UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

June 19, 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: NRC INSPECTION REPORT NO. 03010683/2014001, MONONGALIA GENERAL HOSPITAL, MORGANTOWN, WEST VIRGINIA

Dear Ms. Pust:

On December 15, 2014, and continuing in-office until April 7, 2015, Robert Gallaghar of this office conducted a safety inspection at the above address. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with selected personnel, and a selective examination of representative records. Additional information provided by Mark Perna, Radiation Safety Officer, via electronic mail on January 5, 2015, was also examined as part of the inspection. The enclosed report presents the results of this inspection.

Based on the results of this inspection, two apparent violations were identified and one of the apparent violations is being considered for escalated enforcement in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

The apparent violation being considered for escalated enforcement involved the failure to have two 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 10 CFR 35.40(a). We noted that when the inspector informed your staff of the apparent violation, immediate corrective actions were taken to comply with NRC safety requirements. Specifically: (1) an authorized user of I-131 sodium iodide greater than 1.11 MBq reviewed the two written directives and confirmed that both medical procedures were appropriate; (2) the training and experience of all of the radiologists that service your hospital were reviewed and a list of the radiologists who were authorized users for the administration of I-131 sodium iodide greater than 1.11 MBq was compiled; (3) a list of authorized users was posted in the Nuclear Medicine Department hot lab and training was provided to technical staff on the need to refer to this list prior to administering dosages of I-131 sodium iodide greater than 1.11 MBq; and (4) a request was submitted to amend your license to add a radiologist who had the qualifications of an authorized user but who was not listed on your license.

One additional apparent violation involved the failure to include an authorized user of each type of use permitted by your license on the Monongalia General Hospital's Radiation Safety Committee. This is a repeat violation from a previous inspection (NRC Inspection Report 03010683/2011001); however, it is not being considered for escalated enforcement.

The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with you on April 10, 2015 during the exit meeting via telephone. 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 an escalated enforcement action within the last two inspections (6 years), 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) request a PEC, (2) respond to the apparent violations in writing, or (3) accept the violations as characterized in the letter and its enclosure (in which case the NRC will proceed with its enforcement decision). Please contact James Dwyer at (610) 337-5309 **within 10 days** of the date of this letter to notify the NRC whether you are interested in attending a PEC, providing a written response, or accepting the violations.

If you choose to request a PEC, the meeting should be held in our office in King of Prussia, PA, within 30 days of the date of this letter. The PEC will afford you the opportunity to provide your perspective on the apparent violations 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 the violations occurred, information to determine the significance of the violations, information related to the identification of the violations, and information related to any corrective actions taken or planned to be taken. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the conference time and date.

If you choose, instead, to provide this information in a written response, it should be sent to the NRC within 30 days of the date of this letter. Your response may reference or include previously docketed correspondence. It should be clearly marked as a "Response to Apparent Violations in NRC Inspection Report 03010683/2014001; EA 2015-062," and sent 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, King of Prussia, PA 19406.

Current NRC regulations and guidance are included on the NRC's Web site at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Regulations, Guidance and Communications;** then **Enforcement Policy** (under "**Related Information"**). You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the NRC's Public Document Room without redaction.

Thank you for your cooperation.

Sincerely,

/RA M. S. Ferdas for/

Daniel S. Collins, Director
Division of Nuclear Materials Safety

Enclosures:
1. Inspection Report No. 03010683/2014001
2. Excerpt From NRC Information Notice 96-28

cc w/enclosures: Mark T. Perna, Radiation Safety Officer
State of West Virginia

Thank you for your cooperation.

Sincerely,

/RA M. S. Ferdas/

Daniel S. Collins, Director
Division of Nuclear Materials Safety

Enclosures:
1. Inspection Report No. 03010683/2014001
2. Excerpt From NRC Information Notice 96-28

cc w/enclosures: Mark T. Perna, Radiation Safety Officer
State of West Virginia

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REGION I

INSPECTION REPORT

Inspection No.	03010683/2014001
Docket No.	03010683
License No.	47-16259-01
Licensee:	Monongalia General Hospital
Location:	1200 J.D. Anderson Drive Morgantown, West Virginia 26505
Inspection Date:	December 15, 2014 through April 7, 2015
Exit Date:	April 10, 2015

Inspector: ***/RA/*** ***06/15/15***

Robert Gallaghar — Date
Health Physicist

Approved By: ***/RA/*** ***06/14/15***

James P. Dwyer, Chief — Date
Medical Branch
Division of Nuclear Materials Safety

Document Name: C:\RawFiles\ML15170A357.docx

EXECUTIVE SUMMARY

Monongalia General Hospital
NRC Inspection Report No. 03010683/2014001

Monongalia General Hospital (MGH) is a community hospital authorized to administer radioactive materials described in 10 CFR 35.100, 35.200, Iodine-131 (I-131) permitted by 35.300, and 35.400. The NRC conducted a routine unannounced inspection at the licensee's facilities located at 1200 J.D. Anderson Drive, Morgantown, West Virginia on December 15, 2014.

Based on the results of this inspection, two apparent violations of NRC requirements were identified. Specifically,

- MGH did not ensure that the Radiation Safety Committee (RSC) included an authorized user of each type of use permitted by the license as required by 10 CFR 35.24(f), a repeat violation; and

- MGH did not obtain the signature of an authorized user on two written directives before the administration of dosages of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries) as required by 10 CFR 35.40(a).

REPORT DETAILS

a. Inspection Scope

A routine, unannounced inspection was conducted on December 15, 2014, at the MGH located in Morgantown, West Virginia. Additional information, contained in electronic mail from the MGH Radiation Safety Officer (RSO) on January 5, 2015, was also reviewed as part of this inspection. In-office reviews continued until April 7, 2015. The inspection was performed in accordance with NRC Inspection Procedures 87131 and 87132 and reviewed activities associated with the medical diagnostic and therapeutic use of byproduct material. The following focus areas were reviewed: (i) security and control of licensed material; (ii) shielding of licensed material; (iii) comprehensive safety measures; (iv) radiation dosimetry program; (v) radiation instrumentation and surveys; (vi) radiation safety training and practices; and (vii) management oversight. The inspector conducted interviews with MGH personnel, observed day-to-day operations, toured facilities, and reviewed documents related to the radioactive materials program.

b. Observations and Findings

MGH is authorized to administer radioactive materials described in 10 CFR 35.100, 35.200, I-131 permitted by 35.300, and 35.400. The Nuclear Medicine Department performs a full range of diagnostic studies and is staffed Monday through Friday from 7:00 AM to 5:30 PM, and from 7:00 AM until 3:30 PM (on-call after 3:30 PM) Saturdays and Sundays. There are two full-time nuclear medical technologists (NMTs), two part time NMTs, three imaging cameras, one treadmill and one Hot Lab. Approximately 100 diagnostic studies are performed each week. Dosages are assayed in a dose calibrator prior to administration. Unit doses are obtained from PharmaLogic radiopharmacy of Bridgeport, West Virginia. The primary radioisotope used is Technetium-99m; however a small amount of Iodine-123 is used for thyroid uptake studies. Cardiac studies make up approximately 75% of MGH's total studies, 20% are hepatobiliary scans (HIDA scans) with renal, gastric emptying, thyroid uptake, etc. making up the remainder. Mobile PET services are provided every other week.

The inspector reviewed the minutes of RSC meetings and identified that the licensee did not have an authorized user of each type of use permitted on the license. Specifically, the RSC did not have an authorized user of I-131 permitted by10 CFR 35.300 as a member, contrary to the requirement of 10 CFR 35.24(f). This is an apparent violation of 10 CFR 35.24(f). The inspector noted that this apparent violation is similar to a previously identified violation, (see NRC Inspection Report 03010683/2011001 for additional details), when MGH failed to have an authorized user of 10 CFR 35.400 as a member of the RSC.

The license performed 16 procedures during the inspection interval using I-131 sodium iodide in a quantity greater than 1.11 MBq. All were performed on an out-patient basis, as required by the license. Written directives (WDs) were reviewed during the inspection and the majority of the WDs were found to be appropriately documented; however, the inspector identified two I-131 sodium iodide procedures exceeding 1.11 MBq performed

in February of 2013 for which the WDs were dated and signed by physicians who were not authorized users of I-131 permitted by 10 CFR 35.300 on the MGH license.

Specifically, for the treatment on February 26, 2013, the WD was signed and dated by a physician who was qualified to administer radioactive materials described in 10 CFR 35.100 and 35.200; however, he was not authorized on the MGH license to administer 10 CFR 35.100 and 35.200 materials and he was not qualified to administer I-131 permitted by 10 CFR 35.300. This particular physician was American Board of Radiology (ABR) certified in 1996 in the use of I-131 for hyperthyroid therapies; however, he did not meet the current requirements for recentness of training pursuant to 10 CFR 35.59. The WD for the treatment on February 8, 2013, was signed and dated by a physician who is ABR certified in Diagnostic Radiology but he was not listed on the MGH license as an authorized user to administer 10 CFR 35.100 materials, 35.200 materials, or I-131 permitted by10 CFR 35.300. The inspector reviewed patient release calculations and found they were appropriately documented and patients were provided appropriate release instructions.

The prostate therapy program performs approximately 25 patient treatments each year. The licensee uses both Iodine-125 and Palladium-103 for implantation. Seeds are obtained from the manufacturer identified on the license and were the approved model. Real time planning is used in the operating room and post-implant imaging is performed for verification of seed placement. WDs were reviewed and found to be in accordance with the requirements.

c. Conclusions

Based on the results of this inspection, two apparent violations of NRC requirements were identified as described below.

(1) 10 CFR 35.24(f) requires, in part, that licensees authorized for two or more types of uses of byproduct material under subparts E, F, and H shall establish a RSC to oversee all uses of byproduct material permitted by the license. The RSC must include an authorized user of each type of use permitted by the license. Contrary to the above, as of December 15, 2014, the licensee failed to have a RSC that included an authorized user of each type of use permitted by the license. Specifically, the licensee did not have an authorized user of I-131 permitted by 10 CFR 35.300 as a member of the RSC. This apparent violation is similar to a previously identified violation.

Immediately following the inspection on December 15, 2014, the licensee called an emergency meeting of the RSC to discuss the apparent violation. The RSO reported there had been some confusion about what needed to be done following identification of the violation during the previous inspection and they had named an appropriate individual to represent the nuclear medicine physicians; however, this individual unfortunately was not an authorized user of 10 CFR 35.300 materials. The licensee named an authorized user of 10 CFR 35.300 materials as a temporary member of the RSC pending a final decision on a permanent member.

(2) 10 CFR 35.40(a) requires, in part, that a written directive be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 MBq. Contrary to the above, on February 26 and February 8, 2013, the licensee

failed to have written directives dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 MBq. Specifically:

(a) The individual who signed the WD for the February 26 administration was qualified to administer radioactive materials described in 10 CFR 35.100 and 35.200; however, he was not authorized on the MGH license to administer 10 CFR 35.100 and 35.200 materials and he was not qualified to administer I-131 permitted by 10 CFR 35.300. This particular physician was American Board of Radiology (ABR) certified in 1996 in the use of I-131 for hyperthyroid therapies; however, he did not meet the current requirements for recentness of training pursuant to 10 CFR 35.59.

(b) The individual who signed the WD for the February 8, 2013 administration was signed and dated by a physician who is ABR certified in Diagnostic Radiology but he was not listed on the MGH license as an authorized user to administer 10 CFR 35.100 materials, 35.200 materials, or I-131 permitted by10 CFR 35.300.

After the apparent violations were identified, the licensee took immediate corrective actions including: (1) an authorized user of I-131 sodium iodide greater than 1.11 MBq reviewed the two written directives and confirmed both procedures were appropriate; (2) the RSO and RSC reviewed the training and experience of all of the radiologists that serviced MGH and compiled a list of the radiologists who were authorized users for the administration of I-131 sodium iodide greater than 1.11 MBq; (3) the RSO posted the list of authorized users in the Nuclear Medicine Department hot lab and provided training to the technical staff on the need to refer to this list prior to administering dosages of I-131 sodium iodide greater than 1.11 MBq; and (4) MGH submitted a request to amend their license to add a physician as an authorized user for 10 CFR 35.100, 35.200 and I-131 permitted by 10 CFR 35.300. This amendment was completed on February 20, 2015.

Exit Meeting

On April 10, 2015, the inspector conducted a telephone exit meeting with the individuals identified in the Partial List of Persons Contacted.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

** ++ Peggy Post, Vice President Operations
** ++ Brenda DeBastaini, Director of Imaging
** ++ Mark Perna, Radiation Safety Officer
Various Nuclear Medicine Technologists

** Attended preliminary exit briefing conducted on December 15, 2014
++Attended telephonic exit meeting on April 10, 2015.

DOCUMENTS REVIEWED DURING THE INSPECTION

Radiation dosimetry records November 2011 to present
Radiation Safety Committee records 2012 thru 2014
Dose calibrator calibration records 2012 thru 2014
Radioactive material receipt records 2012 thru 2014
Records of 16 Iodine-131 therapies performed November 2011 to December 2014, including written directives
Patient release records for patients requiring assessment November 2011 to December 2014
Sample of prostrate brachytherapy records, November 2011 to December 2014, including written directives and post-implant evaluations
Training and experience records for physicians who signed written directives
Corrective actions documented with email from the licensee's radiation safety officer to NRC dated January 5, 2015