UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, ILLINOIS 60532-4352

October 8, 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: NOTICE OF VIOLATION – TRUMAN MEDICAL CENTER
NRC ROUTINE INSPECTION REPORT NO. 03030130/2014001(DNMS)

Dear Ms. Jones:

This letter refers to the routine inspection conducted at your facility in Kansas City, Missouri, on May 22 and 23, 2014, with continuing 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 U.S. Nuclear Regulatory Commission (NRC) requirements. 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 during a telephonic exit meeting that was held on June 27, 2014. Details regarding the apparent violation were provided in NRC Inspection Report No. 03030130/2014001(DNMS) dated July 24, 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 August 14, 2014, you provided a response to the apparent violation. You provided additional details about your future corrective actions in an e-mail to the NRC dated September 15, 2014.

Based on the information developed during the inspection and the information that you provided in your responses dated August 14 and September 15, 2014, 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, in response to questions posed by the NRC, your staff determined that they had released a patient on June 27, 2011, and another patient on November 30, 2012, who received I-131 sodium iodide administrations greater than your maximum allowable activity for outpatients, contrary to 10 CFR 35.75(a). Both written directives indicated that the individuals had intact thyroids; therefore, neither individual should have been released as outpatients based on the general calculations. The violation occurred due to your staff's failure to recognize that the administrations of I-131 sodium iodide were in amounts greater than the Truman Medical Center protocol for outpatient administrations, in part, due to inconsistencies between your categorization of patients, the written directive, and the general calculations. The release of individuals who do not meet the release criteria in 10 CFR 35.75(a)

could result in adverse impacts to the health and safety of the general public. 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 you provided in your letter dated August 14, 2014, and your e-mail dated September 15, 2014. Your immediate corrective actions included revising your policy, procedures, written directive and Quality Management program, and training all technologists on the revisions. These documents included a corrected calculation of the maximum I-131 sodium iodide dose for outpatients as well as a requirement for a survey with documentation of the results. Truman Medical Center has changed its maximum outpatient I-131 sodium iodide administrations for post-thyroidectomy limits to 178 millicuries and for hyperthyroidism to 53 millicuries. All patients are now measured with a suitable survey instrument prior to being released as outpatients. On June 20, 2014, mandatory in-service training was provided to all approved technologists and members of the radiology administration and hospital administration by your health physicist consulting group. Each completed I-131 sodium iodide therapy administration and corresponding forms will be reviewed by a supervisor prior to discharge of the respective patient and documented in the patient's medical record. These records will also be reviewed by your health physicist consulting group on a quarterly basis. A summary of all administrations will be documented in the quarterly audit and reported to the Radiation Safety Committee. You also stated that training on I-131 sodium iodide policies and procedures will be administered on an annual basis for all staff nuclear medicine technologists and inpatient nurses participating in I-131 sodium iodide cases. The I-131 sodium iodide training attendance records will be reviewed, dated, and signed by the Radiation Safety Officer. On the basis of 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 the inspection report, in your letter dated August 14, 2014, and in your e-mail on September 15, 2014. 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 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 D. Roberts for/

Cynthia D. Pederson
Regional Administrator

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

Enclosure:
Notice of Violation

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

NOTICE OF VIOLATION

Truman Medical Center
Kansas City, Missouri

Docket No. 030-30130
License No. 24-25816-01
EA-14-115

During an NRC inspection conducted on May 22 and 23, 2014, with continued review through June 26, 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) 35.75(a) states 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 milliSievert (mSv) (0.5 rem).
>
> Contrary to the above, on June 27, 2011, and November 30, 2012, the licensee authorized the release from its control individuals who were administered unsealed byproduct material, but failed to ensure that the total effective dose equivalent to any other individual from exposure to the released individual was not likely to exceed 5 mSv (0.5 rem). Specifically, the licensee released two individuals who had received I-131 sodium iodide administrations of 70 and 69.3 millicuries, respectively, that were in excess of the licensee's maximum outpatient release level of 54 millicuries. The 54 millicuries release level was based on a calculated dose of 5 mSv (0.5 rem) to any other individual. The licensee did not perform surveys or patient-specific calculations, that were reasonable under the circumstances, to evaluate the magnitude and extent of radiation levels.

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. 03030130/2014001(DNMS) dated July 24, 2014, and your responses dated August 14, 2014, and September 15, 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-14-115," 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

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

Dated this 8th day of October, 2014

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 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 D. Roberts for/

Cynthia D. Pederson
Regional Administrator

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

Enclosure:
Notice of Violation

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

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FILE NAME: EA-14-115 Truman Final Action.docx

OFFICE	RIII	RIII	RIII	D:OE	RIII	RIII
NAME	Pelke	McCraw	Louden	Holahan[1]	Orth	Roberts for Pederson
DATE	09/18/14	09/12/14	09/18/14	09/29/14	10/08/14	10/08/14

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[1] OE concurrence provided via e-mail from K. Norman on 09/29/14