972</p>	
<p>6. Byproduct, Source, and/or Special Nuclear Material</p> <p>A. Cobalt 60</p>	<p>7. Chemical and/or Physical Form</p> <p>A. Sealed sources (General Electric Company AB Elekta Model 43047)</p>	<p>8. Maximum Amount that Licensee May Possess at Any One Time Under This License</p> <p>A. 201 sources of not more than 36 curies each and a total not to exceed 6,600 curies</p>
<p>9. Authorized use</p> <p>A. For use 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 and for research purposes including animal studies.</p>		

## CONDITIONS

10. Licensed material may be used at the licensee's facilities located at 900 Walnut Street, Philadelphia, Pennsylvania.
11. A. Licensed material shall be used under the supervision of a team of at least three individuals which includes the following: a Neurosurgeon, a Radiation Therapist, and a Medical Physicist each of whom is specifically named on the license.
- B. Radiation Therapists for this license are Walter J. Curran, Jr. M.D., Maria Werner-Wasik, M.D., Jeffrey G. Rosenstock, M.D. and Benjamin W. Corn, M.D.
- C. Neurosurgeons for this license are W. Warren Goldman, M.D., Ph.D. and David W. Andrews, M.D.
- D. The Medical Physicists for this license are Madge Beverly Downes, M.S. and Greg Bednarz, Ph.D.
12. The Radiation Safety Officer for this license is Madge Beverly Downes, M.S.



MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

37-00783-05

Docket or Reference Number

030-33972

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13. A. Gamma Knife sources shall be tested for leakage at intervals not to exceed 6 months. Records of test results shall be kept in units of microcuries and maintained for inspection by the Commission. In the absence of a certificate from a transferor indicating that a test has been made within 6 months before the transfer, a source received from another person shall not be used until tested for leakage.
- B. The tests shall be sufficiently sensitive to detect 0.005 microcurie of contamination on the test sample.
- C. The test sample shall be taken from selected accessible surfaces of the Gamma Knife. The selected accessible surfaces shall be those surfaces on which one might expect contamination to accumulate if there were to be leakage and shall include the inner surface of the most frequently used helmets. A minimum of a single wipe of the entire surface of the collimator will be taken.
- D. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the Gamma Knife from use and take action to prevent spread of contamination. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken.
14. A set of written emergency instructions shall be posted at the Gamma Knife control console. These instructions shall inform the operator of the procedure to be followed should he be unable to withdraw the patient from the focus beam of radiation with the controls outside the treatment room.
15. A. Access to the Gamma Knife room shall be controlled by a door at each entrance. Such doors shall be normally closed.
- B. Each entrance to the Gamma Knife room shall be equipped with an electrical interlock system that will remove the patient from the focus beam of radiation upon opening of any entrance door. The interlock system shall be connected in such a manner that the patient cannot be returned to the focus beam until all entrance doors are closed and the control is reset at the control panel.
- C. Electrical interlocks on entrance doors to the Gamma Knife room shall be tested for proper operation at the beginning of each day of use. Records of test results shall be maintained for inspection by the Commission.
- D. In the event of malfunction of any door interlock, the Gamma Knife control shall be locked in the "off" condition 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.

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16. A. Any changes made in the treatment room shielding, location of the unit within the treatment room, or use of the Gamma Knife unit that could result in increased radiation levels in areas outside the Gamma Knife treatment room shall be evaluated by a radiation survey made in accordance with Condition 17, and reported to the Commission within 30 days following completion of the change(s).
- B. Relocation of the Gamma Knife unit to a new facility is not permitted without prior approval all the plans and details by the Commission. Following such approval and relocation, a radiation survey shall be made in accordance with Condition 17, and reported to the Commission within 30 days after completion of the move.
17. Before initiation of a treatment program, and subsequent to each set of source changes, radiation surveys and tests shall be performed in accordance with the following:
- A. A radiation survey shall be made of:
- (i) The Gamma Knife source housing, with the shielding door closed. The maximum and average radiation levels at 1 meter from the Gamma Knife housing in the "closed" position shall not exceed 10 milliroentgens per hour and 2 milliroentgens per hour, respectively.
  - (ii) All areas adjacent to the treatment room with the Gamma Knife shielding door in the "open" position. The survey shall be performed with a phantom in the focus beam of radiation and shall clearly establish:
    - (a) That radiation levels in restricted areas are not likely to cause occupational dose in excess of the limits specified in 10 CFR 20.1201 or doses to members of the public in excess of the limits specified in 10 CFR 20.1301, and
    - (b) That quantities of radiation in unrestricted areas do not exceed the limits specified in 10 CFR 20.1301(a)(2).
- B. Tests shall be made to determine proper operation of:
- (i) Electrical interlocks on entrance doors to the Gamma Knife treatment room.
  - (ii) The Gamma Knife treatment timing device.
- C. A report of the results of the above surveys and tests shall be sent to the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406, not more than 30 days after connection of the hydraulic system for the Gamma Knife.

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18. The following shall be performed by the manufacturer or by persons specifically licensed by the Commission or an Agreement State to perform such services:
  - A. Installation, relocation, or removal of the Gamma Knife containing sources.
  - B. Source replacements or adjustments.
  - C. Any maintenance or repair operations on the Gamma Knife unit involving a mechanism that could expose the sources, reduce the shielding around the sources, or compromise the safety of the unit and result in increased radiation levels.
19. Notwithstanding the requirements of 10 CFR 35.632(b)(2), 35.632(b)(3), 35.632(b)(6), 35.634(a)(3), and 35.634(a)(4), the licensee is not required to determine the coincidence of the radiation field and the field indicated by a light beam localizing device, the uniformity of the radiation field and its dependence on the orientation of the useful beam, and the accuracy of all distance measuring and localization devices in medical use.
20. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
21. 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. Application dated September 29, 1995 except QM plan in Appendix II
  - B. Application received November 29, 1995 except QM plan in Appendix II
  - C. Letter received December 1, 1995
  - D. Facsimiles received December 4, 1995 (3)
  - E. Letter dated January 31, 1996
  - F. Letter dated March 14, 1996
  - G. Letter dated March 20, 1996
  - H. Letter dated May 2, 1996

MAY - 8 1997

Date

For the U.S. Nuclear Regulatory Commission

**ORIGINAL SIGNED BY:  
THOMAS K. THOMPSON**

By

Nuclear Materials Safety Branch  
Region I

King of Prussia, Pennsylvania 19406



MAY - 8 1997

Karla S. McCaney  
Assistant Executive Director  
Wills Eye Hospital  
900 Walnut Street  
Philadelphia, PA 19107-5598

Dear Ms. McCaney:

This refers to your license amendment request. Enclosed with this letter is the amended 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) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

**ORIGINAL SIGNED BY:  
THOMAS K. THOMPSON**

Thomas K. Thompson  
Division of Nuclear Materials Safety

License No. 37-00783-05  
Docket No. 030-33972  
Control No. 124521

Enclosure:  
Amendment No. 03

DOCUMENT NAME: R:\WPS\MLTR\L3700783.05

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	<input checked="" type="checkbox"/> N	DNMS/RI	<input checked="" type="checkbox"/> N			
NAME	Beardsley		Thompson	<i>RT</i>			
DATE	05/08/97		05/8/97		05/ /97		05/ /97

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ML 10

April 24, 1997

Mr. Thomas K. Thompson  
Senior Health Physicist  
Division of Nuclear Materials Safety  
**United States Nuclear Regulatory Commission**  
Region 1  
475 Allendale Road  
King of Prussia, PA 19406

RE: LICENSE NO. 37-00783-05  
DOCKET NO. 030-33972

Dear Mr. Thompson:

Wills Eye Hospital requests an amendment to its license No. 37-00783-05 for use of a Leksell Gamma System for the following reasons:

**1. Correction of address on License:**

The correct address on Item No. 2 of the license should be:

900 Walnut Street  
Philadelphia, Pennsylvania 19107-5598

The 211 South Ninth Street address is an administrative building not the Hospital.

**2. Addition of Medical Physicist:**

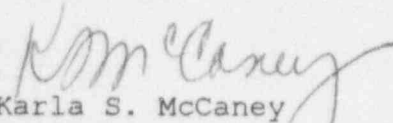
Wills requests the addition of Greg Bednarz, Ph.D., to the license. Dr. Bednarz meets the qualifications as listed in 835.961 Training for Teletherapy Physicist. Attached please find a copy of Dr. Bednarz' curriculum vitae.

Enclosed please find a check in the amount of \$470.00 to cover the request for this amendment to our license.

RE: LICENSE NO. 37-00783-05  
DOCKET NO. 030-33972  
PAGE TWO (2)

Thank you for your assistance with this matter. Please call me as soon as possible at 215-440-3153 if you need any additional information.

Sincerely,

  
Karla S. McCaney  
Assistant Executive Director

KSM/smp

cc: M. Beverly Downes,  
M.S., D.A.B.R.

Enclosures

Check (\$470.00)  
Curriculum Vitae - Greg Bednarz, Ph.D.

APR-24-1997 14:11 TJUH RADIATION ONCOLOGY 1215555551 P.02

## CURRICULUM VITAE

### GREG BEDNARZ

Department of Radiation Oncology  
Thomas Jefferson University Hospital  
111 South 11<sup>th</sup> Street  
Philadelphia, PA 19107  
Phone: (215)-955-8855  
E-mail: bednarz@inca.tjh.tju.edu

#### EDUCATION:

- **Ph.D., Physics**, Dalhousie University, Halifax, Nova Scotia, Canada, 1992
  - **M.S., Physics**, Technical University of Lodz, Lodz, Poland, 1983
- Professional Society Membership: American Association of Physicists in Medicine

#### PROFESSIONAL EXPERIENCE:

**November 1996-present**

**Instructor, at the Department of Radiation Oncology, Thomas Jefferson University Hospital, Philadelphia.**

Faculty appointment related duties, including teaching, research and patient care (radiation treatment planning, clinical dosimetry, machine calibration and quality assurance); also providing medical physics support for the radiosurgery program (Gamma Knife and X-knife) at the Wills Neurosensory Institute at Wills Eye Hospital.

**November 1994 - October 1996**

**Medical Physics Resident, at the Department of Radiation Oncology, University of California, San Francisco.**

Clinical residency program in radiation oncology physics. The program was designed in accordance with the AAPM guidelines, contained in AAPM Report No. 36 on Medical Physics Residencies. The goal of the program was to prepare the trainee for certification examination of the American Board of Medical Physics or the American Board of Radiology. Training and experience in the areas of clinical dosimetry, treatment planning, brachytherapy, radiation shielding, radiation safety, emergency procedures, machine calibration and quality assurance. Program included training and clinical experience in Gamma Knife dosimetry.

**September 1993 - November 1994**

**Research Associate, at the Department of Radiological Sciences, Division of Physics and Engineering, University of California, Irvine.**

Research investigation in the areas of digital radiographic imaging, dual-energy cardiac imaging, coronary blood flow measurement and radiographic beam equalization techniques.



**November 1992-August 1993**

**Research Associate, at the Department of Chemistry, Dalhousie University, Halifax, Nova Scotia, Canada.**

Investigation of physical and chemical properties of solids

**August 1987-October 1992**

**Graduate student and Teaching Assistant, at the Department of Physics, Dalhousie University, Halifax, Nova Scotia, Canada.**

Ph.D. thesis title: "Critical behaviour of gadolinium".

Ph.D. research was focused on the investigation of thermal and magnetic properties of the rare earth metal gadolinium (Gd).

1. Measurement of thermal properties of solids.
2. Graduate course work in solid state physics, chemistry and electronics, including graduate level courses in Radiation Physics and Physics of Radiation Therapy;
3. Teaching in the undergraduate physics laboratories.

**July 1983-August 1987**

**Research Assistant, at the Department of Physics, Technical University of Lodz, Poland.**

1. Experimental and theoretical investigation of crystal growth and structure of water and water solutions.
2. Responsible for teaching at the first year university level.

**Sept. 1978-July 1983**

**Undergraduate and Graduate Student, at the Department of Physics, Technical University of Lodz, Poland.**

1. Investigation of thermal properties of aqueous solutions of gases.
2. Course work in physics, chemistry, mathematics and electronics.

#### **AWARDS:**

- William Leiper Memorial Scholarship (Canada), 1990-1991
- Izaak Walton Killam Memorial Scholarship (Canada), 1989-1991

#### **REFERENCES**

Available on request.

# BIBLIOGRAPHY:

11. G. Bednarz, N. Albright, K. Weaver, "Evaluation of a 3D convolution based treatment planning system", Abstr., Med. Phys., 23, 1173 (1996).
10. S. Molloi, G. Bednarz, J. Tang, Absolute coronary artery blood flow measurement using digital subtraction angiography, Abstr., Med. Phys., 22, 1534 (1995).
9. G. Bednarz, D. Geldart, C. Glorieux, J. Thoen, and M.A. White, "Photoacoustic investigation of the temperature and magnetic field dependence of the specific heat and thermal conductivity near the Curie point in Gadolinium", Phys. Rev. B 52, 12770 (1995).
8. S. Molloi, G. Bednarz, J. Hicks, "Volumetric coronary blood flow measurement using dual-energy DSA", Abstr., Med. Phys., 21, 941 (1994).
7. G. Bednarz, M.A. White, M.R. Pressprich and R. Willett, "Thermal and diffraction studies of phase transitions in the incommensurate compound  $[P(CH_3)_4]_2CuCl_2$ ", Phys. Rev. B 49, 832 (1994).
6. G. Bednarz, D.J.W. Geldart and M.A. White, "Heat capacity of gadolinium near the Curie temperature", Phys. Rev. B 47, 14247 (1993).
5. G. Bednarz and D.J.W. Geldart, "Demagnetization heat capacity of uniaxial ferromagnets near critical point", J. Phys.: Condens. Matter 5, L239-L244 (1993).
4. G. Bednarz, B. Millier and M.A. White, "High-resolution, high-sensitivity AC calorimeter", Rev. Sci. Instrum. 63(8), 3944-3952 (1992).
3. G. Bednarz, G. Stroink, and M.A. White, "A study of the heat capacity of the superconductor  $EuBa_2Cu_3O_{7-x}$ ", Physica C 165, 385-390 (1990).
2. B. Wojciechowski, I. Owczarek and G. Bednarz, "Freezing of aqueous solutions containing gases", Cryst. Res. Technol. 23(7), 843-848 (1988).
1. G. Bednarz and M. Krasinski, "Visualization of the boundary layer on the growing ice", Cryst. Res. Technol. 22(9), K145-K147 (1987).

UNIVERSITY OF CALIFORNIA  
SCHOOL OF MEDICINE

SAN FRANCISCO  
DEPARTMENT OF RADIATION ONCOLOGY

THIS CERTIFIES THAT

*Greg Bednarz, Ph.D.*

SERVED A PHYSICS POSTDOCTORAL RESIDENCY IN

*Radiation Oncology*

*November 1, 1994 - October 31, 1996*



*Theodore L. Phillips*

Theodore L. Phillips, M.D.  
Chairman, Radiation Oncology

*Lynn J. Verhey*

Lynn J. Verhey, Ph.D.  
Director, Physics

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124521

BETWEEN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

(FOR LFMS USE)  
INFORMATION FROM LTS

Program Code: 02300  
Status Code: 0  
Fee Category: 7A  
Exp. Date: 20051231  
Fee Comments: WAS 2-PT LIC  
Decom Fin Assur Req'd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: WILLS EYE HOSPITAL  
Received Date: 970428  
Docket No: 3033972  
Control No.: 124521  
License No.: 37-00783-05  
Action Type: Amendment

2. FEE ATTACHED

Amount: \$ 470.00  
Check No.: 306483

3. COMMENTS

Signed Brown R. J.  
Date 5/5/97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /\_\_\_/)

1. Fee Category and Amount: 7A 8470

2. Correct Fee Paid. Application may be processed for:

Amendment \_\_\_\_\_  
Renewal \_\_\_\_\_  
License \_\_\_\_\_

3. OTHER \_\_\_\_\_

Signed \_\_\_\_\_  
Date \_\_\_\_\_

Log	<u>May 5</u>
Remitter	
Check No.	<u>306483</u>
Amount	<u>\$ 470</u>
Fee Category	<u>7A</u>
Type of Fee	<u>Amo</u>
Date Check Rec'd	<u>5/27/97</u>
Date Completed	
By:	<u>SB</u>

Expedite!  
SK entered 09 for 5/8/97  
B2

REC'D MAY -7 PM 12:30