

Roldan, Lizette

From: Roldan, Lizette
Sent: Tuesday, March 22, 2011 11:10 AM
To: 'ssivak@stlukehealthnet.org'
Subject: REQUEST FOR ADDITIONAL INFORMATION REGARDING CONTROL 574440

License No: 25-29421-01
Docket No.: 030-38419
Control No.: 574440

Dear Mr. Sivak

This is in reference to application dated February 2, 2011 requesting a Nuclear Regulatory Commission License 25-29421-01. In order to continue our review, we need the following information:

1. In support of your request to name Dr. Arthur K. Harris as the Radiation Safety Officer (RSO), please provide one of the following, as applicable:
 - a. Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the physician was specifically named as an RSO for the uses requested; **AND** items outlined in 1d and 1e below; **OR**
 - b. Copy of certification by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The following link provides a list of specialty boards recognized by the NRC under Part 35: <http://www.nrc.gov/materials/miau/med-use/toolkit/spec-board-cert.html>. **AND** items outlined in 1d and 1e below; **OR**
 - c. Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which you seek approval; **AND** items outlined in 1d and 1e below.
 - d. Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO; **AND**
 - e. Written attestation, signed-by a preceptor RSO, that the individual has successfully completed the training and experience specified for certification, as well as the required training and experience in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO
 - f. If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

NRC Form 313A(RSO) (enclosed) may be used to document this information. Please note that if the board certification, or training and experience, was received more than 7 years ago, evidence of recentness of training in accordance with 10 CFR 35.59 must also be submitted.

2. If Dr. Harris is not qualified by any of the pathways listed above, please name a new individual and provide the documentation necessary to show the individual is qualified to be the RSO following one of the pathways listed above.

We will continue our review upon receipt of this information. Please reply to my attention at the Region IV Office and refer to Mail Control No. 574440. Please respond to this e-mail by April 22, 2011. You may reply via e-mail using a PDF format or by fax to 817-860-8263. If we do not receive a reply by the due date, we will assume that you do not wish to pursue your application.

Sincerely,

Lizette Roldán-Otero, Ph.D.

Health Physicist

Nuclear Regulatory Commission

612 E. Lamar Blvd., Suite 400

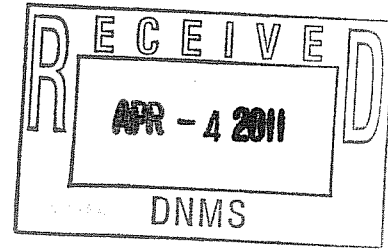
Arlington, TX 76011

Office: 817-276-6596

Fax: 817-860-8263

FROM: Steve Sivak RT (R)
St. Luke Community Hospital
107 6th Ave S
Ronan, MT 59864

TO: Lizette Roldan-Otero, Ph.D
Health Physicist
Nuclear Regulatory Commission
612 E. Lamar Blvd., Suite 400
Arlington, TX 76011



SUBJECT: Request for Change of Information Regarding Control No. 574440
License No.: 25-29421-01
Docket No.: 030-38419

Dear Ms. Roldan-Otero,

This letter is in response for your request for additional information regarding St. Luke's request for a Nuclear Regulatory Commission License, No. 25-29421-01.

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1. St. Luke's is requesting to replace Arthur K. Harris, MD as our Radiation Safety Officer with James H. Brewer, Ph. D.
 2. Please note I have attached a copy of License No. 25-18361-01, Expiration date May 31, 2013 as well as Docket No. 030-14921.
 3. Also attached is a copy of license for licensee:
Community Medical Center, Inc.
2827 Fort Missoula Rd
Missoula, MT 59804

If any additional information is required please contact us as we are looking forward to our April 14, 2011 meeting.

Sincerely,

A handwritten signature in cursive that reads "Steve Sivak RT (R)".
Steve Sivak, RT (R)
Radiology Director
St. Luke Community Hospital
107 6th Ave S.W.
Ronan, MT 59864
Office: 406-676-4441 EXT. 272
Fax: 406-676-0105

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 style="text-align: center;">Licensee</p> <p>1. Community Medical Center, Inc.</p> <p>2. 2827 Fort Missoula Road Missoula, Montana 59804</p>	<p>In accordance with letter dated May 18, 2009</p> <p>3. License number 25-18361-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date May 31, 2013</p> <p>5. Docket No. 030-14921 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 31.11</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Prepackaged kits</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. 500 millicuries</p> <p>D. 50 millicuries</p>
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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. In vitro studies.

CONDITIONS

10. A. Licensed material may be used or stored only at the licensee's facility located at 2827 Fort Missoula Road, Missoula, Montana.
- B. Licensed material permitted by 10 CFR 35.200 (except gases), may be used for nuclear cardiology procedures at temporary job sites of the licensee's anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States.

If the jurisdiction status of a Federal facility within an Agreement State is unknown, the licensee should contact the federal agency controlling the job site in question to determine whether the proposed job site is an area of exclusive Federal jurisdiction. Authorization for use of radioactive materials at job sites in Agreement States not under exclusive Federal jurisdiction shall be obtained from the appropriate state regulatory agency.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
25-18361-01

Docket or Reference Number
030-14921

Amendment No. 24

11. The Radiation Safety Officer for this license is James H. Brewer, Ph.D.
12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for the material and medical uses indicated:

<u>Authorized Users</u>	<u>Material and Use</u>
Newton B. Coutinho, M.D.	35.200
Alan A. Gabster, M.D.	35.200
William J. Birck, M.D.	35.100; 35.200; 31.11; oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries only for imaging and localization studies
Thomas A. Layne, M.D.	35.100; 35.200; 31.11; oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries only for imaging and localization studies
Kyle L. Dale, M.D.	35.100; 35.200; oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries
Joel A. Brake, M.D.	35.100; 35.200
Anthony R. D'Amico, M.D.	35.100; 35.200
Adam J. Benson, M.D.	35.100; 35.200; 35.300
Wayne L. Davis, M.D.	35.100; 35.200; 35.300; 31.11
Sarsfield Patrick Dougherty, M.D.	35.100; 35.200; 35.300; 31.11
Paul H. Eikens, M.D.	35.100; 35.200; 35.300; 31.11
Mark W. Elliott, M.D.	35.100; 35.200; 35.300; 31.11
Daniel M. Fruechte, M.D.	35.100; 35.200; 35.300; 31.11
James E. McKay, Jr., M.D.	35.100; 35.200; 35.300; 31.11
Michael A. Stewart, M.D.	35.100; 35.200; 35.300; 31.11
Michael R. Tryhus, M.D.	35.100; 35.200; 35.300; 31.11
Roy W. "Chip" Zimmer, III, M.D.	35.100; 35.200; 35.300; 31.11

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
25-18361-01Docket or Reference Number
030-14921

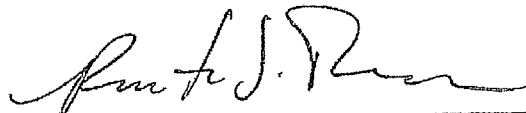
Amendment No. 24

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) for establishing decommissioning financial assurance.
14. 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."
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.
- A. Facsimile dated August 16, 2002 (ML023040685)
B. Application dated December 31, 2002 (ML030300316)
C. Facsimile dated May 16, 2003 (ML080580287)
D. Letter dated February 11, 2008 (ML080520608)
E. E-mails dated February 25 and 27, 2008 (ML080580278)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: June 11, 2009

By:

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



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
612 EAST LAMAR BOULEVARD, SUITE 400
ARLINGTON, TEXAS 76011-4125

June 11, 2009

Community Medical Center, Inc.
ATTN: James H. Brewer, Ph.D.
Radiation Safety Officer
2827 Fort Missoula Road
Missoula, Montana 59804

SUBJECT: LICENSE AMENDMENT

Please find enclosed Amendment No. 24 to NRC License No. 25-18361-01 **granting authorized user status to Kyle L. Dale, M.D., for the following uses: 10 CFR 35.100; 35.200; and oral administration of sodium iodide iodine-131 in quantities less than or equal to 33 millicuries.** An environmental assessment for this action is not required, since this licensing action is categorically excluded under 10 CFR 51.22(c)(14)(iv). You should review the enclosed document carefully and be sure that you understand all conditions. You can contact me at 817-860-8189 if you have any questions about this license.

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;
 - 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.
6. 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.

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 Enforcement Policy is available on the following internet address: <http://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

An electronic version of the NRC's regulations is available on the NRC Web site at www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web site at: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

Community Medical Center, Inc.

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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 <http://www.nrc.gov/reading-rm/adams.html>.

Thank you for your cooperation.

Sincerely,

A handwritten signature in black ink, appearing to read 'Roberto J. Torres', written in a cursive style.

Roberto J. Torres, Senior Health Physicist
Nuclear Materials Safety Branch B

Docket: 030-14921
License: 25-18361-01
Control: 472264

Enclosure: As stated
