INSPECTION RECORD

Region III Inspection Report No. 030-34560/11-01

License No. 21-32033-01
Docket No. 030-34560

Licensee:
Norlivo Internal Medicine, PLLC
20311 Farmington Road
Livonia, Michigan 48152-1411

Licensee Contact: Maureen Hook, Office Manager

Telephone No. 248-442-1400

Priority: 5 Program Code: 2201

Date of Last Inspection: 9/15/2005

Date of This Inspection: 3/24/2011 with continued in-office review through 3/29/2011 to review placement of mini-fridge containing juice drinks

Type of Inspection: ( ) Initial ( ) Announced (X) Unannounced
(X) Routine ( ) Special

Next Inspection Date: March 2016 (X) Normal ( ) Reduced

Summary of Findings and Actions:

( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
(X) Violation(s), regional letter issued
( ) Followup on previous violations

Inspector: Andrew M Bramnik Date: April 6, 2011
Andrew M. Bramnik
Health Physicist

Approved: T E Bloomer Date: 4/11/11
Tamara E. Bloomer, Chief,
Materials Inspection Branch

PART I - LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

Amendment No.	Date	Subject
7	8/4/2009	Change in business name (from Livonia Internal Medicine Associates to Norlivo Internal Medicine)
6	11/12/2007	Removal of previous address from license
5	12/26/2006	Addition of proposed new address to license

2. INSPECTION AND ENFORCEMENT HISTORY:

No violations were identified during prior inspections on September 15, 2005, and April 18, 2002.

3. INCIDENT/EVENT HISTORY:

None

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Management Structure:
Office Manager
Radiation Safety Officer (Consultant)
Nuclear Medicine Technologist

The licensee operated a private clinic that performed approximately 10 diagnostic nuclear medicine procedures per week. One full time nuclear medicine technologist performed all patient procedures Monday through Friday. 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 MUGA, HIDA, and bone scans, and was not authorized to perform or administer therapeutic doses.

The licensee's Radiation Safety Officer (RSO), Mr. Ray Carlson, also served as the clinic's consultant physicist. Mr. Carlson visited the clinic approximately four times per year to conduct routine audits to oversee the radiation protection program.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87130

Focus Areas Evaluated: Sections 03.01 through 03.07

The inspector observed one resting dose and two stress doses of technicium-99m being administered during the inspection. Through these observations, combined with interviews of available staff, the licensee demonstrated an adequate understanding of procedures and techniques to safely handle licensed materials. Dose calibrator

constancy checks, daily surveys, and waste handling and disposal procedures were also successfully demonstrated. One violation was identified for the licensee's failure to adequately assay wipe samples during package receipt, and is discussed in Section 4, below.

Personal whole body and extremity dosimetry were observed being worn by the staff during the inspection, and records did not indicate doses in excess of limits in Title 10 of the Code of Federal Regulations (10 CFR) Part 20. Dosimetry records indicated that the highest annual whole body and extremity readings for the past four years were 58 millirem (mrem) and 82 mrem, respectively.

The inspector observed that the licensee stored juice drinks in a mini-refrigerator in the stress room where patients were injected with radioactive materials. Although the licensee had a license commitment to not store food, drink, or personal effects in areas where radioactive material is stored or used, the drinks were for patient use only. Therefore, this did not represent a violation of the license.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Independent measurements taken did not indicate readings in excess of 10 CFR Part 20 limits in restricted or unrestricted areas. The licensee possessed a radiation survey meter that was calibrated, operational, and performed well in side-by-side comparison with an NRC instrument.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

Condition 15 of NRC License No. 21-32033-01 requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the Application dated October 28, 2002.

A. Line 2.e. of Item 10.7, "Model Procedure for Safely Opening Packages Containing Radioactive Material" of the Application dated October 28, 2002, requires, in part, that the licensee wipe the external surface of the package and assay the wipe sample to determine if there is any removable radioactivity. The procedure further states that a dose calibrator is not sufficiently sensitive for this measurement.

Contrary to the above, on March 17, 18, 22, and 24, 2011, the licensee failed to properly assay wipe samples of incoming packages containing radioactive materials. Specifically, the licensee attempted to assay the wipe samples using a dose calibrator.

The root cause of this violation was a misunderstanding by the nuclear medicine technologist on the status of a well counter used for assaying wipe samples to detect removable radioactivity. On March 17, 2011, the RSO determined that the well counter required maintenance to correct a calibration issue and receive a software update. On March 17, 18, 22, and 24, 2011, the technologist interpreted this to mean that the well counter could not be used for wipe sample analysis. On those days, the technologist attempted to assay wipe samples of incoming packages containing radioactive materials by placing the wipe sample into a disposable glove, and then into the dose calibrator. However, the procedure "Model Procedure for Safely Opening Packages Containing Radioactive Material" stated that a dose calibrator is not sufficiently sensitive for this measurement. The technologist stated that she was not

aware that the well counter could still be used for wipe sample analysis, and thought that the dose calibrator would be acceptable to perform the assay.

As corrective actions, the RSO delivered a portable simulation probe that had been calibrated to assay wipe samples to the facility on March 28, 2011. The RSO trained the technologist on the use of this equipment, and took the well counter for maintenance. The technologist will use the simulation probe until the well counter has been repaired, tested, and returned. These actions will be complete by April 22, 2011.

B. Line 4. of Item 10.6, "Model Guidance for Ordering and Receiving" of the Application dated October 28, 2002, states that there will be no off duty deliveries.

Contrary to the above, on multiple occasions between January 1, 2007, and March 24, 2011, the licensee received off-duty deliveries of packages containing radioactive materials.

The root cause of this violation was a lack of awareness by the licensee's staff and management of the requirement to not receive deliveries of packages containing radioactive materials during off duty hours.

As corrective actions, the RSO submitted a license amendment request to the NRC, removing the requirement of no off duty deliveries contained in your procedure "Model Guidance for Ordering and Receiving." The license amendment request was received by the NRC on March 27, 2011.

5. PERSONNEL CONTACTED:

*Maureen Hook, Office Manager
#Ray Carlson, RSO

Use the following identification symbols:

* Individual present at March 24, 2011, preliminary on-site exit meeting
# Individual present at March 29, 2011, telephone exit meeting

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