



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION I
2100 RENAISSANCE BLVD., SUITE 100
KING OF PRUSSIA, PA 19406-2713

July 14, 2015

Docket No. 03010683

License No. 47-16259-01

EA-15-062

Peggy A. Pust
Vice President of Operations
Monongalia General Hospital
1200 J.D. Anderson Drive
Morgantown, WV 26505

SUBJECT: MONONGALIA GENERAL HOSPITAL, NOTICE OF VIOLATION - INSPECTION
REPORT NO. 03010683/2014001

Dear Ms. Pust:

This letter provides you the U.S. Nuclear Regulatory Commission's (NRC) enforcement decision for the apparent violation identified during the NRC safety inspection conducted on-site on December 15, 2014, at Monongalia General Hospital (Monongalia) in Morgantown, West Virginia, with continued in-office review through April 7, 2015. The inspection consisted of interviews with Monongalia personnel and the examination of selected records to evaluate Monongalia's licensed activities as they relate to radiation safety and to compliance with NRC regulations. Mr. Robert Gallagher, of this office, discussed an apparent violation with you during a telephonic exit meeting on April 10, 2015. The apparent violation was also described in the NRC inspection report sent to you with a letter dated June 19, 2015 (ML15170A357¹).

In the June 19, 2015, 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 (PEC), by providing a written response, or by accepting the violation as characterized in the letter. We also informed you that we had sufficient information regarding the apparent violation and Monongalia's corrective actions to make an enforcement decision without the need for a PEC. In a telephone call on June 22, 2015, with Mr. James Dwyer, Chief, NRC Region I, Medical Branch, Mr. Mark Perna, Radiation Safety Officer, indicated that Monongalia did not require a PEC and did not intend to send a written response.

Based on the information developed during the inspection, 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 were described in detail in the June 19, 2015, letter and in the subject inspection report. The violation involved the failure to have two

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Unless otherwise noted, documents referenced in this letter are publicly-available using the accession number in ADAMS

written directives dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)) as required by Title 10 of the Code of Federal Regulations (10 CFR) 35.40(a). Specifically, on February 8, 2013, and on February 26, 2013, two physicians not authorized by your license to administer I-131 sodium iodide, signed and dated written directives for two separate administrations involving 105 millicuries and 30 millicuries of I-131 sodium iodide, both which required a written directive.

An unauthorized individual conducting licensed activities is a significant regulatory concern. Although, there were no actual consequences, the potential existed for unauthorized individuals to sign and date written directives for the administration of I-131 sodium iodide in amounts greater than 30 microcuries. Additionally, the possibility existed for unauthorized individuals to have administered an incorrect dose of I-131 sodium iodide.

Therefore, the violation has been categorized at Severity Level (SL) III in accordance with the NRC Enforcement Policy. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is considered for a SL III violation. Because Monongalia has not been the subject of escalated enforcement action 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 NRC Enforcement Policy. The NRC has concluded that credit is warranted for Monongalia's corrective actions taken to address the violation. Specifically, Monongalia: (1) directed an authorized user of I-131 sodium iodide greater than 30 microcuries to review the two written directives and confirmed that both medical procedures were appropriate; (2) reviewed the training and experience of all of the radiologists that service the hospital and compiled a list of the radiologists who were authorized users for the administration of I-131 sodium iodide greater than 30 microcuries; (3) posted a list of authorized users in the Nuclear Medicine Department hot lab and provided training to technical staff on the need to refer to the list prior to administering dosages of I-131 sodium iodide greater than 30 microcuries; and (4) submitted a request to amend its license to add a physician who had been qualified for medical uses under 10 CFR 35.300, but was not listed as an authorized user on the license.

Therefore, to encourage prompt and comprehensive correction of violations, in recognition of the absence of previous escalated enforcement action, and after consultation with the Director, Office of Enforcement, I have been authorized 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 reasons for the violation; (2) the actions planned or already taken to correct the violation and prevent recurrence; and, (3) the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03010683/2014001 and in this letter. 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 and its enclosure 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 Website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response, if you choose to provide one, should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld, and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

Sincerely,

/RA David C. Lew for:/

Daniel H. Dorman
Regional Administrator

Docket No. 03010683

Enclosure: Notice of Violation

cc w/enclosure:
State of West Virginia

Document Room or from the NRC's document system (ADAMS), accessible from the NRC Website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response, if you choose to provide one, should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld, and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

Sincerely,

/RA David C. Lew for:/

Daniel H. Dorman
Regional Administrator

Docket No. 03010683

Enclosure: Notice of Violation

cc w/enclosure:
State of West Virginia

ML15195A171

Distribution: see next page

DOCUMENT NAME: S:\Enf-allg\Enforcement\Proposed-Actions\Region1\Monongalia NOV-III EA-15-062.docx

X SUNSI Review/		X Non-Sensitive □ Sensitive		X Publicly Available □ Non-Publicly Available	
OFFICE	RI/ORA	RI/DNMS	RI/DNMS	RI/ORA	RI/ORA
NAME	C Crisden/cjc*	J Dywer/JPD*	D Collins/DSC*	B Klukan/BMK*	B Bickett/BAB*
DATE	7/2/15	7/5/15	7/6/15	7/6/15	7/7/15
OFFICE	OE	RI/DNMS	RA		
NAME	L Sreenivas via email*	D Collins/DSC*	D Dorman/DCL for*		
DATE	7/7/15	7/9/15	7/13/15		

* See previous concurrence page

OFFICIAL RECORD COPY

Letter to P. Pust from D. Dorman dated July 14, 2015

SUBJECT: Monongalia General Hospital Notice of Violation – Inspection Report No.
03010683/2014001

DISTRIBUTION w/encl:

ADAMS (PARS)

SECY

M Satorius, EDO

M Weber, DEDMRT

Y Chen, OEDO

J Foster, OEDO

P Holahan, OE

B Sosa, OE

N Hilton, OE

L Sreenivas, OE

N Hasan, OE

S Rodriguez, OE

C Haney, NMSS

S Moore, NMSS

J Piccone, NMSS

P Henderson, NMSS

M Burgess, NMSS

R Sun, NMSS

Enforcement Coordinators

RII, RIII, RIV (D Gamberoni; R Skokowski; N Taylor)

C Scott, OGC

H Harrington, OPA

H Bell, OIG

C McCrary, OI

M Williams, OCFO

L Bates, OCFO

D Dorman, RA, RI

D Lew, DRA, RI

D Collins, DNMS, RI

J Nick, DNMS, RI

J Dwyer, DNMS, RI

R Gallagher, DNMS, RI

D Screnci, PAO-RI / N Sheehan, PAO-RI

D Janda, SAO-RI / M Ford, SAO-RI

B Bickett, ORA, RI

M McLaughlin, ORA, RI

C Crisden, ORA, RI

B Klukan, Esq, ORA, RI

D Bearde, ORA, RI

S Villar, RI

Region I OE Files (with concurrences)

NOTICE OF VIOLATION

Monongalia General Hospital
Morgantown, West Virginia

Docket No. 03010683
License No. 47-16259-01
EA-15-062

During an NRC inspection conducted on December 15, 2014, with continued in-office review through April 7, 2015, for which an exit meeting was conducted on April 10, 2015, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.40(a) requires, in part, that a written directive must be signed and dated by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries).

Contrary to the above, on February 8, 2013, and February 26, 2013, the licensee administered greater than 1.11 MBq (30 μ Ci) of I-131 sodium iodide, and the written directives were not signed and dated by an authorized user before the administration. Specifically, Monongalia administered 105 millicuries of I-131 and 30 millicuries of I-131, respectively, and the individuals that signed and dated the written directives were not listed as authorized users for medical uses under 10 CFR 35.300 on NRC License No. 47-16259-01.

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

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the actions planned or already taken to correct the violation and prevent recurrence; and (3) the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03010683/2014001 and in the letter transmitting this Notice. Therefore, you are not required to respond to this Notice. 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-15-062," 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 I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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 Web site at <http://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 two working days of receipt.

Dated this 14th day of July, 2015