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

August 18, 2010

EA-10-066

Ms. Joan Casey, CAO
Bryan LGH Medical Center
dba Bryan LGH Heart Institute
1600 South 48th St., 5th Floor
Lincoln, NE 68506

SUBJECT: NRC INSPECTION REPORT 150-00026/10-001 AND NOTICE OF VIOLATION

Dear Ms. Casey:

This letter refers to the in-office inspection conducted between December 22, 2009, and July 23, 2010, regarding Bryan LGH Medical Center dba Bryan LGH Heart Institute (Bryan Heart). The in-office inspection was a review of mobile nuclear medicine operations conducted in NRC jurisdiction during calendar year 2009 and included an examination of activities conducted under the State of Nebraska Radioactive Materials License 02-52-01 and compliance with the Commission's rules and regulations. Within these areas, the inspection consisted of telephonic interviews with Bryan Heart personnel and reviews of electronic documents submitted to the NRC. On May 11, 2010, the NRC held a preliminary exit meeting telephonically with Bryan Heart staff. The NRC conducted an exit briefing telephonically with you on July 23, 2010. The enclosed report presents the results of this in-office inspection.

During the preliminary telephonic exit briefing, Mr. Jack Whitten and Ms. Michelle Simmons of my staff informed you that the NRC was considering escalated enforcement for an apparent violation of NRC requirements. The apparent violation involved the failure to file a submittal to engage in licensed activities in NRC jurisdiction as required by 10 CFR 150.20(b). A general license is granted in accordance with 10 CFR 150.20(a), to any person who holds a specific license from an Agreement State, provided, in part, the provisions in 10 CFR 150.20(b) are met. Specifically, it appears you did not file a submittal containing an initial NRC Form 241, a copy of your State of Nebraska Radioactive Materials License, and the appropriate reciprocity fee prior to conducting mobile nuclear medicine operations in the state of Missouri, an area of NRC jurisdiction, during calendar year 2009. The circumstances surrounding the apparent violation, the significance of the issues, and the need for lasting and effective corrective actions were discussed with you during the inspection exit briefing. Additionally, you have initiated corrective actions to address the apparent violation. These corrective actions are documented in the subject inspection report and in your letter dated May 13, 2010. Further, we provided you an opportunity to (1) respond to the apparent violation addressed in this inspection report within 30 days of the date of this letter or (2) request a predecisional enforcement conference.

During the final exit briefing on July 23, 2010, Mr. Whitten informed you that the NRC had sufficient information regarding the apparent violation and your corrective actions to make an enforcement decision without the need for a predecisional enforcement conference or a written

response from you. You agreed that a predecisional enforcement conference was not needed and stated that you had no further information to convey through a written response.

Therefore, based on the information developed during the in-office inspection and the information you provided in your letter dated May 13, 2010, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding the violation are described in detail in the subject inspection report. As noted above, the violation involved the failure to file a submittal containing an NRC Form 241, "Report of Proposed Activities in Non-Agreement States," a copy of your Agreement State specific license, and the appropriate fee as prescribed in 10 CFR 170.31, prior to engaging in licensed activities within NRC jurisdiction in calendar year 2009.

The NRC considers this violation significant because when an Agreement State licensee fails to file for reciprocity prior to conducting licensed activities in NRC jurisdiction, the NRC's ability to meet its regulatory responsibility to ensure that those activities are conducted in a safe and secure manner is impacted. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III. The NRC Enforcement Policy may be found on the NRC's Web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $3,500 is considered for a Severity Level III violation.

Because your facility has not been the subject of escalated enforcement actions within the last two years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Based on your prompt and comprehensive corrective actions, the NRC has determined that *Corrective Action* credit is warranted. Your immediate corrective actions included halting licensed activities upon notification that reciprocity was required and promptly filing a submittal containing an NRC Form 241, "Report of Proposed Activities in Non-Agreement States," a copy of your Agreement State specific license, and the appropriate fee as prescribed in 10 CFR 170.31 for calendar years 2009 and 2010. Your long-term corrective actions included reviewing of applicable NRC regulations; placing an annual calendar alert for early December in the radiation safety officer's electronic calendar indicating the need to file the annual reciprocity forms with the NRC; completing a review by both Bryan LGH Medical Center and Bryan Heart staff of the NRC records manual containing reciprocity records in an effort to ensure continuity of the reciprocity program and to ensure that more than one individual is familiar with the reciprocity records and their specific location; ensuring that all NRC correspondence is provided to both Bryan LGH Medical Center and Bryan Heart; posting reciprocity documents in the mobile nuclear medicine laboratory; and performing a review of reciprocity documentation located in the mobile nuclear medicine laboratory during quarterly radiation safety audits.

Therefore, to encourage prompt and comprehensive correction of violations I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report 150-00026/10-001 and your letter dated May 13, 2010. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC's Web site at http://www.nrc.gov/reading-rm/adams.html.

Should you have any questions regarding this letter, the enclosed report, or the enclosed Notice, please contact Mr. Jack Whitten, Chief, Nuclear Materials Safety Branch B at (817) 860-8197.

Sincerely,

/RA/ by CC for

Elmo E. Collins
Regional Administrator

Docket: 150-00026
License: General License Pursuant to
10 CFR 150.20 (NE License 02-52-01)

Enclosures:
1. Notice of Violation
2. Inspection Report 150-00026/10-001

cc w/Enclosures 1 and 2
Julia A. Schmitt, Program Manager
NE Dept. of Health & Human Services
Division of Public Health
P.O. Box 95026
Lincoln, NE 68509-5026

Keith Henke, Planner
Dept of Health and Senior Services
Section for Environmental Public Health
P.O. Box 570
Jefferson City, MO 65102-0570

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Hard Copy:
RIV Materials Docket File - 5th floor

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ADAMS	☐ No	☑ Yes	☑SUNSI Review Complete	Reviewer Initials: MCM
☑ Publicly Available	☐Non-publicly Available	☐Sensitive	☑ Non-sensitive	
Category – **KEYWORD**:	NOV EA-10-066 Bryan LGH Heart Institute			

RIV:DNMS:NMSBB	BC:NMSBB	ACES	RC	D:DNMS
MRSimmon	JEWhitten	MCMaier	KSFuller	ATHowell
/RA/	***/RA/***	***/RA/***	***/RA/***	***/RA/ w/comments***
07/28/2010	07/28/2010	08/04/2010	08/04/2010	08/04/2010

DRA	OE	RA		
CACasto	LSreenivas	EECollins		
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08/05/2010	08/17/2010	08/18/2010		

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NOTICE OF VIOLATION

Bryan LGH Medical Center
dba Bryan LGH Heart Institute
Lincoln, Nebraska

Docket 150-00026
License 02-52-01
EA-10-066

During an NRC in-office inspection conducted between December 22, 2009, and July 23, 2010, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 150.20(a)(1) provides, in part, that any person who holds a specific license from an Agreement State is granted an NRC general license to conduct the same activity in non-Agreement States and areas of exclusive Federal jurisdiction within Agreement States provided that the provisions of 10 CFR 150.20(b) have been met.
>
> 10 CFR 150.20(b)(1) requires, in part, that any person engaging in activities in a non-Agreement State or in an area of exclusive Federal jurisdiction within an Agreement State, shall at least 3 days before engaging in each activity for the first time in a calendar year, file a submittal containing an NRC Form 241, "Report of Proposed Activities in Non-Agreement States," a copy of its Agreement State specific license, and the appropriate fee as prescribed in 10 CFR 170.31 with the Regional Administrator for the region in which the Agreement State that issued the license is located.
>
> Contrary to the above, the licensee failed to, at least 3 days before engaging in licensed activities for the first time in calendar year 2009, file a submittal containing an NRC Form 241, "Report of Proposed Activities in Non-Agreement States," a copy of its Agreement State specific license, and the appropriate fee as prescribed in 10 CFR 170.31, with the Regional Administrator for the region in which the Agreement State that issued the license is located. Specifically, as of December 16, 2009, Bryan LGH Medical Center dba Bryan LGH Heart Institute, a holder of a Nebraska State license, provided mobile nuclear medicine services at a temporary job site in the State of Missouri, a non-Agreement State, without filing a reciprocity submittal for calendar year 2009 with the Regional Administrator, NRC Region IV.

This is a Severity Level III violation (Supplement VI).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report 150-00026/10-001 and the letter from the Licensee dated May 13, 2010. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation; EA-10-066", and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region IV, 612 East Lamar Blvd., Suite 400, Arlington, Texas 76011-4125, within 30 days of the date of the letter transmitting this Notice.

ENCLOSURE 1

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC's Web site at www.nrc.gov/reading-rm/pdr.html or www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within 2 working days.

Dated this 18th day of August 2010

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket:	150-00026
Report:	150-00026/10-001
General Licensee:	Bryan LGH Medical Center dba Bryan LGH Heart Institute
EA:	EA-10-066
Location:	Lincoln, Nebraska
Dates:	December 22, 2009 – July 23, 2010
Inspector:	Michelle Simmons, Health Physicist Nuclear Materials Safety Branch B
Approved By:	Jack E. Whitten, Chief Nuclear Materials Safety Branch B
Attachment:	Supplemental Inspection Information

ENCLOSURE 2

EXECUTIVE SUMMARY

Bryan LGH Medical Center dba Bryan LGH Heart Institute
NRC Inspection Report 150-00026/10-001

Bryan LGH Medical Center dba Bryan LGH Heart Institute (Bryan Heart) is a medical licensee in the State of Nebraska. Bryan Heart provides mobile nuclear medicine services at a temporary job site in the State of Missouri under its State of Nebraska Radioactive Materials License 02-52-01. The State of Missouri is a non-Agreement State. Bryan Heart has previously worked in areas of NRC jurisdiction under the name Intergrated Cardiology. Integrated Cardiology was purchased by Bryan Heart Medical Center in August 2008 and the name changed to Bryan LGH Medical Center dba Bryan LGH Heart Institute. Therefore, Bryan Heart has a history of working in areas of NRC jurisdiction under the provisions of a general license issued pursuant to 10 CFR 150.20, "Recognition of Agreement State Licenses."

Bryan Heart contacted the NRC on December 17, 2009, to request reciprocity for mobile nuclear medicine activities being conducted in the State of Missouri during calendar year 2009. On December 16, 2009, an annual radiation safety audit was performed by a contractor hired by Bryan Heart. During the audit, it was discovered that Bryan Heart had inadvertently failed to file for reciprocity and pay the required fee prior to performing licensed activities within NRC jurisdiction. Bryan Heart, after becoming aware of this failure to file for reciprocity, submitted the initial notification and the required fee for calendar years 2009 and 2010 on December 22, 2009. The NRC Region IV office conducted an in-office inspection between December 22, 2009, and July 23, 2010. An apparent violation of 10 CFR 150.20(b)(1) was identified.

10 CFR 150.20(b)(1) requires, in part, that any person engaging in activities in non-Agreement States shall, at least 3 days prior to engaging in each activity for the first time in a calendar year file a submittal containing an NRC Form 241, a copy of its Agreement State license, and the appropriate fee. A preliminary exit meeting was held with Bryan Heart on May 11, 2010, to discuss the circumstances surrounding the violation, the significance of the issue, the need for lasting and effective corrective actions, and the extent of circumstances. Additional long term corrective actions were submitted by Bryan Heart on May 13, 2010. A final exit meeting was held on July 23, 2010.

Report Details

Bryan LGH Medical Center dba Bryan LGH Heart Institute (Bryan Heart) is a medical licensee located in the State of Nebraska. Bryan Heart provides mobile nuclear medicine services at a temporary job site in the State of Missouri under its State of Nebraska Radioactive Materials License 02-52-01. The State of Missouri is a non-Agreement State and as such, the NRC retains the authority to license and inspect byproduct, source, and special nuclear materials used or possessed within Missouri borders. Bryan Heart contacted the NRC regarding reciprocity requirements when they discovered that in calendar year (CY) 2009 that they had inadvertently conducted licensed activities in the State of Missouri without filing for reciprocity with NRC.

1 Program Overview

1.1 Inspection Scope

The NRC evaluated the State of Nebraska licensee's activities under reciprocity as authorized by 10 CFR 150.20, "Recognition of Agreement State Licenses."

1.2 Observations and Findings

Bryan Heart is a State of Nebraska medical licensee that provides mobile nuclear medicine services at a temporary job site in the State of Missouri under its State of Nebraska radioactive materials license. The State of Missouri is a non-Agreement State under NRC regulatory authority. Bryan Heart has previously worked in areas of NRC jurisdiction under the provisions of a general license under the name Intergrated Cardiology. Integrated Cardiology was purchased by Bryan Heart Medical center in August 2008 and the name changed from Integrated Cardiology to Bryan LGH Medical Center dba Bryan LGH Heart Institute. Therefore Bryan Heart under the name Integrated Cardiology has a history of working in areas of NRC jurisdiction under the provisions of a general license issued pursuant to 10 CFR 150.20, "Recognition of Agreement State Licenses."

On December 16, 2009, a representative from Cardinal Health Services, at the request of Bryan Heart, conducted an audit of their radiation safety program. The audit identified that Bryan Heart in CY 2009 had not submitted an initial filing for reciprocity, nor paid the annual fee that is required by 10 CFR 150.20 before conducting mobile nuclear medicine activities in a non-Agreement State (Missouri). The auditor from Cardinal Health Services immediately notified his supervisor. His supervisor contacted the chief technologist for Bryan Heart's mobile nuclear medicine services and instructed this individual to cancel any additional trips into the State of Missouri until Bryan Heart could resolve the reciprocity issue with the NRC. The chief technologist contacted the Missouri client and informed them that no additional nuclear medicine services could be provided until further notice. Then, the chief technologist contacted the Director of Cardinal Health Services and informed him that all future trips into the State of Missouri had been cancelled. The Director, at the request of his client, immediately contacted the NRC about the client's failure to initially file for reciprocity in CY 2009 and pay the required fee.

On December 17, 2009, the Reciprocity Project Manager in Region IV informed the Director of Cardinal Health Services that Bryan Heart should immediately file for reciprocity for mobile nuclear medicine activities conducted in the State of Missouri for CY 2009. On December 22, 2009, Bryan Heart following the telephone call with the NRC staff submitted an application for reciprocity dated December 21, 2009, and paid the requisite reciprocity fees for both CYs 2009 and 2010.

On January 18, 2010, NRC submitted a letter to Bryan Heart requesting a written response to the questions in the letter concerning their mobile nuclear medicine activities in the State of Missouri in CY 2009. On January 29, 2010, Bryan Heart submitted a response to the NRC's letter addressing the questions and describing the short-term and long-term corrective actions they had undertaken to ensure that the reciprocity violation did not occur again.

On May 11, 2010, Mr. Jack Whitten, Chief, and Ms. Michelle Simmons, Health Physicist, of the Nuclear Materials Safety Branch B, spoke with Ms. Joan Casey, Chief Administrative Officer of Bryan Heart by telephone. During the teleconference, the NRC staff explained NRC's requirement for providing a complete reciprocity submittal before working in areas of exclusive Federal jurisdiction. The NRC staff explained that a complete submittal would contain a copy of their Agreement State radioactive materials license, the appropriate reciprocity fee, and the requisite NRC Form 241. On the basis of this conversation, Bryan Heart agreed to supplement the corrective actions provided in their January 18, 2010, letter to include more descriptive long term corrective actions. In a letter dated May 13, 2010, to the NRC, Bryan Heart provided a description of the long-term corrective actions taken to prevent recurrence of the reciprocity violation.

1.3 Conclusion

Based on the information developed from the in-office inspection, the NRC identified a violation of 10 CFR 150.20(b)(1) for failing to file a submittal containing an NRC Form 241, a copy of its Agreement State license, and the appropriate reciprocity fee prior to engaging in activities for CY 2009 in the State of Missouri, a non-Agreement State under NRC regulatory authority.

2 Corrective Actions

The licensee's immediate corrective actions included halting licensed activities upon notification that reciprocity was required and promptly filing a submittal containing an NRC Form 241, "Report of Proposed Activities in Non-Agreement States," a copy of its Agreement State specific license, and the appropriate fee as prescribed in 10 CFR 170.31 for calendar years 2009 and 2010. The long-term corrective actions included: reviewing the applicable NRC regulations; placing an annual calendar alert for early December in the radiation safety officer's electronic calendar indicating the need to file the annual reciprocity forms with the NRC; completing a review by both Bryan LGH Medical Center and Bryan Heart's staff of the NRC records manual maintained by Bryan Heart containing reciprocity records in an effort to ensure continuity of the reciprocity program and to ensure that more than one individual is familiar with the reciprocity records and their specific location; ensuring that all NRC correspondence is provided to both Bryan LGH Medical Center and Bryan Heart; posting reciprocity documents in the

mobile nuclear medicine laboratory; and performing a quarterly review of reciprocity documentation in the mobile nuclear medicine laboratory during quarterly radiation safety audits.

3 Exit Meeting Summary

The NRC held a preliminary exit meeting telephonically with Bryan Heart staff on May 11, 2010. A final exit meeting was conducted telephonically with Bryan Heart representatives on July 23, 2010. The overall scope and findings of the in-office inspection were discussed. The licensee representatives acknowledged the inspector's findings. No proprietary information was identified.

Supplemental Inspection Information

PARTIAL LIST OF PERSONS CONTACTED

Joan Casey, Chief Administrative Officer
Keith Miller, Radiation Safety Officer
Duane Kanne, Contractor (Consultant)

ITEMS OPENED, CLOSED, OR DISCUSSED

Opened

15000026/10-001	VIO	Failure to file a submittal containing an NRC Form 241, a copy of its Agreement State license, and the appropriate reciprocity fee for Calendar Year 2009 prior to performing licensed activities within NRC jurisdiction.

Closed

None

Discussed

None

LIST OF ACRONYMS USED

APV	Apparent Violation
CFR	*Code of Federal Regulations*
NRC	Nuclear Regulatory Commission

ATTACHMENT