



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, ILLINOIS 60532-4352

August 26, 2014

EA-14-108

Ms. Kelly Thomas
Clinical Services Manager
Diagnostic Imaging Centers, P.A.
7101 College Boulevard, Suite 1200
Overland Park, Kansas 66210

SUBJECT: NOTICE OF VIOLATION – DIAGNOSTIC IMAGING CENTERS, P.A.;
NRC ROUTINE INSPECTION REPORT NO. 03038424/2014001(DNMS)

Dear Ms. Thomas:

This letter refers to the routine inspection conducted at your facility located in Lee's Summit, Missouri, on May 22, 2014, with continued in-office NRC review through June 19, 2014. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements, including a review of authorized users approved for administrations of iodine-131 (I-131) sodium iodide. 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 and your staff during the exit meeting held on June 23, 2014. Details regarding the apparent violation were provided in NRC Inspection Report No. 03038424/2014001(DNMS) dated July 15, 2014.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated July 21, 2014, you provided a written response to the apparent violation, which was amended in a letter dated August 18, 2014.

Based on the information developed during the inspection and the information that you provided in your responses, 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 the subject inspection report. Specifically, the NRC identified that two written directives were signed by individuals not authorized on your NRC license for the particular medical use prescribed by the written directive. The individuals were authorized users for different medical uses. The root cause of the violation was your failure to ensure that staff were aware of the requirements for signing written directives. The NRC expects licensees to be fully aware of their requirements and to ensure that all authorized users are aware of their limitations in the dispensing of radiopharmaceuticals for diagnostic and therapeutic purposes. Therefore, this violation has been categorized, in accordance with the NRC Enforcement Policy, at Severity Level III.

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 or two inspections, 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. The NRC considered the information provided in the inspection report and in your July 21, 2014, letter. Your immediate corrective actions were to verify that no other instances occurred where written directives were signed by unauthorized users. As long-term corrective actions, among others: (1) you posted a list of authorized and unauthorized users at each location where nuclear medicine is performed; (2) you notified clinic managers and physicians as to those persons who are not authorized to sign written directives; (3) you counseled the nuclear medicine staff on proper written directive authorization; and (4) you reviewed the list of authorized users at several staff and corporate meetings. You also committed to have your physicists incorporate a review of authorized users during the annual radiation safety training in March 2015. Based on these corrective actions, the NRC determined that *Corrective Action* credit was warranted.

Therefore, to encourage prompt and 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. 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: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in your July 21 and August 18, 2014, letters. 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 you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the

K. Thomas

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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/

Cynthia D. Pederson
Regional Administrator

Docket No. 030-38424
License No. 15-35219-01

Enclosure:
Notice of Violation

cc: State of Missouri
State of Kansas
Sidney A. Crawley, M.D.,
Radiation Safety Officer

NOTICE OF VIOLATION

Diagnostic Imaging Centers
Overland Park, Kansas

Docket No. 03038424
License No. 15-35219-01
EA-14-108

During an NRC inspection conducted on May 22, with continued review through June 19, 2014, 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 (CFR) 35.40(a) states, in part, that a written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries).

Condition 12.B. of NRC License No. 15-32819-01 lists the individuals who are authorized users and the specific type of medical use.

Contrary to the above, on September 3, 2008, and December 8, 2010, the licensee failed to have a written directive dated and signed by an authorized user before the administration of 5 millicuries of I-131 sodium iodide to patients. Specifically, both written directives were signed by individuals who were not authorized users for medical uses under 10 CFR 35.300 on NRC License No. 15-32819-01. Both individuals were authorized users for medical use under 10 CFR 35.100 and 35.200 on the license.

This is a Severity Level III violation (Section 6.3).

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 No. 03038424/2014001(DNMS) dated July 15, 2014, and your responses dated July 21 and August 18, 2014. 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-14-108," 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 (Notice).

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.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in 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, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

Enclosure

Notice of Violation

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

Dated this 26th day of August, 2014.

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/

Cynthia D. Pederson
Regional Administrator

Docket No. 030-38424
License No. 15-35219-01

Enclosure:
Notice of Violation

cc: State of Missouri
State of Kansas
Sidney A. Crawley, M.D.,
Radiation Safety Officer

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FILE NAME: EA-14-108 Diagnostic Imaging Centers Final Action.docx

| OFFICE | RIII | RIII | RIII | D:OE | RIII | RIII |
|--------|-------------------|----------|----------|------------------------------------|----------|----------|
| NAME | Orth for Lougheed | McCraw | Louden | Holahan ¹ Norman for | Orth | Pederson |
| DATE | 08/14/14 | 08/15/14 | 08/18/14 | 08/25/14 | 08/26/14 | 08/26/14 |

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¹ OE concurrence provided via email from K. Norman on August 25, 2014