

April 11, 2011

Ms. Maureen Hook
Office Manager
Norlivo Internal Medicine, PLLC
20311 Farmington Road
Livonia, Michigan 48152-1411

SUBJECT: NRC INSPECTION REPORT NO. 030-34560/11-01(DNMS) AND NOTICE OF VIOLATION – NORLIVO INTERNAL MEDICINE

Dear Ms. Hook:

On March 24, 2011, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at your Livonia, Michigan facility, with continued NRC in-office review through March 29, 2011. The in-office review was related to an evaluation of the placement of a mini-refrigerator containing drinks in your stress room. A telephone exit meeting between your Radiation Safety Officer (RSO) Mr. Ray Carlson and Andrew Bramnik of my staff was conducted on March 29, 2011, to discuss the inspection findings.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff confirmed your compliance with the conditions of your license as well as the Commission's rules and regulations. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations involved the failure to: (1) assay wipe samples of incoming packages containing radioactive materials to determine if there was any removable radioactivity; and (2) comply with a license commitment to not receive off duty deliveries of packages containing radioactive materials. The violations are cited in the enclosed Notice of Violation (Notice) because they were identified by the NRC. The potential corrective actions to address the above violations were discussed between yourself and members of the NRC staff during the site inspection and telephone exit meeting.

The root cause of the first 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, your 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 nuclear medicine 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, your procedure "Model Procedure for Safely Opening Packages Containing Radioactive Material" states, in part, that "The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement." As corrective actions, your RSO delivered a portable simulation probe that had been calibrated to assay wipe samples to your facility on March 28, 2011. The RSO trained the technologist on the use of this equipment at that time, 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.

The root cause of the second violation was a lack of awareness of the requirement in your license to not receive deliveries of packages containing radioactive materials during off duty hours. As corrective actions, your 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.

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence is already adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description herein 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 Title 10 of the Code of Federal Regulations (10 CFR) Section 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 or from 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>. 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.

M. Hook

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We will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch

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

Enclosure:
Notice of Violation

cc w/encl: Ray Carlson, RSO
State of Michigan

M. Hook

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We will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch

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

Enclosure:
Notice of Violation

cc w/encl: Ray Carlson, RSO
State of Michigan

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NOTICE OF VIOLATION

Norlivo Internal Medicine, PLLC
Livonia, Michigan

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

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on March 23, 2011, with continued NRC in-office review through March 29, 2011, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

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.

This is a Severity Level IV violation (Section 6.3.d.3).

- 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.

This is a Severity Level IV violation (Section 6.3.d.3).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violations and prevent recurrence, and the date when full compliance will be achieved, is already adequately addressed on the docket in the letter transmitting this Notice of Violation (Notice). However, you are required to submit a written statement or explanation pursuant to Title 10 of the Code of Federal Regulations (CFR) Section 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," 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.

Enclosure

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access & Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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

Dated this 11th day of April 2011.