

NRC FORM 591M PART 1 (07-2012) 10 CFR 2.201		U.S. NUCLEAR REGULATORY COMMISSION																	
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION																			
1. LICENSEE/LOCATION INSPECTED: VC Reddy, MD & SS Dandamundi, MD, PC 714 S Trumbull St, Suite 201 Bay City, MI 48708		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352																	
REPORT NUMBER(S) 2013-001																			
3. SOCKET NUMBER(S) 030-36266	4. LICENSE NUMBER(S) 21-32453-01	5. DATE(S) OF INSPECTION April 19, 2013																	
<p>LICENSEE:</p> <p>The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:</p> <p><input type="checkbox"/> 1. Based on the inspection findings, no violations were identified.</p> <p><input type="checkbox"/> 2. Previous violation(s) closed.</p> <p><input type="checkbox"/> 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.</p> <p>Non-cited violation(s) were discussed involving the following requirement(s):</p> <p><input checked="" type="checkbox"/> 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to passing in accordance with 10 CFR 19.11. (Violations and Corrective Actions)</p> <p>10 CFR 20.1801 requires that licensees secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. As defined in 10 CFR 20.1003, controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason. Contrary to the above:</p> <p>(A) On April 18, 2013, the licensee failed to secure from unauthorized removal or access approximately 60 times the 10 CFR 20 Appendix C quantities of material located in the facility's hot lab, which is a controlled area. Specifically, the technologist left the imaging room and hot lab doors ajar when he left the area for another part of the facility, and did not maintain control of access to the imaging room or the hot lab.</p>																			
<p align="center">Statement of Corrective Actions</p> <p>I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.</p> <table border="1"> <thead> <tr> <th>TITLE</th> <th>PRINTED NAME</th> <th>SIGNATURE</th> <th>DATE</th> </tr> </thead> <tbody> <tr> <td>LICENSEE'S REPRESENTATIVE</td> <td>VC REDDY MD</td> <td>VC Reddy</td> <td>5-2-13</td> </tr> <tr> <td>NRC INSPECTOR</td> <td>Ryan Craftley</td> <td>Ryan Craftley</td> <td>4/24/13</td> </tr> <tr> <td>BRANCH CHIEF</td> <td>Tamara Bloomer</td> <td>Tamara Bloomer</td> <td>5/13/13</td> </tr> </tbody> </table>				TITLE	PRINTED NAME	SIGNATURE	DATE	LICENSEE'S REPRESENTATIVE	VC REDDY MD	VC Reddy	5-2-13	NRC INSPECTOR	Ryan Craftley	Ryan Craftley	4/24/13	BRANCH CHIEF	Tamara Bloomer	Tamara Bloomer	5/13/13
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LICENSEE'S REPRESENTATIVE	VC REDDY MD	VC Reddy	5-2-13																
NRC INSPECTOR	Ryan Craftley	Ryan Craftley	4/24/13																
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SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

VC Reddy, MD & SS Dandamundi, MD, PC
714 S Trumbull St, Suite 201
Bay City, MI 48708

REPORT NUMBER(S) 2013-001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
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5. DATE(S) OF INSPECTION

April 19, 2013

(Continued)

(B) On April 18, 2013, the licensee failed to secure from unauthorized removal or access a limited quantity of Technetium-99m in the form of injection waste in a locked and shielded sharps container located in the facility's imaging room, which is also a controlled area. Specifically, the technologist left the imaging room door ajar when he left the area for another part of the facility, and did not maintain control of access to the imaging room.

In accordance with Section 6.7.D.6 of the NRC's Enforcement Policy, these examples represent a Severity Level IV violation.

The inspector discussed the requirement to secure licensed material with the technologist, who promptly locked the hot lab door throughout the remainder of the inspection whenever he left the immediate vicinity of the imaging area. The inspector also discussed the requirement with the technologist and Dr. Reddy during the preliminary exit meeting. The licensee agreed to create a procedure for securing the lab under various circumstances, and also committed to securing the leaded sharps box in the imaging area at all times. The technologist provided a draft copy to the inspector on April 23, 2013.

Docket File Information
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6. INSPECTION PROCEDURES USED

87130

7. INSPECTION FOCUS AREAS

03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02201

2. PRIORITY

5

3. LICENSEE CONTACT

Stephen Messana, DO - RSO

4. TELEPHONE NUMBER

(989) 893-5541

☒ Main Office Inspection

Next Inspection Date: April 2018

☐ Field Office Inspection☐ Temporary Job Site Inspection**PROGRAM SCOPE**

The licensee is a physician's office authorized by its NRC materials license to use unsealed byproduct material for diagnostic procedures under 10 CFR 35.200 at its facility in Bay City, Michigan. A local radiopharmacy delivers unit doses of Technicium-99m to the clinic for cardiac studies. The department is staffed Monday through Friday by one full-time nuclear medicine technologist, who performs approximately two to four procedures per day. The physician's office retained the services of a medical physics consultant to perform instrument calibrations and quarterly audits.

Performance Observations

The inspector toured the nuclear medicine laboratory, where the nuclear medicine technologist demonstrated package receipt procedures, daily and weekly area surveys as well as waste handling practices. The inspector witnessed the preparation and administration of two cardiac stress tests and noted satisfactory use of ALARA principles. The inspector performed independent and confirmatory surveys of the hot lab, injection and imaging rooms, and interviewed the nuclear medicine technologist who demonstrated adequate knowledge of radiation safety principles and procedures. The inspector reviewed a selection of licensee records, including those for package receipt, area surveys, dose calibrator quality control, well counter quality control, inventories and quarterly audits. The inspector also reviewed monthly dosimetry records, which indicated annual whole-body and extremity doses below regulatory limits.

The inspector identified one violation of 10 CFR 20.1801 for failure to secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.