

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION IV 612 EAST LAMAR BLVD, SUITE 400 ARLINGTON, TEXAS 76011-4125

January 18, 2010

Bryan LGH Medical Center d.b.a Bryan-LGH Heart Institute ATTN: Keith Miller, M.D. Radiation Safety Officer 1600 South 48th St. 5th Floor Lincoln, NE 68506

SUBJECT: APPARENT ENFORCEMENT ACTION REQUIRING A WRITTEN RESPONSE

Dr. Miller:

This letter is in regards to the legal entity change of Integrated Cardiology during the third quarter of 2008. It is our understanding that Integrated Cardiology was purchased by Bryan-LGH Medical Center, dba Bryan-LGH Heart Institute. On December 17, 2009, the NRC became aware of the legal change and that Bryan-LGH Heart Institute had worked in areas of NRC jurisdiction as a mobile medical service during the remainder of 2008 and calendar year 2009 without a general license as required by 10 CFR 150.20. In a telephone conversation and follow up email to Mr. Duane Kanne with Cardinal Health, who was contracted by your company to perform an annual audit, I informed him that your company would need to apply for reciprocity under 10 CFR 150.20 for calendar year 2009 and, if you wanted to continue to work in 2010 in areas of NRC jurisdiction then file for calendar year 2010 as well. On December 22, 2009, our office received the appropriate documents and payments for reciprocity activities for calendar years 2009 and 2010.

The NRC enforcement jurisdiction is drawn from the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. The primary purpose of the NRC's Enforcement Policy (Policy) is to support the NRC's overall safety mission in protecting the public health and safety and the environment. Consistent with the purpose, the Policy endeavors to deter noncompliance by emphasizing the importance of compliance with NRC requirements and encouraging prompt identification and prompt, comprehensive correction of violations. Therefore, licensees, contractors and their employees who do not achieve a high standard of compliance which the NRC expects will be subject to enforcement sanctions. Each enforcement action is dependent on the circumstances of the case.

There are several elements that the NRC evaluates to make a logical determination for the severity level of an apparent violation. These elements are more fully described in the Policy which is available on the NRC's Web site at: http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html, and include:

- 1. Actual consequences
- 2. Potential consequences
- 3. Impacting the regulatory process
- 4. Willfulness

Once these elements are addressed, then the NRC considers whether credit is given for no civil penalty. These questions include:

- 1. Previous enforcement?
- 2. Did the licensee identify the violations themselves?
- 3. Did the licensee have prompt and comprehensive corrective actions?

The NRC is considering escalated enforcement and the potential for civil penalty for apparent violations involving the failure to notify our office of the legal entity change of Integrated Cardiology and the failure to file for a general license under 10 CFR 150.20 for calendar year 2009. In order to review the information regarding the apparent violations and the corrective actions taken by Bryan-LGH Heart Institute, we request a written response from you. Please provide the following information.

- 1. Summary of the events that happened and the circumstances contributing to the apparent violations for not filing for a general license under 10 CFR 150.20 for Calendar Year 2009. for not submitting any further dates after August 2008 as a new entity due to the legal entity change, and for not informing the NRC of the legal entity change prior to the effected date of the change. The regulation under 10 CFR 30.34(b) states in part that no license issued or granted pursuant to the regulations nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing. Although not specifically addressed by 10 CFR 30.34. licensees undergoing a name change and general licenses may also be affected by this regulation. Licensees must notify the Commission when they are undergoing a possible change of control and/or a change of name. While this notification is not required within a certain time frame, NRC needs adequate time to review the submittal to ensure that the transfer is in accordance with the regulations.
- 2. Provide a complete description of the transaction, including the name change. Describe any personnel or duties that relate to the licensed program that changed as a result of the legal entity change.
- 3. Provide the list of dates that were worked in NRC jurisdiction during the remainder of Calendar Year 2008 and Calendar Year 2009, under the legal entity change to Bryan-LGH Heart Institute.
- 4. Provide detailed information regarding the prompt and comprehensive corrective actions that have and will be taken to ensure they are lasting and effective.

Please provide your response to this request within 20 business days. If you need additional time to respond, please submit your request in writing or by email to this office at rachel.browder@nrc.gov. If you have any questions regarding this letter or working in NRC jurisdiction, please contact me at 817-276-6552 or Ms. Michelle Simmons at 817-276-6590.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter 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.

Sincerely,

Rachel S. Browder, Sr. Health Physicist Nuclear Materials Safety Branch B

License No.: 150-00026

CC:

Michelle Simmons, DNMS/NMSBB

Mr. Joe Milone Bryan LGH Medical Center d.b.a Bryan-LGH Heart Institute 1600 South 48th St. 5th Floor Lincoln, NE 68506