



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

January 5, 2005

Docket No. 03001239
Control No. 136223

License No. 06-00253-04

Peter Mas
Radiation Safety Officer
Hartford Hospital
80 Seymour Street
Hartford, CT 06102

SUBJECT: HARTFORD HOSPITAL, ISSUANCE OF LICENSE AMENDMENT, CONTROL
NO. 136223

Dear Mr. Mas:

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) 337-5239, 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).

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

Thank you for your cooperation.

Sincerely,

Original signed by Tara L. Weidner

Tara L. Weidner
Health Physicist
Medical Branch
Division of Nuclear Materials Safety

P. Mas
Hartford Hospital

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Enclosure:
Amendment No. 93

P. Mas
Hartford Hospital

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|--------|--------------|---|---------|--|---------|--|--|--|
| OFFICE | DNMS/RI | N | DNMS/RI | | DNMS/RI | | | |
| NAME | TWeidner/TLW | | | | | | | |
| DATE | 1/5/05 | | | | | | | |

OFFICIAL RECORD COPY

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.

| | | |
|---|--|--|
| <p>Licensee</p> <p>1. Hartford Hospital</p> <p>2. 80 Seymour Street Hartford, Connecticut 06102</p> | <p>In accordance with the letter dated January 3, 2005,</p> <p>3. License number 06-00253-04 is amended in its entirety to read as follows:</p> <p>4. Expiration date September 30, 2004 (extended)</p> <p>5. Docket No. 030-01239 Reference No.</p> | |
| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p> <p>D. Any byproduct material permitted by 10 CFR 35.400</p> <p>E. Any byproduct material permitted by 10 CFR 35.500</p> <p>F. Iridium 192</p> <p>G. Hydrogen 3</p> <p>H. Carbon 14</p> | <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Sealed sources</p> <p>E. Sealed sources (North American Scientific Model MED 3601; DuPont Merck Model NES-8412; IPL Model NES 8497)</p> <p>F. Sealed Sources (Best Industries Model 81-01)</p> <p>G. Any</p> <p>H. Any</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. 1.0 curies</p> <p>D. 5 curies</p> <p>E. 300 millicuries per source and 9 curies total</p> <p>F. No single source to exceed 33 millicuries, in a three-ribbon set containing 6, 10, or 14 iridium-192 seeds per ribbon; 2 ribbon sets of 2 curies total</p> <p>G. 50 millicuries</p> <p>H. 20 millicuries</p> |

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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. Phosphorus 32 | I. Any | I. 100 millicuries |
| J. Sulfur 35 | J. Any | J. 20 millicuries |
| K. Chromium 51 | K. Any | K. 20 millicuries |
| L. Technetium 99m | L. Any | L. 200 millicurie |
| M. Iodine 125 | M. Any | M. 20 millicuries |
| N. Iodine 131 | N. Any | N. 20 millicuries |
| O. Ytterbium 169 | O. Any | O. 20 millicuries |
| P. Nickel 63 | P. Foil contained in Hewlett-Packard Model 18724A detector cell | P. Not to exceed 15 millicuries per source and 150 millicuries total |
| Q. Cesium 137 | Q. Sealed sources (Oak Ridge National Laboratories Model ISO-1000) | Q. 720 curies |
| R. Cesium 137 | R. Sealed source (J. L. Shepherd Model 6810) | R. 225 millicuries |
| S. Strontium 90 | S. Sealed source (Nuclear Enterprises Model 2503/3) | S. 10 millicuries |
| T. Strontium 90/Yttrium 90 | T. Sealed Sources [BEBIG Model Sr0.S03 or AEAT SICW Series (SICW.1 and SICW.2)] | T. 5.0 millicuries per source; 800 millicuries total |
| U. Iridium-192 permitted by 10 CFR 35.600 | U. Sealed Sources [Nucletron Model 105.002 (manufactured by Mallinckrodt Medical B.V. or AEA Technology)] | U. 12 curies per source and 22 curies total |

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.

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- E. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
- F. One source assembly for medical use in a Cordis Checkmate intravascular brachytherapy remote afterloader unit. One source assembly in its shipping container as necessary for replacement of the source assembly in the intravascular brachytherapy remote afterloader unit.
- G. through O. Research and development as defined in 10 CFR 30.4; animal studies.
- P. For use in gas chromatographs for sample analysis.
- Q. For use in an AECL Gammacell, Model 1000A Irradiator for the irradiation of material except explosives, flammables, or corrosives.
- R. and S. For instrument calibration.
- T. One source assembly for medical use in a Novoste A1000 series intravascular brachytherapy remote afterloader unit. One source assembly in its shipping container as necessary for replacement of the source assembly in the intravascular brachytherapy remote afterloader unit.
- U. One source for medical use permitted by 10 CFR 35.600, in a Nucletron Corp. Model 105.999 remote afterloader unit. The source shall 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.

CONDITIONS

10. A. Licensed material may be used or stored only at the licensee's facilities located at Hartford Hospital, 80 Seymour Street, Hartford, Connecticut.
- B. Only licensed material listed in 6.A., 6.B., 6.C. and 6.D. may be used or stored at Connecticut Childrens Medical Center (CCMC), 282 Washington Street, Hartford Connecticut.
- C. Only licensed material listed in 6.A., 6.B. and 6.E. may be used or stored at 100 Simsbury Road, Suite 202, Avon, Connecticut.
- D. Only licensed material listed in 6.B. and 6.E. may be used or stored at 704 Hebron Avenue, Glastonbury, Connecticut.
- E. Only licensed material listed in 6.A., 6.B. and 6.E. may be used or stored at 100 Retreat Avenue, Suite 811, Hartford, Connecticut.
- F. Only licensed material listed in 6.A, 6.B. and 6.E. may be used or stored at 1260 Silas Deane Highway, Suite 106, Wethersfield, Connecticut.
11. The Radiation Safety Officer for this license is Peter J. Mas, M.S.

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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 use as indicated:

Authorized UsersMaterial and Use

William J. Aberizk, M.D.

35.300; 35.400; Iridium 192 for intravascular brachytherapy procedures and in a High Dose Rate afterloader unit; Strontium 90/Yttrium 90 in Novoste A1000 series systems

Bruce F. Bower, M.D.

35.100; 35.300

Judith A. Buckley, M.D.

35.300; 35.400; Iridium 192 for intravascular brachytherapy procedures and in a High Dose Rate afterloader unit; Strontium 90/Yttrium 90 in Novoste A1000 series systems

Edward Bowen Cronin, M.D.

35.100; 35.200; 35.300; 35.500

Robert J. Dowsett, M.D.

35.300; 35.400; Iridium 192 for intravascular brachytherapy procedures and in a High Dose Rate afterloader unit; Strontium 90/Yttrium 90 in Novoste A1000 series systems

Gary V. Heller, M.D.

35.100; 35.200; 35.500

Allan S. Kratzer, M.D.

35.300; 35.400; Iridium 192 for intravascular brachytherapy procedures and in a High Dose Rate afterloader unit; Strontium 90/Yttrium 90 in Novoste A1000 series systems

Richard M. Linburg, M.D.

35.500

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Jacqueline M. Lyon, M.D.

35.300; 35.400; Iridium 192 for intravascular brachytherapy procedures and in a High Dose Rate afterloader unit; Strontium 90/Yttrium 90 in Novoste A1000 series systems

Ronald J. Rosenberg, M.D.

35.100; 35.200; 35.300; 35.500

Andrew L. Salner, M.D.

35.300; 35.400; Iridium 192 for intravascular brachytherapy procedures and in a High Dose Rate afterloader unit; Strontium 90/Yttrium 90 in Novoste A1000 series systems

Paul R. C. Sullivan, M.D.

35.100; 35.300

Helaine Bertsch, M.D.

35.300; 35.400; Iridium 192 for intravascular brachytherapy procedures and in a High Dose Rate afterloader unit; Strontium 90/Yttrium 90 in Novoste A1000 series systems

Kenneth Leopold, M.D.

35.300; 35.400; Iridium 192 for intravascular brachytherapy procedures and in a High Dose Rate afterloader unit; Strontium 90/Yttrium 90 in Novoste A1000 series systems

John Opalacz, M.D.

35.100; 35.200; 35.300; 35.500

Christopher J. Leary, M.D.

35.100; 35.200; 35.500

Roger Shih-Shien Yang, M.D.

35.100; 35.200; 35.500

Allen A. Currier, M.D.

35.100; 35.200; 35.500

Timothy S. Boyd, M.D.

35.300; 35.400; Iridium 192 for intravascular brachytherapy procedures and in a High Dose Rate afterloader unit; Strontium 90/Yttrium 90 in Novoste A1000 series systems

Abdul Alkeylani, M.D.

35.100; 35.200; 35.500

Mary C. deGroot, M.D.

35.100; 35.200; 35.500

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| Melissa Ferraro-Borgida, M.D. | 35.100; 35.200; 35.500 |
| Brett Duncan, M.D. | 35.100; 35.200; 35.500 |
| Andrea T. Fossati, M.D. | 35.100; 35.200; 35.500 |
| Michael S. Fowler, M.D. | 35.100; 35.200; 35.500 |
| Carol Y. Gemayel, M.D. | 35.100; 35.200; 35.500 |
| M. Reza Mansoor, M.D. | 35.100; 35.200; 35.500 |
| Asad A. Rizvi, M.D. | 35.100; 35.200; 35.500 |
| Ahmad Salloum, M.D. | 35.100; 35.200; 35.500 |
| Steven B. Goldblatt, M.D. | 35.100; 35.200; 35.500 |
| Susan Y. Kim, M.D. | 35.300; 35.400; Iridium 192 for intravascular brachytherapy procedures and in a High Dose Rate afterloader unit; Strontium 90/Yttrium 90 in Novoste A1000 series systems |
| Stephen H. Hauser, M.D. | 35.300; 35.400; Iridium 192 for intravascular brachytherapy procedures and in a High Dose Rate afterloader unit; Strontium 90/Yttrium 90 in Novoste A1000 series systems |

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

| <u>Authorized Users</u> | <u>Material and Use</u> |
|---------------------------|--|
| Raymond C. Bartlett, M.D. | Nickel 63 |
| Laurine M. Bow, Ph.D. | Hydrogen 3; Carbon 14; Phosphorus 32; Sulfur 35; Chromium 51; Iodine 125 |
| Peter J. Mas, M.S. | Cesium 137 for instrument calibration |
| Robert E. Moore, Ph.D. | Hydrogen 3; Carbon 14; Phosphorus 32; Sulfur 35; Chromium 51; Nickel 63; Technetium 99m; Iodine 125; Iodine 131; Cesium 137; Ytterbium 169 |
| Robert E. Rice, M.S. | Strontium 90 for instrument calibration |

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Ronald J. Rosenberg, M.D.

Hydrogen 3; Carbon 14; Phosphorus 32;
Sulfur 35; Chromium 51; Nickel 63;
Technetium 99m; Iodine 125; Iodine 131;
Cesium 137; Ytterbium 169

Robert Schweizer, M.D.

Hydrogen 3; Carbon 14; Phosphorus 32;
Sulfur 35; Chromium 51; Nickel 63;
Technetium 99m; Iodine 125; Iodine 131;
Cesium 137; Ytterbium 169

Herbert Silver, M.D.

Hydrogen 3
Cesium 137 for irradiation of material

Gregory J. Tsongalis, Ph.D.

Hydrogen 3; Phosphorus 32; Sulfur 35

Charles L. Woronick, Ph.D.

Chromium 51; Iodine 125

Bradford Sherburne, M.D.

Cesium 137 for irradiation of material

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

Authorized Medical Physicists

Material and Use

Janet D. Gortney

Iridium 192 and Sr90/Y90 in an
Intravascular Brachytherapy Afterloader
Device and High Dose Rate remote
afterloader unit for calibrations, spot-checks,
and training

Iwona S. Miazek

Iridium 192 and Sr90/Y90 in an
Intravascular Brachytherapy Afterloader
Device and High Dose Rate remote
afterloader unit for calibrations, spot-checks,
and training

Jay Friedman

Iridium 192 and Sr90/Y90 in an
Intravascular Brachytherapy Afterloader
Device and High Dose Rate remote
afterloader unit for calibrations, spot-
checks, and training

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Authorized Medical Physicists

Robert E. Rice, III

Kevin Norton

Kevin O. Khadivi, Ph.D.

Douglas E. Boccuzzi

Material and Use

Iridium 192 and Sr90/Y90 in an Intravascular Brachytherapy Afterloader Device and High Dose Rate remote afterloader unit for calibrations, spot-checks, and training

Iridium 192 and Sr90/Y90 in an Intravascular Brachytherapy Afterloader Device and High Dose Rate remote afterloader unit for calibrations, spot-checks, and training

Iridium 192 and Sr90/Y90 in an Intravascular Brachytherapy Afterloader Device and High Dose Rate remote afterloader unit for calibrations, spot-checks, and training

Iridium 192 and Sr90/Y90 in an Intravascular Brachytherapy Afterloader Device and High Dose Rate remote afterloader unit for calibrations, spot-checks, and training

E. Intravascular brachytherapy procedures shall be conducted under the supervision of the authorized user, who will consult with the interventional cardiologist/physician and authorized medical physicist prior to initiating treatment. The procedures shall be conducted in the physical presence of the authorized user or the authorized medical physicist.

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.

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15. In lieu of the source inventory described in 10 CFR 35.406, the licensee shall:
- A. Promptly determine that all sources have been returned to the safe, shielded position at the conclusion of each intravascular 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 35.2406.
16. In lieu of 10 CFR 35.404, immediately after retracting the source from the patient into its shielded position in the intravascular brachytherapy device, a radiation survey shall be made of the patient and the intravascular brachytherapy 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 35.2404.
17. 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. 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.
 - 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.

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- 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.
- F. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
18. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
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 number, and the date of the inventory.
20. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.
21. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
22. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash, provided:
- A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.
 - B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
23. 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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24. The intravascular brachytherapy afterloader device shall be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair shall be performed by the manufacturer or persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
25. 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 October 5, 1990
 - B. Letter dated April 23, 1991
 - C. Letter dated June 11, 1993
 - D. Letter dated June 14, 1993
 - E. Letter dated June 21, 1993
 - F. Letter dated August 11, 1993
 - G. Letter dated August 19, 1993
 - H. Letter dated August 31, 1993
 - I. Letter dated March 11, 1994
 - J. Letter dated May 31, 1994
 - K. Letter dated September 1, 1994
 - L. Letter dated January 13, 1995
 - M. Letter dated April 15, 1996
 - N. Letter dated June 24, 1996
 - O. Letter dated October 30, 1996
 - P. Letter dated December 22, 1997
 - Q. Letter dated May 5, 1999
 - R. Letter dated September 18, 1999
 - S. Letter dated October 2, 2000
 - T. Letter dated December 18, 2000
 - U. Letter dated April 3, 2001
 - V. Letter dated April 18, 2001
 - W. Letter dated July 2, 2001
 - X. Letter dated July 31, 2001
 - Y. Letter dated June 14, 2002
 - Z. Letter dated May 28, 2003, except items relating to mobile HDR services
 - AA. Letter dated July 10, 2003
 - BB. Letter dated July 14, 2003
 - CC. Letter dated April 2, 2004
 - DD. Letter dated April 23, 2004

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For the U.S. Nuclear Regulatory Commission

Original signed by Tara L. Weidner

Date January 5, 2005

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By

Tara L. Weidner

Medical Branch

Division of Nuclear Materials Safety

Region I

King of Prussia, Pennsylvania 19406