



Medical Physics Department

To: Toye Simons  
Materials Licensing Branch  
USNRC Region III  
2443 Warrenville Road  
Lisle, IL 60532-4351  
Fax: 630 515 1078

October 27, 2010

RE: 13-15882-01 License amendment

Mrs. Simmons:

Please re-add on our license the user Erlinda Roque-Kerekas, MD as AU for 35.300. Please find attached our amendment 61 that lists Erlinda Roque-Kerekas, MD as AU for 35.300.

If you need additional information, please contact me at 219-836-7368 Voice, 219-852-6487 Fax, or MPALAMARU@COMHS.ORG E-mail.

Sincerely,

  
Mirel Palamaru, MS., DABR Regional Director  
Medical Physics  
Radiation Safety Officer

cc: RSC



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, ILLINOIS 60532-4352

SEP 28 2006

Eric Zickgraf, Ph.D.  
Radiation Safety Officer  
The Community Hospital  
901 MacArthur Blvd  
Munster, IN 46321

Dear Dr. Zickgraf:

Enclosed is Amendment No. 61 to your NRC Material License No. 13-15882-01 in accordance with your request. Please note that the changes made to your license are printed in **bold** font.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability. The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf> and the link for frequently asked questions regarding protection of security related sensitive information may be located at: <http://www.nrc.gov/reading-rm/sensitive-info/faq.html>. A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room)

Sincerely,

A handwritten signature in cursive script that reads "Toye L. Simmons".

Toye L. Simmons  
Materials Licensing Branch

License No. 13-15882-01  
Docket No. 030-09964

Enclosure: Amendment No. 61

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Amendment No. 61

**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. The Community Hospital</p> <p>2. 901 MacArthur Boulevard Munster, IN 46321</p>	<p>In accordance with the letter dated <b>July 13, 2006</b>,</p> <p>3. License number 13-15882-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date August 31, 2015</p> <hr/> <p>5. Docket No. 030-09964 Reference No.</p>
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<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>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Sealed sources (3M Model 6D6C; IPL Models 67-800 Series, 67-820 Series, 67-6500 Series; 3M Models 6711, 6702; Best Medical Int. Model 2301; Theragenics Model 125.S06; IsoAid Model Advantage; Draximage LS-1; Bard Model STM 1251; Implant Science Corp. Model 3500; North American Scientific Model MED 3631; Isotope Products Model I125.S06; and Best Medical International Model 81-01)</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 curie</p> <p>D. 3 curies</p>
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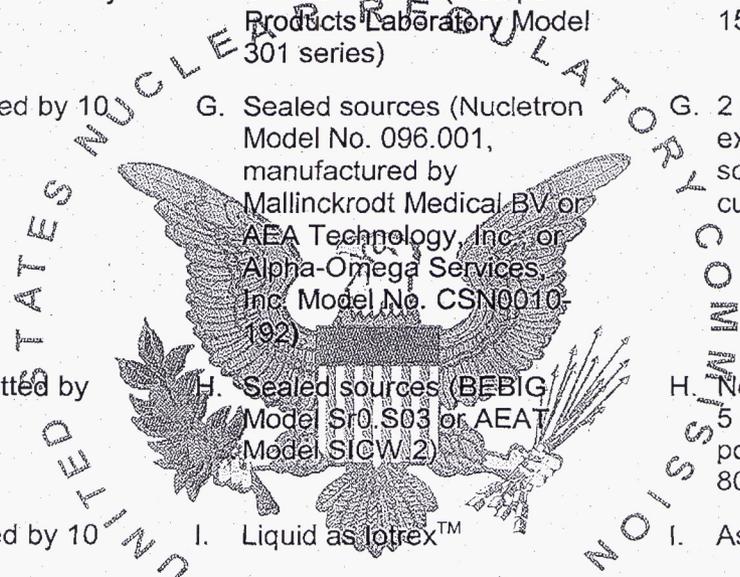
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- |   |  |  |
|---|--|--|
| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form   | 8. Maximum amount that licensee may possess at any one time under this license               |
| E. Any byproduct material identified in 10 CFR 31.11  | E. Prepackaged Kits  | E. As needed   |
| F. Americium-241 permitted by 10 CFR 35.500           | F. Sealed source (Isotopes Products Laboratory Model 301 series)   | F. 1 source not to exceed 150 millicuries  |
| G. Iridium-192 permitted by 10 CFR 35.600             | G. Sealed sources (Nucletron Model No. 096.001, manufactured by Mallinckrodt Medical BV or AEA Technology, Inc. or Alpha-Omega Services, Inc. Model No. CSN0010-192) | G. 2 sources, 1 source not to exceed 12 curies and 1 source not to exceed 10 curies          |
| H. Strontium-90 permitted by 10 CFR 35.1000           | H. Sealed sources (BEBIG Model Sr0, S03 or AEAT Model SICW 2)  | H. No single source to exceed 5 millicuries; total possession not to exceed 800 millicuries. |
| I. Iodine-125 permitted by 10 CFR 35.1000             | I. Liquid as Iotrex™   | I. As needed   |
| J. Iridium-192 permitted by 10 CFR 35.600             | J. Sealed sources (Nucletron Model No. 105.002, manufactured by Mallinckrodt Medical BV or AEA Technology, Inc.)   | J. 2 sources, total possession not to exceed 21 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.

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- C. Any diagnostic and therapy study permitted by 10 CFR 35.300.
- D. Any manual brachytherapy use permitted by 10 CFR 35.400.
- E. In vitro studies.
- F. One source for use in a Siemens Music Attenuation Correction System MULTISPEC3 line source device for diagnostic medical use permitted by 10 CFR 35.500.
- G. One source for therapeutic medical use permitted by 10 CFR 35.600, in a Nucletron-Oldelft Corporation MicroSelectron HDR Classic remote afterloading brachytherapy device. The source activity may not exceed 10 curies at the time of installation. One source (not to exceed 12 curies while stored pending installation) in a shipping container for source replacement.
- H. The source assemblies may be used in Novoste Model A1000-series devices for medical use permitted by 10 CFR 35.1000; source assemblies may also be used for physics calibrations and quality assurance testing; one source assembly in a shipping container for replacement and disposal.
- I. For medical use permitted by 10 CFR 35.1000 in Proxima Therapeutics' GliaSite® Radiotherapy System.
- J. One source for therapeutic medical use permitted by 10 CFR 35.600, in a Nucletron Corporation MicroSelectron HDR Model 105-999 remote afterloading brachytherapy device. The source activity may not exceed 12 curies at the time of installation. One source (not to exceed 13 curies while stored pending installation) in a shipping container for source replacement.

**CONDITIONS**

- 10. Location of Use: 901 MacArthur Boulevard, Munster, Indiana.
- 11. A. Radiation Safety Officer: Eric C. Zickgraf, Ph.D.  
B. Authorized Medical Physicists: Eric Zickgraf, Ph.D. and Zenan Hu, 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 authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

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B. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users

Material and Use

John W. Gustaitis, Jr., M.D.

10 CFR 35.100, 35.200, 35.300, 35.500, 31.11 and americium-241 in Siemens MULTISPECT3 line source device for diagnostic medical use permitted by 35.500.

Wail Asfour, M.D.

10 CFR 35.100 and 35.200 (excluding generators, xenon-133 and aerosols) limited to cardiovascular clinical procedures.

Andrej Zajac, M.D.

10 CFR 35.300, 35.400, 35.500, iridium-192 in remote afterloading brachytherapy unit for medical use permitted by 35.600; strontium-90 in Novoste Model A1000 series intravascular brachytherapy devices and iodine-125 in the Proxima Therapeutics' GlioSite<sup>®</sup> Radiotherapy system for medical use permitted by 35.1000.

Michael A. Nicholas, D.O.

10 CFR 35.100 and 35.200 (excluding generators, xenon-133 and aerosols) limited to cardiovascular clinical procedures and americium-241 in Siemens MULTISPECT3 line source device for diagnostic medical use permitted by 35.500.

Robert Litchfield, D.O.

10 CFR 35.100 and 35.200 (excluding generators, xenon-133 and aerosols) limited to cardiovascular clinical procedures and americium-241 in Siemens MULTISPECT3 line source device for diagnostic medical use permitted by 35.500.

Kenneth J. Ramsey, D.O.

10 CFR 35.100 and 35.200 (excluding generators, xenon-133 and aerosols) limited to cardiovascular clinical procedures and americium-241 in Siemens MULTISPECT3 line source device for diagnostic medical use permitted by 35.500.

Ali H. Kutom, M.D.

10 CFR 35.100 and 35.200 (excluding generators, xenon-133 and aerosols) limited to cardiovascular clinical procedures.

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- Vijay P. Shah, M.D. 10 CFR 35.100 and 35.200 (excluding generators, xenon-133 and aerosols) limited to cardiovascular clinical procedures.
- Thomas M. Hoess, M.D. 10 CFR 35.100, 35.200, 35.500, 31.11, and americium-241 in Siemens MULTISPECT3 line source device for diagnostic medical use permitted by 35.500.
- Riyaz H. Nomani, M.D. 10 CFR 35.100 and 35.200 (excluding generators and xenon-133) limited to cardiovascular clinical procedures.
- Jong-Yuan Kuo, M.D. 10 CFR 35.100, 35.200, 35.300, 35.500 and 31.11.
- Arvind N. Gandhi, M.D. 10 CFR 35.100 and 35.200 (excluding generators, xenon-133 and aerosols) limited to cardiovascular clinical procedures.
- David Bryant, M.D. 10 CFR 35.300, 35.400, 35.500, iridium-192 in remote afterloading brachytherapy unit for medical use permitted by 35.600, strontium-90 in Novoste Model A1000 series intravascular brachytherapy devices and iodine-125 in the Proxima Therapeutics' Gliasite® Radiotherapy system for medical use permitted by 35.1000.
- Mark T. Nootens, M.D. 10 CFR 35.100 and 35.200 (excluding generators, xenon-133 and aerosols) limited to cardiovascular clinical procedures.
- Shawn R. Kenney, M.D. 10 CFR 35.100, 35.200, 35.500, 31.11 and americium-241 in Siemens MULTISPECT3 line source device for diagnostic medical use permitted by 35.500.
- Jonathon T. Lee, M.D. 10 CFR 35.100, 35.200, 35.300, 35.500, 31.11 and americium-241 in Siemens MULTISPECT3 line source device for diagnostic medical use permitted by 35.500.
- Francis X. Roche, M.D. 10 CFR 35.100, 35.200, 35.300, and 31.11.
- Krishnakant Raiker, M.D. 10 CFR 35.100 and 35.200 (excluding generators, xenon-133 and aerosols) limited to cardiovascular clinical procedures.

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- Erlinda Roque-Kerekas, M.D. 10 CFR 35.100, 35.200, 35.300, 35.500, 31.11 and americium-241 in Siemens MULTISPECT3 line source device for diagnostic medical use permitted by 35.500.
- Mohamad S. Martini, M.D. 10 CFR 35.100 and 35.200 (excluding generators, xenon-133 and aerosols) limited to cardiovascular clinical procedures.
- Sandhya Donepudi, M.D. 10 CFR 35.100 and 35.200 (excluding generators) limited to cardiovascular clinical procedures.
- Ionut Oravitan, M.D. 10 CFR 35.100 and 35.200 (excluding generators) limited to cardiovascular clinical procedures.
- Jaime Cebedo, M.D. 10 CFR 35.100 and 35.200 (excluding generators and xenon-133) and 35.300.
- Mikhail Jeha, M.D. 10 CFR 35.100 and 35.200 (excluding generators and xenon-133).
- Jesse Reyes, M.D. 10 CFR 35.100 and 35.200 (excluding generators and xenon-133).
- Mary Nicholson, M.D. 10 CFR 35.100, 35.200, 35.500, 31.11, americium-241 in Siemens MULTISPECT3 line source device for diagnostic medical use permitted by 35.500.
- Miguel Gambetta, M.D. 10 CFR 35.100, 35.200 (limited to cardiovascular clinical procedures).
- Mohan Kesani, M.D. 10 CFR 35.100, 35.200 (excluding generators) limited to cardiovascular clinical procedures.
- Sheeyp J. Chan, D.O. 10 CFR 35.100, 35.200 (excluding generators, xenon-133 and aerosols) limited to cardiovascular clinical procedures.

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Anupama W. Thakrar, M.D.

10 CFR 35.300, 35.400, 35.500, iridium-192 in remote afterloading brachytherapy unit for medical use permitted by 35.600, strontium-90 in Novoste Model A1000 series intravascular brachytherapy devices and iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy system for medical use permitted by 35.1000.

Charles-Lauwanga Okoro, D.O.

10 CFR 35.200 (excluding generators, xenon-133, and aerosols) limited to cardiovascular clinical procedures.

13. Licensed material listed in Subitem No. H. of Items 6., 7., 8., and 9. shall be used by or under the supervision of an authorized user named in Condition No. 12., and in the physical presence of an authorized user named in Condition No. 12. or a medical physicist who meets the requirements in 10 CFR 35.961. The authorized user named in Condition No. 12. shall consult with a medical physicist who meets the requirements in 10 CFR 35.961 and an interventional cardiologist prior to each treatment.
14. 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.
15. 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. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
  - C. 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.
  - D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

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- E. 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.
  - F. 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.
  - G. 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.
16. In lieu of 10 CFR 35.404(b), immediately after retracting the source from the patient into its shielded position in the Novoste A1000 series intravascular brachytherapy device, a radiation survey shall be made of the patient and the Novoste Beta-Cath System 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(c).
17. In lieu of the source inventory required 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 Novoste A1000 series intravascular brachytherapy treatment.
  - 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 the survey instrument used, dose rate expressed in mrem/hr ( $\mu$ Sieverts/hr), 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(c).
18. The licensee shall conduct a physical inventory every 6 months to account for all sealed 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 numbers, and the date of the inventory.
19. 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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20. 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 May 19, 2005; and
  - B. Letters dated July 29, 2005, July 13, 2006 and September 22, 2006.



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date SEP 28 2006

By

Toye L. Simmons  
Materials Licensing Branch  
Region III