



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

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

July 24, 2014

EA-14-115

Ms. Carole Jones, Director of Medical Imaging  
Truman Medical Center, Department of Radiology  
2301 Holmes Street  
Kansas City, Missouri 64108

**SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03030130/2014001(DNMS) AND  
NOTICE OF VIOLATION – TRUMAN MEDICAL CENTER**

Dear Ms. Jones:

On May 22, 2014 through May 23, 2014, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facility in Kansas City, Missouri, with continued in-office review through June 26, 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. The in-office review included a review of your program to administer radiopharmaceuticals requiring a written directive. The enclosed inspection report presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, one apparent violation of NRC requirements was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violation concerned the release from your control of two individuals who had been administered byproduct material and the total effective dose equivalent to any other individual from exposure to the released individuals was likely to exceed 5 milliSievert, as prohibited by Title 10 of the *Code of Federal Regulations* (CFR) section 35.75(a).

Because the NRC has not made a final determination in this matter, the NRC is not issuing a Notice of Violation for this inspection finding at this time. The circumstances surrounding this apparent violation, the significance of the issue, and the need for lasting and effective corrective action were discussed with you at the inspection exit meeting on June 27, 2014.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond in writing to the apparent violation addressed in the enclosed inspection report within 30 days of the date of this letter; or (2) request a Predecisional Enforcement Conference (PEC). 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. **Please contact Mr. Aaron T. McCraw at 630-829-9650 within 10 days of the date of this letter to notify the NRC of your intended response.**

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violation in Inspection Report No. 03030130/2014001(DNMS); EA-14-115," 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 was or will be achieved. 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. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the information notice on the NRC's website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. 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.

Because your facility has not been the subject of escalated enforcement action within the last two years or two inspections, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. In addition, based upon NRC's understanding of the facts and your corrective actions, it may not be necessary to conduct a PEC in order to enable the NRC to make a final enforcement decision. Our final decision will be based on your confirming on the license docket that the corrective actions previously described to the inspector have been or are being taken.

Please be advised that the number and characterization of the apparent violations described in the enclosed inspection report 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 addition to the apparent violation discussed above and based on the results of the inspection, the NRC also determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The violation concerned the failure to ensure that written directives were dated and signed by an authorized user before the administration of iodine-131 (I-131) sodium iodide greater than 30 microcuries, as required by 10 CFR 35.40(a). Specifically, an individual who was not authorized on your NRC license for the medical use prescribed by the written directive signed two written directives dated January 15 and 17, 2014. The individual was listed in Condition 12.B. of your NRC License No. 24-25816-01 as an authorized user for medical uses under 10 CFR 35.100 and 35.200, but the individual was not listed under 10 CFR 35.300 which was required for this administration. The violation, identified by the inspector, is cited in the enclosed Notice of Violation (Notice).

The root cause of the severity Level IV violation was a misunderstanding by the authorized user. Specifically, the individual who signed the written directives believed that she was listed on your NRC license as an authorized user for medical uses under 10 CFR 35.300. As corrective actions to restore compliance and to prevent recurrence you: (1) informed the individual that she was not allowed to sign any written directives until she was authorized on the NRC license, (2) verified that the individual met the regulatory requirements to be listed on the NRC license for administrations of I-131 sodium iodide less than or equal to 33 millicuries, (3) revised your policy titled "Safety—Radiation Safety Officer (RSO) – Duties and Responsibilities" to help prevent a recurrence of this issue in the future; and (4) committed to submit a license amendment request to add authorization for the individual for medical uses under 10 CFR 35.300 before July 1, 2014.

The NRC has concluded that information regarding the reason for the Severity Level IV violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in this letter and in your letter (with attachments) to the NRC dated May 29, 2014. Therefore, you are not required to respond to the Severity Level IV violation described in this letter and enclosed inspection report unless the description herein 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 enclosures, and your response, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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 publicly available without redaction.

C. Jones

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Please feel free to contact Mr. Bramnik of my staff if you have any questions regarding this inspection. Mr. Bramnik can be reached at 630-829-9543.

Sincerely,

***/RA by John B. Giessner Acting for/***

Patrick L. Loudon, Director  
Division of Nuclear Materials Safety

Docket No. 030-30130  
License No. 24-25816-01

Enclosures:

1. Notice of Violation
2. IR 03030130/2014001(DNMS)

cc w/encls: Dr. Lawrence Ricci, Radiation Safety Officer  
State of Missouri

C. Jones

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Please feel free to contact Andrew Bramnik of my staff if you have any questions regarding this inspection. Mr. Bramnik can be reached at 630-829-9543.

Sincerely,

*/RA by John B. Giessner Acting for/*

Patrick L. Loudon, Director  
Division of Nuclear Materials Safety

Docket No. 030-30130  
License No. 24-25816-01

Enclosures:

1. Notice of Violation
2. IR 03030130/2014001(DNMS)

cc w/encls: Dr. Lawrence Ricci, Radiation Safety Officer  
State of Missouri

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## NOTICE OF VIOLATION

Truman Medical Center  
Kansas City, Missouri

License No. 24-25816-01  
Docket No. 030-30130

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on May 22, 2014 through May 23, 2014, with continued in-office review through June 26, 2014, one 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) Section 35.40(a) states, in part, that a written directive must be signed and dated by an authorized user before the administration of iodine-131 (I-131) sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries).

Condition 12.B. of NRC License No. 24-25816-01 lists the individuals who are authorized users for medical use as indicated.

Contrary to the above, on January 15 and 17, 2014, the licensee failed to ensure that written directives were dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries. Specifically, an individual who was not authorized on NRC license No. 24-25816-01 for the medical use prescribed by the written directive signed written directives for administrations of 16 and 20 millicuries of I-131. The individual was listed in Condition 12.B. of the NRC License as an authorized user for medical uses under 10 CFR 35.100 and 35.200. Prior to the administrations, the individual met the requirements to be an authorized user for medical uses under 10 CFR 35.300 for the oral administration of I-131 sodium iodide requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), but was not authorized on the license.

This is a Severity Level IV 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 the letter transmitting this Notice of Violation and your letter (with attachments) to the NRC dated May 29, 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, IR 03030130/2014001(DNMS)" 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.

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's website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

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, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Dated this 24<sup>th</sup> day of July 2014.

**U.S. Nuclear Regulatory Commission  
Region III**

Docket No.	030-30130
License No.	24-25816-01
Report No.	03030130/2014001(DNMS)
EA No.	EA-14-115
Licensee:	Truman Medical Center
Facility:	2301 Holmes Street Kansas City, Missouri 64108
Inspection Dates:	May 22, 2014 - May 23, 2014 with continued in-office review through June 26, 2014
Exit Meeting Date:	June 27, 2014
Inspector:	Andrew Bramnik, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

## **EXECUTIVE SUMMARY**

### **Truman Medical Center NRC Inspection Report 03030130/2014001(DNMS)**

This was a routine inspection of licensed activities involving the use of byproduct material for medical uses. Truman Medical Center operated a 260-bed hospital in Kansas City, Missouri, with authorization under U.S. Nuclear Regulatory Commission (NRC) License No. 24-25816-01 to use byproduct material for medical uses permitted by 10 CFR Sections 35.100, 35.200, and 35.300. During a routine inspection on May 22 and 23, 2014, a Region III materials inspector identified an apparent violation of Title 10 of the *Code of Federal Regulations* (CFR) section 35.75(a) concerning the licensee's release of two individuals who had been administered byproduct material and the total effective dose equivalent to any other individual from exposure to the released individuals was likely to exceed 5 milliSievert (mSv) (0.5 rem).

Specifically, in response to questions posed by the NRC during its in-office review, the licensee determined that they had released two individuals who had received I-131 sodium iodide administrations greater than the licensee's maximum allowable activity for outpatients. During the NRC in-office review, the licensee determined that their maximum outpatient I-131 administration limits were 190 millicuries (mCi) for a post-thyroidectomy patient and 54 mCi for a hyperthyroidism (intact thyroid) patient. On June 27, 2011, and November 30, 2012, the licensee administered 70.0 and 69.3 mCi of I-131 to patients (respectively) and released the individuals from its control as outpatients. Both written directives indicated that the patients had intact thyroids; therefore, neither patient should have been released as outpatients based on the licensee's general calculations. As of June 11, 2014, the licensee had changed its policies and procedures to include a more thorough review of outpatient documentation and survey results prior to being discharged from the facility. The licensee also conducted observation, training, and testing of its nuclear medicine technologists. Since April 2014, the licensee has used maximum outpatient I-131 administration limits of 178 mCi for post-thyroidectomy patients and 53 mCi for hyperthyroidism patients.

The inspector also identified one Severity Level IV violation concerning the failure to ensure that written directives were dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries, as required by 10 CFR 35.40(a). Specifically, an individual who was not authorized on NRC License No. 24-25816-01 for the medical use prescribed by the written directive signed two written directives dated January 15 and 17, 2014. The individual was listed in Condition 12.B. of the NRC License as an authorized user for medical uses under 10 CFR 35.100 and 35.200. Prior to the administrations, the individual met the requirements to be considered qualified as an authorized user for oral administrations of I-131 sodium iodide less than or equal to 33 mCi described in 10 CFR 35.392.

The root cause of the violation was a misunderstanding by the authorized user. Specifically, the individual who signed the written directives believed that she was listed on the NRC license as an authorized user for medical uses under 10 CFR 35.300. As corrective actions to restore compliance and to prevent recurrence the licensee: (1) informed the individual that she was not allowed to sign any written directives until she was authorized on the NRC license; (2) verified

that the individual met the regulatory requirements to be qualified for administrations of I-131 sodium iodide less than or equal to 33 mCi; (3) revised their policy titled “Safety—Radiation Safety Officer (RSO) – Duties and Responsibilities” to help prevent a recurrence of this issue in the future; and (4) committed to submit a license amendment request to add authorization for the individual for medical uses under 10 CFR 35.300 before July 1, 2014.

## **REPORT DETAILS**

### **1 Program Overview**

Truman Medical Center operated a 260-bed hospital with authorization under NRC License No. 24-25816-01 to use byproduct material for medical uses permitted by 10 CFR Sections 35.100, 35.200, and 35.300. Three nuclear medicine technologists used material at two locations in the hospital: the Cardiology and Radiology Departments. Waste items from inpatient I-131 administrations were secured in a locked and posted storage area in a parking garage adjacent to the hospital. The previous NRC inspection on August 12, 2011, did not identify any violations of NRC requirements.

### **2 Radiopharmaceuticals Requiring a Written Directive**

#### **2.1 Inspection Scope**

The inspector reviewed and evaluated the licensee's use of byproduct material under 10 CFR 35.300. The inspector interviewed nuclear medicine staff members and the Radiation Safety Officer (RSO) and reviewed records of written directives for oral administration of I-131 sodium iodide.

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

During a records review of the licensee's administration of radiopharmaceuticals requiring a written directive, the inspector observed that the licensee treated many individuals who received greater than 33 mCi of I-131 as outpatients. The inspector asked how the licensee ensured compliance with the patient release requirements in 10 CFR 35.75. The licensee stated that they had completed calculations for the maximum amount of I-131 they could administer to individuals as outpatients in accordance with the regulatory requirements. The licensee said these calculations demonstrated that they could administer up to 200 mCi of I-131 to post-thyroidectomy patients and up to 55 mCi of I-131 to hyperthyroidism patients. The licensee's written directive form had a check box which referred back to these calculations as the basis for the patient's release; however, the licensee could not locate the calculations during the on-site inspection.

On May 29, 2014, the RSO e-mailed a letter to the inspector with several attachments. One of the attachments was the release criteria calculations used by the licensee prior to April 2014. In April 2014, the licensee changed its written directive form and calculations to better align with those used by their health physics consultant service. The inspector observed that the calculations used prior to April 2014 improperly stated that the licensee could administer up to 220 mCi of I-131 to post-thyroidectomy patients and up to 60.5 mCi of I-131 to non-thyroidectomy patients. The inspector identified the inconsistencies with the licensee's written directive form and also observed that the assumptions and algebra used on the calculations were incorrect. In a telephone conversation with the licensee on May 30, 2014, the inspector asked the licensee to: (1) revise its calculations and determine what activity limits were in place to ensure compliance with 10 CFR 35.75 prior to April 2014; and (2) review its case history since 2011 to determine whether any patients had been released from the licensee's control after being administered I-131 greater than the activity limits.

On June 11, 2014, the RSO e-mailed a letter to the inspector with answers to the items above. The licensee worked with a Certified Health Physicist to correct their mathematical errors and re-evaluate their maximum permissible activities of I-131 prior to April 2014. The licensee determined that the correct values should have been a maximum of 190 mCi for post-thyroidectomy patients and 54 mCi for hyperthyroidism patients. In the letter, the RSO wrote that “we asked [our] consultant physicist to review all outpatient cases that occurred between 2011 and 2014 for compliance with the 54 mCi. We found that two patients (one in 2011 and one in 2012) may have been released in excess of that standard.” The inspector called the RSO and requested copies of the written directive, pharmacy information, and physician’s order for both patients.

On June 27, 2011, and November 30, 2012, the licensee administered 70.0 and 69.3 mCi of I-131 to patients (respectively) and released the individuals from its control as outpatients. The written directive for both patients indicated that the patients had intact thyroids; therefore, neither patient should have been released from the licensee’s control as outpatients based on their general calculations.

This is an apparent violation of 10 CFR 35.75(a), which states, in part, that a licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). The licensee released two patients with intact thyroids from its control, and when assessing their release using the licensee’s patient-specific calculations, the total effective dose equivalent to any other individual from exposure to the individuals was likely to exceed 5 mSv.

While reviewing records of the licensee’s program to administer radiopharmaceuticals requiring a written directive, the inspector also identified a Severity Level IV violation of 10 CFR 35.40(a) for a failure to ensure that written directives were dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries. Specifically, the inspector identified that two written directives dated January 15 and 17, 2014, were signed by an individual who was not authorized on the NRC license for medical use under 10 CFR 35.300. The written directives were for oral administrations of 16 and 20 mCi of I-131, respectively. The individual was listed in Condition 12.B. of NRC License No. 24-25816-01 as an authorized user for medical uses under 10 CFR 35.100 and 35.200. Immediately following the preliminary on-site exit meeting on May 23, 2014, the licensee provided the inspector with a copy of the individual’s specialty board certification in Diagnostic Radiology from the American Osteopathic Board of Radiology, dated July 22, 2009. The certification satisfied the requirements for the individual to be considered qualified as an authorized user for oral administrations of I-131 sodium iodide less than or equal to 33 mCi as described in 10 CFR 35.392.

The root cause of the violation was a misunderstanding by the authorized user. Specifically, the individual who signed the written directives believed that she was listed on the NRC license as an authorized user for medical uses under 10 CFR 35.300. As corrective actions to restore compliance and to prevent recurrence the licensee: (1) informed the individual that she was not allowed to sign any written directives until she was authorized on the NRC license; (2) verified that the individual met the regulatory

requirements to be qualified for administrations of I-131 sodium iodide less than or equal to 33 mCi; (3) revised their policy titled "Safety—Radiation Safety Officer (RSO) – Duties and Responsibilities" to help prevent a recurrence of this issue in the future; and (4) committed to submit a license amendment request to add authorization for the individual for medical uses under 10 CFR 35.300 before July 1, 2014.

### 2.3 Conclusions

The inspector identified an apparent violation of 10 CFR 35.75(a) concerning the licensee's release of two individuals who had been administered byproduct material and the total effective dose equivalent to any other individual from exposure to the released individuals was likely to exceed 5 mSv. The inspector also identified a Severity Level IV violation of 10 CFR 35.40(a) and License Condition 12.B on NRC License No. 24-25816-01, involving the licensee's failure to have an authorized user for medical uses under 10 CFR 35.300 sign two written directives, dated January 15 and 17, 2014.

## 3 **Other Areas of Radiation Safety Program**

### 3.1 Inspection Scope

The inspector reviewed and evaluated a representative sample of the remainder of the licensee's program to determine whether licensed activities were being conducted in accordance with NRC requirements.

### 3.2 Observations and Findings

The inspector reviewed the licensee's medical uses of byproduct materials under 10 CFR 35.100 and 10 CFR 35.200. One of the licensee's three nuclear medicine technologists conducted diagnostic administrations for six to eight patients per day in the Cardiology Department. The licensee's other two nuclear medicine technologists conducted diagnostic administrations for five to six patients per day in the general Radiology Department. These procedures were primarily bone, gastric emptying, lung, and gall bladder scans. The licensee received almost entirely unit doses from an area nuclear pharmacy and did not use generators.

The inspector observed two diagnostic administrations of licensed material during the inspection. These observations, combined with interviews of available staff, revealed an adequate level of understanding of emergency and material handling procedures and techniques. The licensee successfully demonstrated routine equipment checks, package receipt, area surveys, and waste handling and disposal procedures. A contract physicist performed quarterly audits to help oversee the nuclear medicine program. The inspector confirmed that these activities were routinely completed by reviewing selected records.

Licensed material was adequately secured and not readily accessible to members of the general public. The licensee possessed radiation survey meters that were calibrated and operational. Personal whole body and extremity dosimetry badges were observed being worn by the staff during the inspection, and records did not indicate doses in excess of 10 CFR Part 20 limits. Dosimetry records indicated that the highest annual whole body and extremity readings since the previous inspection were 596 millirem and 3420 millirem, respectively. Using a Ludlum 2403 survey meter with a model 44-38

energy-compensated Geiger-Mueller (GM) detector, the inspector conducted independent surveys at each of the locations inspected. The inspector found no readings that would indicate residual contamination or exposures to members of the public in excess of regulatory limits.

### 3.3 Conclusions

The inspector did not identify any violations related to the licensee's use of radioactive materials under 10 CFR 35.100 and 35.200.

## 4 **Exit Meeting Summary**

The NRC inspector presented preliminary inspection findings following the onsite inspection on May 23, 2014, and during the final telephone exit meeting on June 27, 2014. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary. The licensee acknowledged the findings presented.

### **LIST OF PERSONNEL CONTACTED**

- \* Dr. Lawrence Ricci, Chief Radiologist, RSO
- Dr. Joseph Witham, Authorized User
- # Lynda Donegan, Administration
- # Carole Jones, Director of Medical Imaging
- \* Donna Gordon, Manager of Medical Imaging
- # Renee Carlson, Health Physics Consultant, Cardinal Health
- Evetta Bailey, Nuclear Medicine Technologist
- \* Andrea McQueen, Senior Administrative Assistant
- # Priyanka Patel, Supervisor and Nuclear Medicine Technologist
- Nuclear medicine technologists and nursing staff in Cardiology and Radiology departments
  
- \* Attended preliminary on-site exit meeting on May 23, 2014
- # Attended final telephone exit meeting on June 27, 2014.

### **INSPECTION PROCEDURES USED**

87131: Nuclear Medicine Programs, Written Directive Required