

## UNITED STATES NUCLEAR REGULATORY COMMISSION REGION IV 611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TEXAS 76011-4005

June 22, 2006

Avera St. Luke's dba Avera St. Luke's Hospital ATTN: Stephen R. Peters, M.D. Radiation Safety Officer 305 South State Street Aberdeen, South Dakota 57401

SUBJECT: LICENSE AMENDMENT

Please find enclosed Amendment No. 29 to License No. 40-18000-01, **authorizing the release for unrestricted use of the old location of the North Central Heart Clinic.** Please note that **license condition no. 10.B. was updated to reflect the new location of use of the North Central Heart Clinic (second floor of 305 South State Street).** An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14)(iv). You should review this license carefully and be sure that you understand all conditions. If you have any questions, you may contact me at 817-860-8189.

NRC's Regulatory Issue Summary (RIS) 2005-31, provides criteria to identify securityrelated sensitive information and guidance for handling and marking such documents. This ensures that potentially sensitive information is not made publicly available through NRC's electronic document system (ADAMS). The RIS may be located on the NRC Web site at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ and the link for frequently asked questions may be located at: http://www.nrc.gov/readingrm/sensitive-info/faq.html. Pursuant to NRC's RIS 2005-31, this letter and its accompanying materials license will be made publicly available.

NRC expects licensees to conduct their programs with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your radiation safety program according to the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

- 1. Operate by NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
- 2. Notify NRC in writing of any change in mailing address.

- 3. By 10 CFR 30.36(d) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
  - a. When you decide to terminate all activities involving materials authorized under the license whether at the entire site or any separate building or outdoor area; or
  - b. If you decide not to acquire or possess and use authorized material; or
  - c. When no principal activities under the license have been conducted for a period of 24 months.
- 4. In accordance with 10 CFR 35.14, notify the NRC no later than 30 days after:
  - a. The date that the licensee permits an individual to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under 10 CFR 35.13(b)(1) through (b)(4);
  - b. An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues duties under the license or has a name change;
  - c. The licensee's mailing address changes;
  - d. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 10 CFR 30.34(b); or
  - e. The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either 35.100 or 35.200.
- 5. Request and obtain a license amendment before you:
  - a. Change Radiation Safety Officers;
  - b. Order byproduct material in excess of the amount, radionuclide or form authorized on the license;
  - c. Add or change the areas or address(es) of use identified in the license application or on the license, except for areas of use where byproduct material is used only in accordance with either 10 CFR 35.100 or 35.200; or
  - d. Change the name or ownership of your organization.
- Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant. Since the NRC also accepts a letter requesting amendment or renewal of an NRC license, the signatory for such a request should also be the licensee or certifying official rather than a consultant.

NRC will periodically inspect your radiation safety program. Failure to conduct your program according to NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action against you. This could include issuance of a notice of violation; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the NRC Enforcement Policy.

The NRC no longer publishes the <u>NRC Rules and Regulations</u> loose leaf supplements due to budget constraints. However, an electronic version of the NRC's regulations is available on the NRC Web site at <u>www.nrc.gov</u>. To view these regulations, highlight "Electronic Reading Room" and choose "Regulations" on the drop down menu. An electronic version of the NUREG-1556 Series publications is also available on the NRC Web site. To view these guidance documents, highlight "Electronic Reading Room"; choose "All Document Types" on the drop down menu; scroll down to "NUREG-Series Publications"; and select "Publications Prepared by the NRC Staff". Then, choose "NUREG-1556" from the table and select the appropriate volume(s) for your license type.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <a href="http://www.nrc.gov/reading-rm/adams.html">http://www.nrc.gov/reading-rm/adams.html</a>.

Thank you for your cooperation.

Sincerely,

## /**RA**/

Roberto J. Torres, Senior Health Physicist Nuclear Materials Licensing Branch

Docket: 030-13778 License: 40-18000-01 Control: 470935

Enclosure: As stated

PAGE NRC FORM 374 1\_\_\_OF\_\_\_\_ 3 PAGES U.S. NUCLEAR REGULATORY COMMISSION Amendment No. 29 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 dated March 24, 2006 1. Avera St. Luke's 3. License number 40-18000-01 is amended in dba Avera St. Luke's Hospital EAR its entirety to read as follows: 2. 305 South State Street 4. Expiration date June 30, 2015 Aberdeen, South Dakota 57401 5. Docket No. 030-13778 Reference No. 6. Byproduct, source, and/or special 7. Chemical and/or physical form 8. Maximum amount that licensee may nuclear material possess at any one time under this license A. Any byproduct material A. As needed Any permitted by 10 CFR 35.100 Any B. As needed B. Any byproduct material Β. permitted by 10 CFR 35.200 C. Any C. Any byproduct material 400 millicuries permitted by 10 CFR 35.300 Sealed Sources (3M Health D. Any byproduct material D. 940 millicuries D. permitted by 10 CFR 35.400 Physics Service, Model 6500 Series, Amersham Corporation Model CDC.S) E. Any byproduct material E. Prepackaged Kits E. 100 millicuries permitted by 10 CFR 31.11 F. Sealed sources (Isotope F. Gadolinium-153 F. 300 millicuries per housing; Products Laboratories, total possession 1 curie Model NES8412) G. Strontium-90 G. Sealed sources (ICN Model G. 60 millicuries M1, and Nuclear Enterprises Model 2503) 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 use permitted by 10 CFR 35.300. D. Any manual brachytherapy procedure permitted by 10 CFR 35.400. E. In vitro studies.

NRC FORM 374A	U.S. NUCLEAR REGULATORY COMMIS	SION PAGE 2 of 3 PAGES		
		License Number 40-18000-01		
MATERIALS LICENSE SUPPLEMENTARY SHEET		Docket or Reference Number 030-13778		
		Amendment No. 29		
<ul> <li>F. To be used for attenuation correction in an ADAC Laboratories Model Vantage line source housing for SPECT cameras.</li> <li>G. Storage only pending disposal.</li> </ul>				
CONDITIONS				
<ol> <li>A. Licensed material may be used or stored only at the licensee's facilities located at Avera St. Luke's Hospital, 305 South State Street, Aberdeen, South Dakota.</li> </ol>				
B. Licensed material may be used only at the licensee's facilities located at North Central Heart Clinic, 305 South State Street, 2 <sup>nd</sup> Floor, Aberdeen, South Dakota.				
11. The Radiation Safety Officer for this license is Stephen R. Peters, M.D.				
12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of:				
Authorized U	sers 🗧 💊 💬	Material and Use		
Roy G. Burt,	M.D. 5	31.11		
Lawrence Ale	exander, M.D.	31.11		
Melchor J. Ag	guilar, M.D.	35.100; 35.200, Gadolinium-153 for patient attenuation correction		
Douglas Kimi	mel, M.D.	35.100; 35.200; Gadolinium-153 for patient attenuation correction		
Caroline J. Lu	undell, M.D.	35.100; 35.200; Gadolinium-153 for patient attenuation correction		
Sheryl Ann S	iegmund, M.D.	35.100; 35.200; Gadolinium-153 for patient attenuation correction		
Larry S. Sida	way, M.D.	35.100; 35.200; Gadolinium-153 for patient attenuation correction		
Stephen R. P	Peters, M.D.	35.100; 35.200; 35.300; 31.11; Gadolinium-153 for patient attenuation correction		
Leslie H. Len	ter, M.D.	35.100; 35.200; 35.300; 35.400; 31.11; Gadolinium-153 for patient attenuation correction		
Enrique F. M	endoza, M.D.	35.300; 35.400		

NRO	C FORM	I 374A U.S. NUCLEAR REGULATORY COMMISSION	PAGE 3 of 3 PAGES		
			License Number 40-18000-01		
		MATERIALS LICENSE SUPPLEMENTARY SHEET	Docket or Reference Number 030-13778		
			Amendment No. 29		
13.	<ol> <li>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.</li> </ol>				
14.	<ol> <li>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."</li> </ol>				
15. 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.					
	<ul> <li>A. Application dated January 12, 2005</li> <li>B. Email dated May 25, 2005</li> <li>C. Letter dated December 12, 2005</li> <li>D. Letter dated March 24, 2006</li> </ul>				
		FOR THE U	J.S. NUCLEAR REGULATORY COMMISSION		
		/RA/	,		

By:

Date: June 22, 2006

Roberto J. Torres, Senior Health Physicist Nuclear Materials Licensing Branch Region IV Arlington, Texas 76011