

July 19, 2012

EA-12-142

Ms. Kathryn Ziegler  
Clinical Manager  
The Christ Hospital – Mobile  
2139 Auburn Avenue  
Cincinnati, Ohio 45219

SUBJECT: NRC INSPECTION REPORT NO. 15000034/2012003(DNMS) - THE CHRIST HOSPITAL – MOBILE

Dear Ms. Ziegler:

On May 8, 2012, the U.S. Nuclear Regulatory Commission (NRC) contacted you concerning work your company had performed at a site in Lawrenceburg, Indiana, between January 2009 and March 8, 2012. The NRC performed additional in-office review of documentation concerning the Lawrenceburg facility through July 5, 2012, including determination of the circumstances and significance of the issues identified.

Based on the results of this review one apparent violation was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is located on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violation involved the possession and use of technetium-99m compounds in Indiana, a non-Agreement State, on multiple occasions between January 2009 and March 8, 2012, without first requesting reciprocity from the NRC via filing NRC Form 241 for each calendar year, as required by Title 10 of the Code of Federal Regulations (CFR), Section 150.20(b)(1).

The circumstances surrounding the apparent violation, the significance of the issue, and the need for lasting and effective corrective actions were discussed with you at the inspection exit meeting on July 5, 2012. As a result, it may not be necessary to conduct a Pre-decisional Enforcement Conference (PEC) in order to enable the NRC to make an enforcement decision.

In addition, since your facility has not been the subject of escalated enforcement actions within the last two years or last two inspections, and based on our understanding of your corrective actions, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violation addressed in the enclosed inspection report within 30 days of the date of this letter; (2) request a PEC; or (3) provide no further response. If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference. A PEC should be held within 30 days of the date of this letter.

Please contact Tamara E. Bloomer at 630-829-9627 within ten days of the date of this letter to notify the NRC as to which of the above three options you intend to use.

If you choose to provide a written response, it should be clearly marked as a "Response to an Apparent Violation in Inspection Report No. 15000034/2012003(DNMS); EA-12-142" and should include for the apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation.

In addition, please be advised that the number and characterization of apparent violations may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, 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 Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

K. Ziegler

- 3 -

Please contact Geoffrey Warren of my staff at 630-829-9742 to discuss any questions you have concerning this inspection.

Sincerely,

*/RA/*

Anne T. Boland, Director  
Division of Nuclear Materials Safety

Docket No. 150-00034  
Ohio License No. 02220310000

Enclosure:  
Inspection Report No. 15000034/2012003(DNMS)

cc w/encls: Lori Becker, Supervisor,  
Diagnostic Testing Centers  
State of Ohio  
State of Indiana

K. Ziegler

- 3 -

Please contact Geoffrey Warren of my staff at 630-829-9742 to discuss any questions you have concerning this inspection.

Sincerely,

*/RA/*

Anne T. Boland, Director  
Division of Nuclear Materials Safety

Docket No. 150-00034  
Ohio License No. 02220310000

Enclosure:  
Inspection Report No. 15000034/2012003(DNMS)

cc w/encls: Lori Becker, Supervisor,  
Diagnostic Testing Centers  
State of Ohio  
State of Indiana

DISTRIBUTION w/encls:  
See next page

\*See previous concurrence

**ADAMS Accession Number: ML12201A340**

DOCUMENT NAME: G:\DNMS\Work in progress\IR- Christ Hospital OH.docx

Publicly Available     Non-Publicly Available     Sensitive     Non-Sensitive

To receive a copy of this document, indicate in the concurrence box "C" = Copy without attach/encl "E" = Copy with attach/enc "N" = No copy

OFFICE	RIII DNMS	E	RIII DNMS		RIII EICS		RIII DNMS		
NAME	GMWarren:ps*GMW		TEBloomer*TEB		SKOrth*SKO		ATBoland ATB		
DATE	07/16/12		07/17/12		07/18/12		07/19/12		

OFFICIAL RECORD COPY

Letter to Kathryn Ziegler from Anne T. Boland dated July 19, 2012

SUBJECT: NRC INSPECTION REPORT NO. 15000034/2012003(DNMS) – THE CHRIST HOSPITAL – MOBILE

DISTRIBUTION w/encls:

OCADistribution  
Bill Borchardt  
Michael Weber  
Roy Zimmerman  
Nick Hilton  
Kerstun Day  
Marvin Itzkowitz  
Catherine Scott  
Mark Satorius  
Brian McDermott  
Leela Sreenivas  
Michele Burgess  
Duane White

Daniel Holody  
Carolyn Evans  
Heather Gepford  
Holly Harrington  
Hubert Bell  
Cheryl McCrary  
Mona Williams  
Charles Casto  
Cynthia Pederson  
Patricia Pelke  
Allan Barker  
Harral Logaras  
James Lynch

Viktoria Mitlyng  
Prema Chandrathil  
Steven Orth  
Patricia Loughheed  
Paul Pelke  
Sarah Bakhsh  
Magdalena Gryglak  
Patricia Buckley  
Tammy Tomczak  
MIB Inspectors  
OEMAIL

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No. 150-00034

License No. Ohio License No. 02220310000

Report No. 15000034/2012003(DNMS)

EA No. EA-12-142

Licensee: The Christ Hospital – Mobile  
Cincinnati, Ohio

Location of work: Partners in Health  
Lawrenceburg, Indiana

Inspection Dates: April 25, 2012, with continuing in-office review until  
July 5, 2012

Final Exit Meeting: July 5, 2012

Inspector: Geoffrey M. Warren, Health Physicist

Approved by: Tamara E. Bloomer, Chief  
Materials Inspection Branch  
Division of Nuclear Materials Safety

Enclosure

## **EXECUTIVE SUMMARY**

### **The Christ Hospital - Mobile Cincinnati, Ohio NRC Inspection Report 15000034/2012003(DNMS)**

On approximately April 25, 2012, The Christ Hospital (company) contacted the U.S. Nuclear Regulatory Commission (NRC) Region III office concerning release of a site in Lawrenceburg, Indiana, where the company had been providing mobile cardiology services but had ceased such activities.

Based on this and additional communications, the NRC identified an apparent violation of Title 10 of the Code of Federal Regulations (CFR), Section 150.20, concerning the company's failure to request reciprocity from the NRC by filing an NRC Form 241 prior to conducting licensed activities in a non-Agreement State where the NRC maintained jurisdiction. From January 2009 through March 2012, the company possessed and used technetium-99m (Tc-99m) cardiac doses twice a month at a temporary job site in Lawrenceburg, Indiana, without first filing an NRC Form 241 for each calendar year.

The root cause of the apparent violation was the company's lack of understanding that such a filing was required, believing that maintaining a registration with the State of Indiana was sufficient to authorize such use. As corrective action, The Christ Hospital retroactively submitted NRC Forms 241 for calendar years 2009, 2010, 2011, and 2012, paying a total of \$7,400 in reciprocity fees, and notified multiple management and company personnel about this requirement in order to prevent company personnel from working in NRC jurisdiction in the future without making proper notification to NRC.

## Report Details

### **1 Program Scope and Inspection History**

The Christ Hospital – Mobile (company) is a licensee of the State of Ohio authorized under Ohio License No. 02220310000 to possess and use radioactive materials for diagnostic imaging purposes at the facilities in Cincinnati, Ohio, as well as temporary client sites throughout Ohio. The company performed mobile nuclear cardiology imaging services in the Cincinnati, Ohio, area. The company has not been inspected by the NRC, and therefore has no enforcement history within NRC jurisdiction.

### **2 Reciprocity**

#### **2.1 Inspection Scope**

The inspector interviewed company staff and reviewed selected documents concerning the possession and use of radioactive material requiring a license within Indiana, a non-Agreement State, between January 2009 and March 2012.

#### **2.2 Observations and Findings**

On approximately April 25, 2012, the company's supervisor of diagnostic testing centers contacted the NRC Region III Materials Control, ISFSI, and Decommissioning (MCID) Branch concerning release of a site in Lawrenceburg, Indiana, where they had been providing mobile nuclear medicine services twice monthly for several years, ending on March 8, 2012. The individual she contacted noted that the company did not have an NRC license for operating at that site, and had not filed NRC Form 241, "Report of Proposed Activities in Non-Agreement States," requesting reciprocity for the current year or previous years to authorize such use under a general license.

The company had acquired control of Ohio Heart and Vascular (OHV), a State of Ohio licensee, in October 2008. OHV had provided nuclear cardiology services at the site in Lawrenceburg, Indiana, under reciprocity. The company continued to provide such services at the Indiana site after taking control of the license, but did not file for authorization under reciprocity. The company did maintain registration with the State of Indiana, believing that this registration authorized the use of licensed materials at the site. As a result, the company did not file for reciprocity during calendar years 2009, 2010, 2011, or 2012. According to company personnel, they were not aware of the requirement to file for reciprocity. Company personnel further stated that the company did not provide nuclear cardiology services at any sites in NRC jurisdiction other than in Lawrenceburg, Indiana, since they took control of the license, and had no current plans to provide such services in the future. Company personnel received licensed materials at a facility in Ohio and transported them to the Indiana job site.

Title 10 CFR 150.20(a), 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, provided that the provisions of 10 CFR 150.20(b) have been met. Title 10 CFR 150.20(b)(1) states, in part, that any person engaging in activities in non-Agreement States shall, at least three days before engaging in each such activity, file a submittal containing an NRC Form 241, "Report of Proposed



Activities in Non-Agreement States," with the Regional Administrator of the appropriate NRC regional office.

The company's failure to file NRC Forms 241 for each calendar year from 2009 through 2012 prior to performing work requiring a license is an apparent violation of 10 CFR 150.20. The root cause was that company personnel did not understand that the use of licensed materials in the State of Indiana required authorization from the NRC. The company believed incorrectly that their registration with the State of Indiana provided authorization to work in Indiana.

As corrective action, the company retroactively filed NRC Form 241 with the NRC Region III office for 2009 through 2012 on June 12, 2012, and paid the \$7,400 fee for the four years. On June 25, 2012, the regional office received the company's payment. Company personnel are now aware of the requirements in 10 CFR 150.20 for conducting work activities in Indiana and other non-Agreement States under the State of Ohio license. Company personnel stated that they would file NRC Form 241 prior to performing licensed activities in NRC jurisdiction in the future. In addition, the company informed multiple personnel in management positions over the mobile nuclear medicine operations about this requirement to prevent company personnel from working in NRC jurisdiction in the future without making proper notification to NRC.

### 2.3 Conclusions

The inspector identified one apparent violation of 10 CFR 150.20, involving the company's failure to request reciprocity from the NRC by filing an NRC Form 241 prior to conducting licensed activities in Indiana, a non-Agreement State, in calendar years 2009, 2010, 2011, and 2012. The company retroactively filed documents and payment for previous years and took action to prevent recurrence of the violation.

### 3 **Exit Meeting Summary**

The inspector discussed the preliminary conclusions as described in this report with company staff during the July 5, 2012, telephone exit meeting. The inspector discussed the inspection findings, the apparent violation, and the company's corrective actions. Company personnel did not identify any information reviewed during the inspection and proposed for inclusion in the inspection report as proprietary in nature.

#### **LIST OF PERSONS CONTACTED**

- \* Lori Becker, Supervisor, Diagnostic Testing Centers
- \* Kathryn Ziegler, Clinical Manager, Testing Centers
- \* Individuals present during telephonic exit meeting on July 5, 2012