April 16, 2012

EA-12-068

Floro Miraldi, Sc.D., M.D.
Chief Executive Officer
and Radiation Safety Officer
neo-pet, LLC
34555 Chagrin Boulevard, Suite 200
Cleveland, Ohio 44022

SUBJECT: NRC INSPECTION REPORT NO. 15000034/2012001(DNMS) AND NOTICE OF VIOLATION – NEO-PET LLC

Dear Dr. Miraldi:

On March 20, 2012, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted an inspection at a temporary job site at St. Vincent Health St. Joseph Hospital in Kokomo, Indiana. The NRC also conducted an in-office review on March 9 through April 5, 2012, to evaluate neo-pet's work activities conducted in areas under NRC jurisdiction. A telephonic exit meeting was conducted between yourself and Andrew Bramnik and Geoffrey Warren of my staff on April 5, 2012, to discuss the inspection findings.

During this inspection, the NRC staff examined activities conducted under the general license provisions of Title 10 of the Code of Federal Regulations (CFR), Section 150.20, related to public health, safety, and security. This inspection also examined activities your company performed in the State of Indiana during the calendar years of 2010, 2011, and 2012 as they relate to safety and compliance with 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 one apparent violation was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is located on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violation involved the possession and utilization of fluorine-18 fluorodeoxyglucose (FDG) in Indiana, a non-Agreement State, on multiple occasions between April 6, 2010, and March 9, 2012, without first requesting reciprocity from the NRC via filing an NRC form 241 for each calendar year. The circumstances surrounding the apparent violation, the significance of the issue, and the need for lasting and effective corrective actions were discussed with you at the inspection exit meeting on April 5, 2012. As a result, it may not be necessary to conduct a Pre-decisional Enforcement Conference (PEC) in order to enable the NRC to make an enforcement decision.

In addition, since your facility has not been the subject of escalated enforcement actions within the last two years or last two inspections, and based on our understanding of your corrective actions, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) respond in writing to the apparent violation addressed in the enclosed inspection report within 30 days of the date of this letter; (2) request a PEC; or (3) respond to the NRC that the information contained in this letter and the enclosed inspection report is correct, and that no additional information will be provided. If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference. A PEC should be held within 30 days of the date of this letter.

Please contact Tamara Bloomer at 630-829-9627 within ten days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a "Response to an Apparent Violation in Inspection Report No. 15000034/2012001(DNMS); EA-12-068" and should include for the apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation.

In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

Additionally, based on the results of this inspection, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The violation involved the failure to control and maintain constant surveillance of a syringe containing fluorine-18 that was located inside a mobile coach at a temporary job site. The violation is cited in the enclosed Notice of Violation (Notice) because it was identified by an NRC inspector.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved, is already adequately addressed on the docket in the subject inspection report. Therefore, you are not required to respond to the Severity Level IV violation described in 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 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, 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.

Sincerely,

***/RA/***

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 150-00034
Ohio License No. 02220180046

Enclosures:
1. Notice of Violation
2. Inspection Report No. 15000034/2012001(DNMS)

cc w/encls: State of Ohio
State of Indiana
State of Illinois

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved, is already adequately addressed on the docket in the subject inspection report. Therefore, you are not required to respond to the Severity Level IV violation described in 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.
regarding the security of licensed materials. As long-term corrective actions, you committed to include security in an annual training session for all technologists, and stated that this training would be complete by June 30, 2012.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, 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.

Sincerely,

***/RA/***

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 150-00034
Ohio License No. 02220180046

Enclosures:
3. Notice of Violation
4. Inspection Report No. 15000034/2012001(DNMS)

cc w/encls: State of Ohio
State of Indiana
State of Illinois

DISTRIBUTION w/encls:
See next page

*See previous concurrence
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***OFFICIAL RECORD COPY***

Letter from Anne T. Boland to Floro Miraldi, dated April 16, 2012.

SUBJECT: NRC INSPECTION REPORT NO. 15000034/2012001(DNMS) AND NOTICE OF VIOLATION – NEO-PET LLC

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NOTICE OF VIOLATION

neo-pet, LLC
Cleveland, Ohio

Docket No. 150-00034
Ohio License No. 02220180046

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on March 20, 2012, with continued in-office review between March 9 and April 5, 2012, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> Title 10 of the Code of Federal Regulations (CFR) 20.1802 states that the licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.
>
> Contrary to the above, on March 20, 2012, the licensee did not maintain constant surveillance of 17.2 millicuries of fluorine-18 fluorodeoxyglucose located in the licensee's coach outside St. Joseph Hospital in Kokomo, Indiana, which was an unrestricted area.

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

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to be taken to correct the violation, and the date when full compliance will be achieved is already adequately addressed in the subject Inspection Report No. 15000034/2012001(DNMS). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the descriptions therein do 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, Inspection Report No. 15000034/2012001(DNMS)" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice.

If you contest the enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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 and 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 16th day of April 2012.

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

| | |
|---|---|
| Docket No. | 150-00034 |
| License No. | Ohio License No. 02220180046 |
| Report No. | 15000034/2012001(DNMS) |
| EA No. | EA-12-068 |
| Licensee: | neo-pet, LLC<br>Cleveland, Ohio |
| Location of work: | Temporary Job Site:<br>St. Vincent Health St. Joseph Hospital<br>1907 West Sycamore St<br>Kokomo, IN |
| Inspection Dates: | March 9 through April 5, 2012 |
| Exit Meeting: | April 5, 2012 |
| Inspectors: | Andrew M. Bramnik, Health Physicist<br>Geoffrey M. Warren, Health Physicist |
| Approved by: | Tamara E. Bloomer, Chief<br>Materials Inspection Branch<br>Division of Nuclear Materials Safety |

## EXECUTIVE SUMMARY

### neo-pet, LLC
### Cleveland, Ohio
### NRC Inspection Report 15000034/2012001(DNMS)

On March 9, 2012, the U.S. Nuclear Regulatory Commission (NRC) initiated an inspection of neo-pet, LLC, a licensee authorized by the State of Ohio to possess and use radioactive materials for diagnostic imaging purposes at the company's office in Cleveland, Ohio, as well as temporary client sites throughout Ohio. Neo-pet operated mobile positron emission tomography (PET) scanning coaches at temporary job sites throughout the Midwest and New England. The NRC initiated the inspection because of information provided by the licensee indicating that they had conducted licensed activities within Indiana, a non-Agreement State, for parts of three calendar years without first requesting reciprocity from the NRC. On March 20, 2012, an NRC inspector conducted an on-site inspection at a temporary job site located in Kokomo, Indiana.

The inspectors identified one apparent violation of Title 10 of the Code of Federal Regulations (CFR) 150.20, involving neo-pet's failure to request reciprocity from the NRC by filing an NRC Form 241 prior to conducting licensed activities in a non-Agreement State where the NRC maintains jurisdiction. Specifically, for 35 days in 2010, 48 days in 2011, and approximately 10 days in 2012, the licensee possessed and utilized doses of fluorine-18 (F-18) fluorodeoxyglucose (FDG) at a temporary job site in Kokomo, Indiana, without first filing an NRC Form 241 for each calendar year. The root cause was the licensee's lack of awareness that the use of Naturally-Occurring and Accelerator-Produced Radioactive Materials in the State of Indiana was regulated by the NRC. The licensee mistook two-year registrations with the State of Indiana for mobile PET scan activities obtained in 2009 and 2011 as approvals to possess and use licensed materials in Indiana under their State of Ohio license. As corrective action, neo-pet submitted an NRC Form 241 with the correct fee payment, as appropriate, for calendar years 2010, 2011, and 2012, paying a total of $4,200 in reciprocity fees.

The inspectors also identified a Severity Level IV violation of 10 CFR 20.1802 associated with the licensee's failure to maintain constant surveillance of a syringe containing 17.2 millicuries of F-18 FDG that was not in storage. The root cause of the violation was the technologist's oversight in not returning the syringe to storage or locking the coach or hot lab prior to leaving the area. As an immediate corrective action, the licensee re-trained the technologist regarding security of licensed materials. As long-term corrective action, the licensee committed to include security in an annual training session for all technologists. The licensee stated that the annual training would be complete by June 30, 2012. The licensee also committed to send a memo describing security requirements to all technologists if the training could not be completed before July 2012.

Report Details

## 1 Program Scope and Inspection History

Neo-pet, LLC is a licensee of the State of Ohio authorized under Ohio License No. 02220180046 to possess and use radioactive materials for diagnostic imaging purposes at the company's office in Cleveland, Ohio, as well as temporary client sites throughout Ohio. Neo-pet operated mobile positron emission tomography (PET) scanning coaches at temporary job sites throughout the Midwest and New England. The company had not been inspected by the U.S. Nuclear Regulatory Commission (NRC) before, and therefore had no enforcement history within NRC jurisdiction.

## 2 Reciprocity

### 2.1 Inspection Scope

The inspectors interviewed licensee staff and reviewed selected documents concerning the possession and use of licensed radioactive material within Indiana, a non-Agreement State, between April 2010 and March 2012.

### 2.2 Observations and Findings

On March 8, 2012, a Region III materials license reviewer received a telephone call from the Radiation Safety Officer (RSO) at St. Vincent Health St. Joseph Hospital in Kokomo, Indiana. The RSO was calling to inquire whether neo-pet needed a license to operate at the St Vincent Health St Joseph Hospital in Indiana. The reviewer stated that neo-pet did require either an NRC license or reciprocity to work in an area regulated by the NRC. At that time neo-pet discontinued operations in Indiana.

On March 9, 2012, the reviewer received a telephone call from the RSO at neo-pet. The RSO indicated that he did not realize that the use of fluorine-18 (F-18) fluorodeoxyglucose (FDG) for PET scans required either a license or reciprocity from the NRC. A Region III materials inspector spoke with the RSO at neo-pet, who explained that he had registered with the State of Indiana in 2009 and 2011 for mobile PET scan activities, but was not aware of the need to file paperwork or fees with the NRC. The authority for regulating Naturally-Occurring and Accelerator-Produced Radioactive Materials (NARM) in Indiana became the NRC's responsibility in 2007, including F-18. Because the licensee had already conducted mobile PET scan activities in Indiana, a non-Agreement State, during 2012, the licensee submitted an NRC Form 241 for reciprocity for calendar year 2012, including the correct fee payment, on March 9, 2012 (ML120740164). The RSO sent a letter to the NRC dated March 16, 2012, which explained that neo-pet conducted mobile PET scan activities one day every week at St. Vincent Health St. Joseph Hospital in Kokomo, Indiana, beginning in approximately March 2010 (ML12089A150).

Title 10 of the Code of Federal Regulations (CFR) 150.20(a) provides, in part, that any person who holds a specific license from an Agreement State is granted an NRC general license to conduct the same activity in non-Agreement States, provided that the provisions of 10 CFR 150.20(b) have been met.

Title 10 CFR 150.20(b)(1) requires, in part, that any person engaging in activities in non-Agreement States shall, at least three days before engaging in each such activity, file a submittal containing an NRC Form 241, "Report of Proposed Activities in Non-Agreement States," with the Regional Administrator of the appropriate NRC regional office.

The company's failure to request reciprocity from the NRC by filing an NRC Form 241 prior to conducting licensed activities is an apparent violation of 10 CFR 150.20. Specifically, for 35 days in 2010, 48 days in 2011, and approximately 10 days in 2012, the licensee possessed and utilized doses of F-18 at a temporary job site in Kokomo, Indiana, without first filing an NRC Form 241 for each calendar year.

The root cause was the licensee's lack of awareness that the use of NARM in the State of Indiana was regulated by the NRC. Specifically, the licensee applied for and received two-year registrations with the State of Indiana for mobile PET scan activities in 2009 and 2011. The licensee mistook these as approvals possess and use licensed materials in Indiana under their State of Ohio license.

As corrective action, the company filed applications for reciprocity retroactive to calendar years 2010 and 2011 on March 27, 2012 (ML12090A447). Neo-pet had previously filed an NRC Form 241 for reciprocity with the NRC in May 2010, when the licensee was attempting to obtain contract work at the Womack Army Medical Center in Fort Bragg, North Carolina. The licensee was advised by the Army at that time to contact the appropriate regulator for approval, which in this case was the NRC. Although the licensee's 2010 application included the correct fee payment for calendar year 2010, it did not include information about ongoing work activities in Indiana that had begun approximately two months prior. Therefore, on March 27, 2012, the licensee submitted a revised request for activities conducted in 2010 in addition to an initial request and payment for activities conducted in 2011. The licensee is now aware of the requirements in 10 CFR 150.20 for conducting work activities in Indiana and other non-Agreement States under reciprocal recognition of their State of Ohio license.

### 2.3 Conclusions

The inspectors identified one apparent violation of 10 CFR 150.20, involving neo-pet's failure to request reciprocity from the NRC by filing an NRC Form 241 prior to conducting licensed activities in a non-Agreement State where the NRC maintains jurisdiction. As corrective actions, neo-pet submitted an NRC Form 241 with the correct fee payment, as appropriate, for calendar years 2010, 2011, and 2012, paying a total of $4,200 in reciprocity fees.

## 3 Temporary Job Site Inspection

### 3.1 Inspection Scope

The inspector observed licensed activities, interviewed the technologist, and reviewed selected records concerning use of licensed materials, security of such materials, and other aspects of the radiation safety program at a temporary job site outside St. Vincent Health St. Joseph Hospital in Kokomo, Indiana. In addition, the inspector performed

independent and confirmatory surveys in areas of radioactive materials use and in public areas.

3.2 Observations and Findings

One technologist performed diagnostic imaging procedures, limited to F-18 FDG tumor imaging, in a mobile coach at the temporary job site. Except as described below, the technologist controlled access to radioactive materials in use and in storage in the coach. The technologist wore personal dosimetry, and records indicated that no individual had received doses approaching regulatory limits. Licensee personnel were trained concerning the use of the materials and the technologist demonstrated knowledge of nuclear medicine procedures and radiation safety concepts. Dose calibrators and survey instruments were properly calibrated and used. The inspector found no issues with diagnostic procedures. Surveys of F-18 use areas and public areas indicated radiation levels consistent with licensee surveys and postings. Doses were delivered to the coach by a nuclear pharmacy located in Romeoville, Illinois. The technologist stated that licensee management personnel performed unannounced audits of activities at temporary job sites.

The inspector observed that the technologist left one syringe containing 17.2 millicuries of F-18 FDG unsecured. Additional licensed materials were secured in accordance with the licensee's procedure in a locked cabinet. The technologist stated that she had prepared the syringe when she believed that a patient was being sent from the hospital to the coach but did not secure the syringe when she later left the coach to get the patient. Neither the coach nor the hot lab inside the coach was secured while the technologist was out of the coach, and the technologist did not maintain surveillance of the door into the coach. This is a violation of 10 CFR 20.1802, which requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

The root cause of the violation was the technologist's oversight in not returning the syringe to storage or locking the coach or hot lab prior to leaving the area. As immediate corrective action, the licensee re-trained the technologist regarding security of licensed materials. As long-term corrective action, during the telephone exit meeting on April 5, 2012, the licensee committed to include security in an annual training session for all technologists. The RSO stated that the annual training would be complete by June 30, 2012. The RSO also stated that he would send a memo describing security requirements to all technologists if the training could not be completed before July 2012.

3.3 Conclusions

The inspector identified a violation of 10 CFR 20.1802 concerning the licensee's failure to maintain constant surveillance of licensed material not in storage. The licensee committed to re-training staff members in order to prevent recurrence of the violation.

## 4 Exit Meeting Summary

The inspectors discussed the preliminary conclusions as described in this report with the RSO during the April 5, 2012 telephone exit meeting. The inspectors discussed the inspection findings, the apparent violation, and neo-pet's corrective actions. The company did not identify any information reviewed during the inspection and proposed for inclusion in the inspection report as proprietary in nature.

## LIST OF PERSONS CONTACTED

* Floro Miraldi, Sc.D., MD – CEO and RSO
Carla Cort – COO and CFO
\# Vito Salvo, Vice President of Operations (# by telephone)
\# Christina Matthews, Nuclear Medicine Technologist

\# Individual present during preliminary exit meeting on March 20, 2012
* Individuals present during final telephone exit meeting on April 5, 2012