

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:
Levan Internists, P.C.
15130 Levan Road, Suite 200
Livonia, MI 48154
REPORT NUMBER(S): 11-01

2. NRC/REGIONAL OFFICE
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532

3. DOCKET NUMBER(S)
030-35235

4. LICENSEE NUMBER(S)
21-32215-01

5. DATE(S) OF INSPECTION
March 22, 2011

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

1 Non-cited violation(s) were discussed involving the following requirement(s):

Condition 15 of NRC License No. 21-32215-01 requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the Application dated August 10, 2009.

Item 10 of the Application dated August 10, 2009, states, in part, that the licensee has developed and will implement and maintain procedures for safe use of unsealed byproduct material that meets the requirements of 10 CFR 21.1101 and 10 CFR 20.1301.

The licensee's Radiation Protection Program, under the procedure titled "Rules for the Safe Use of Radiopharmaceuticals" states, in part, "Do not eat, or drink, in any restricted area."

Contrary to the above, on April 15, 2010, the licensee ate or drank in a restricted area. Specifically, the licensee's contract physicist identified that the licensee ate and drank in the nuclear medicine room, which is a restricted area.

This issue was identified and documented by the licensee's consultant physicist during a routine audit. The licensee took immediate corrective actions to remove the food and drink from the nuclear medicine room, and reinforced that this practice was not allowed through training. The inspector did not observe any food or drink in the nuclear medicine room during the onsite visit on March 22, 2011.

- 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

Statement of Corrective Actions

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			
NRC INSPECTOR	Andrew M. Bramnik	<i>Andrew M. Bramnik</i>	3/29/2011
Branch Chief	Tamara E. Bloomer	<i>T. Bloomer</i>	3/29/11

Docket File Information
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6. INSPECTION PROCEDURES
87130

7. INSPECTION FOCUS AREAS
03.01 – 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM
2201

2. PRIORITY
5

3. LICENSEE CONTACT
Abhinav Raina, M.D.

4. TELEPHONE NUMBER
734-779-2100

Main Office Inspection

Next Inspection Date: March 2016

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine inspection of a private clinic that performed approximately 4-8 diagnostic nuclear medicine procedures per day. Three part time nuclear medicine technologists performed all patient procedures on Mondays, Tuesdays, and Saturdays. The licensee obtained licensed material as unit doses from an area nuclear pharmacy, and did not use xenon-133, bulk doses, or molybdenum/technetium generators. The licensee performed primarily cardiac scans, as well as occasional bone and HIDA scans, and was not authorized to perform or administer therapeutic doses.

Performance Observations

The inspector observed two resting doses of technetium-99m being administered to patients. These observations, combined with interviews of available staff, revealed an adequate level of understanding of emergency and material handling procedures and techniques. Dose calibrator constancy checks, package receipt, daily surveys, and waste handling and disposal procedures were successfully demonstrated. An outside consultant performed quarterly program audits that were adequate to oversee the program.

Licensed material was adequately secured and not readily accessible to members of the general. The licensee possessed a radiation survey meter that was calibrated, operational, and performed well in side-by-side comparison with an NRC instrument.

Independent measurements did not indicate readings in excess of Title 10 of the Code of Federal Regulations (10 CFR) Part 20 limits in restricted or unrestricted areas. Personal whole body and extremity dosimetry were observed worn by the staff at both locations during the inspection, and records did not indicate doses in excess of 10 CFR Part 20 limits. Dosimetry records indicated that maximum whole body and extremity readings for 2010 were 132 millirem (mrem) and 458 mrem, respectively. Maximum readings for 2009 were 155 mrem and 594 mrem.

One Non-Cited Violation (NCV) was identified for the licensee eating or drinking in the nuclear medicine room, which is a restricted area. The NCV is described in Part One, above.