



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

Region III
2443 Warrenville Road, Suite 210
Lisle IL 60532-4352

August 28, 2012

EA-12-142

David Parlato
Director, Cardiovascular Testing
The Christ Hospital
8250 Kenwood Crossing Way, Suite 225
Cincinnati, OH 45236

**SUBJECT: NOTICE OF VIOLATION; THE CHRIST HOSPITAL – MOBILE
NRC ROUTINE INSPECTION REPORT NO. 15000034/2012003(DNMS)**

Dear Mr. Parlato:

This refers to an NRC in-office inspection conducted from May 8 through July 5, 2012. Specifically, the NRC reviewed work that The Christ Hospital – Mobile performed at a site in Lawrenceburg, Indiana, between January 2009 and March 8, 2012, to verify compliance with the Nuclear Regulatory Commission's (NRC) rules and regulations. During the inspection, an apparent violation of NRC requirements was identified. The significance of the issue and the need for lasting and effective corrective actions were discussed with you at the final telephonic exit meeting on July 5, 2012. Details regarding the apparent violation were provided in NRC Inspection Report No. 15000034/2012003(DNMS) dated July 19, 2012.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report in one of three ways: (1) by providing a written response; (2) by requesting a pre-decisional enforcement conference, or (3) by verbally responding to the NRC that no additional information would be provided. In a letter dated August 14, 2012, you provided a response to the apparent violation.

Based on the information developed during and following the in-office inspection, as documented in the inspection report, and the information that you provided in the above-mentioned letter, 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 it are described in detail in our inspection report dated July 19, 2012. Specifically, from January 2009 through March 8, 2012, The Christ Hospital – Mobile possessed and used technetium-99m (Tc-99m) cardiac doses twice a month at a temporary job site in Lawrenceburg, Indiana, without either holding an NRC license or without filing a Form-241, "Report of Proposed Activities in Non-Agreement States," with the Regional Administrator of the appropriate NRC regional office at least three days prior to the first date of use in a calendar year.

The failure to file for reciprocity impacted the NRC's regulatory process by preventing the NRC from knowing that The Christ Hospital – Mobile was conducting activities within NRC's jurisdiction and, therefore, preventing the NRC from performing inspections to assure that licensed material was being used safely and in accordance with NRC requirements. Therefore, the violation has been categorized, in accordance with the NRC Enforcement Policy, as a Severity Level III violation.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3500 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 2.3.4 of the Enforcement Policy. Credit was warranted for your corrective actions which included filing for reciprocity for 2012, retroactively filing for previous years, and paying the required fees. Additionally, you have taken steps to ensure that all management responsible for nuclear testing have been made aware of the requirement of filing for reciprocity in NRC jurisdiction states such as Indiana.

Therefore, to encourage comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, 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.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 15000034/2012003(DNMS) and your letter dated August 14, 2012. 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 enclosure, and your response, if any, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access

D. Parlato

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and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

Sincerely,

/RA by C. Pederson for/

Charles A. Casto
Regional Administrator

Docket No. 150-00034
Ohio License No. 02220310000

Enclosure:
Notice of Violation

cc w/encl: State of Ohio
State of Indiana

NOTICE OF VIOLATION

The Christ Hospital – Mobile
Cincinnati, Ohio

Docket No. 150-00034
Ohio License No. 02220310000
EA-12-142

During an NRC in-office inspection conducted from May 8 through July 5, 2012, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the Code of Federal Regulations (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) requires, in part, that any person engaging in activities in non-Agreement States shall, at least three 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," with the Regional Administrator of the appropriate NRC regional office.

Contrary to the above, on multiple occasions between January 2009 and March 8, 2012, The Christ Hospital – Mobile, a licensee of the State of Ohio, possessed and used syringes containing technetium-99m at a temporary job site in Lawrenceburg, Indiana, a non-Agreement State, without first filing a Form-241 with the NRC. Specifically, the company used these materials for 24 days in 2009, 24 days in 2010, 24 days in 2011, and 5 days in 2012.

This is a Severity Level III violation (Section 6.9).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 15000034/2012003(DNMS) and your letter dated August 14, 2012. 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-12-142, 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 III, within 30 days of the date of the letter transmitting this Notice of Violation.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

ENCLOSURE

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 Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, or proprietary, 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 of Violation within two working days of receipt.

Dated this 28th day of August, 2012

D. Parlato

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and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

Sincerely,

/RA by C. Pederson for/

Charles A. Casto
Regional Administrator

Docket No. 150-00034
Ohio License No. 02220310000

Enclosure:
Notice of Violation

cc w/encl: State of Ohio
State of Indiana

DISTRIBUTION:
See next page

FILE NAME: G:\ORAI\IEICS\ENFORCEMENT\Cases\Enforcement Cases 2012\EA-12-142 Christ Hospital\EA-12-142 The Christ Hospital draft Final Action.docx
Publicly Available, Non-Sensitive

OFFICE	RIII	RIII	RIII	D:OE	RIII	RIII
NAME	Lougheed	Bloomer KLambert for	Boland PPelke for	Zimmerman ¹	Orth	Casto CPederson for
DATE	08/21/12	08/21/12	08/22/12	08/27/12	08/28/12	08/28/12

OFFICIAL RECORD COPY

1 OE concurrence received via e-mail from L. Sreenivas on August 27, 2012.

Letter to David Parlato from Charles A. Casto dated August 28, 2012

SUBJECT: NOTICE OF VIOLATION; THE CHRIST HOSPITAL – MOBILE
NRC ROUTINE INSPECTION REPORT NO. 15000034/2012003(DNMS)

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