U.S. NUCLEAR REGULATORY COMMISSION

NRC FORM 591M PART 1
(10-2003)
10 CFR 2.201

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Nuclear Medicine, Inc. P.O. Box 6480 Santa Rosa Unit Bayamón, Puerto Rico 00960-9005 @ Edificio Médico Menonita, Carr 14, Cayey REPORT Nos 2009-001	**U.S. Nuclear Regulatory Commission Region I, 475 Allendale Road King of Prussia, Pennsylvania 19406-1415**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36419	52-30841-01	June 17, 2009

LICENSEE:

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:

☐ 1. Based on the inspection findings, no violations were identified.

☐ 2. Previous violation(s) closed.

☒ 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, NUREG-1600, to exercise discretion, were satisfied.

☒ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

10 CFR 20.1502 requires in part, that a licensee monitor exposures to radiation and radioactive materials at levels sufficient to demonstrate compliance with the occupational dose limits of this part. As a minimum, the licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from the sources external to the body, a dose in excess of 10 percent of the limits in § 20.1201(a).

Contrary to the above, between January 2007 and July 2008, the technologist did not use the dosimeter provided by the licensee to monitor exposures to radiation and radioactive materials. The licensee self identified the problem and ordered the technologist to wear the dosimeter. The technologist refused to wear the dosimeter. As a corrective action, the licensee terminated the employment of the technologist.

☒ 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

10 CFR 35.60(b) requires, that for direct measurements performed in accordance with § 35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient and a licensee shall calibrate the instrumentation in accordance with nationally recognized standards or the manufacturer's instructions.

Contrary to the above, between March 2007 and June 17, 2009 an accuracy test was not performed on the Capintec CRC-15R dose calibrator. According to the manufacturer's instructions this type of measurement should be performed at installation and annual there after. As a corrective action, the licensee performed an accuracy test for the dose calibrator and committed in writing to perform this type of test annually.

10 CFR 35.63 requires in part, that a licensee determine and record the activity of each dosage before medical use and requires that a licensee retain a record of the dosage determination required by this section in accordance with § 35.2063. Furthermore, 10 CFR 35.2063 requires in part, that the record must contain, the prescribed dosage, the determined dosage, the date and time of the dosage determination; and the name of the individual who determined the dosage.

Contrary to the above, between January of 2007 and June 17, 2009, the licensee did not record the activity of each dosage before medical use. Specifically, the licensee's records did not contain, the prescribed dosage, the determined dosage, the date and time of the dosage determination, and the name of the individual who determined the dosage. As a corrective action the licensee committed to recording the activity of a radiopharmaceutical containing radioactive material before it is administered to a patient for medical use effective immediately. Also, the licensee committed to include in their records the prescribed dosage, the determined dosage, the date and time of the dosage determination, and the name of the individual who determined the dosage.

Licensee's Statement of Corrective Actions for Item 4, above.

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.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE	Humberto O. Quintana-Irazola, M.D.	Quintana	08-25-09 1115
NRC INSPECTOR	Lizette Roldán, Ph.D./Health Physicist	Lizette Roldán	08/25/09

SUNSI Review Completed By: */ RA /* Lizette Roldán [X] Public [X] Non-Sensitive