



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

Region III
2443 Warrenville Road, Suite 210
Lisle IL 60532-4352

June 13, 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: NOTICE OF VIOLATION – NEO-PET, LLC
NRC ROUTINE INSPECTION REPORT NO. 15000034/2012001(DNMS)**

Dear Dr. Miraldi:

This refers to the inspection conducted on March 20, 2012, at a temporary neo-pet, LLC (neo-pet) jobsite at St. Vincent Health St. Joseph Hospital in Kokomo, Indiana. The purpose of the inspection was to review activities involving the general license provisions of Title 10 of the Code of Federal Regulations (CFR), Section 150.20, related to public health, safety, and security. The inspection also examined activities neo-pet performed in the State of Indiana during the calendar years of 2010, 2011, and 2012 as they related to safety and compliance with the Nuclear Regulatory Commission's (NRC) rules and regulations. During the inspection, a self-identified apparent violation of NRC requirements was discussed. The significance of the issue and the need for lasting and effective corrective actions were discussed with you at the final inspection exit meeting on April 5, 2012. Details regarding the apparent violation were provided in NRC Inspection Report No. 15000034/2012001(DNMS) dated April 16, 2012.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. On May 2, 2012, you informed us that you did not wish to provide any additional response beyond that already provided during the inspection and in your letters dated March 16 and 27, 2012, along with your March 9, 2012, faxed request to perform activities in Indiana for the remainder of 2012.

Based on the information developed during and following the inspection, as documented in the inspection report, and the information that you provided in the above-mentioned letters, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in our inspection report dated April 16, 2012. Specifically, during the years 2010, 2011, and up through March 6, 2012 neo-pet possessed and used fluorine-18 fluorodeoxyglucose in Indiana without either holding an NRC license or without filing a Form-241, "Report of Proposed Activities in Non-Agreement States," with the Regional Administrator of the appropriate NRC regional office at least 3 days prior to the first date of use in a calendar year.

The failure to file for reciprocity impacts the NRC's regulatory process by preventing the NRC from knowing that neo-pet is conducting activities within NRC's jurisdiction and, therefore, preventing the NRC from performing inspections to assure that licensed material is being used safely and in accordance with NRC requirements. Therefore, the violation has been categorized, in accordance with the NRC Enforcement Policy, as a Severity Level III violation.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3500 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. Credit was warranted for your corrective actions which included filing for reciprocity for 2012, retroactively filing for 2010 and 2011 and paying the required fees.

Therefore, to encourage prompt identification and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 15000034/2012001(DNMS) and your letters dated March 16 and 27, 2012, along with your March 9 faxed request to perform activities in Indiana for the remainder of 2012. Therefore, you are not required to respond to this letter unless the description therein 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 enclosure, and your response, if any, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access

F. Miraldi

-3-

and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

Sincerely,

/RA by C. Pederson for/

Charles A. Casto
Regional Administrator

Docket No. 150-00034
Ohio License No. 02220180046

Enclosure:
Notice of Violation

cc w/encl: State of Ohio
State of Indiana

NOTICE OF VIOLATION

neo-pet, LLC
Cleveland, Ohio

Docket No. 150-00034
Ohio License No. 02220180046
EA-12-068

During an NRC inspection conducted on March 20, 2012, a violation of NRC requirements, that was identified by neo-pet on March 9, 2012, was discussed. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the Code of Federal Regulations (10 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.

Ten 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 activity for the first time in a calendar year, 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.

Contrary to the above, on multiple occasions between April 6, 2010, and March 6, 2012, neo-pet, LLC, a licensee of the State of Ohio, possessed and used doses of fluorine-18 in Indiana, a Non-Agreement State, without filing a Form 241 with the NRC. Specifically, for 35 days in 2010, 48 days in 2011, and approximately 10 days in 2012, the licensee possessed and used doses of fluorine-18 at a temporary job site in Kokomo, Indiana, without filing a Form 241 with the NRC.

This is a Severity Level III violation (Section 6.9).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 15000034/2012001(DNMS) and your letters dated March 16 and 27, 2012, along with your March 9, 2012, faxed request to perform activities in Indiana for the remainder of 2012. However, you are required to submit a written statement or explanation pursuant to 10 CFR 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," EA-12-068, 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 of Violation.

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

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 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, or proprietary, 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 of Violation within two working days of receipt.

Dated this 13th day of June, 2012

and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

Sincerely,

/RA by C. Pederson for/

Charles A. Casto
Regional Administrator

Docket No. 150-00034
Ohio License No. 02220180046

Enclosure:
Notice of Violation

cc w/encl: State of Ohio
State of Indiana

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See next page

SEE PREVIOUS CONCURRENCE

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| OFFICE | RIII | RIII | RIII | D:OE | RIII | RIII |
| NAME | Lougheed | Bloomer | Boland | Zimmerman ¹ | Orth | Casto CP for |
| DATE | 5/04/12 | 5/07/12 | 5/08/12 | 6/7/12 | 6/12/12 | 6/13/12 |

OFFICIAL RECORD COPY

¹ OE concurrence received via e-mail from K. Day on June 7, 2012.

Letter to Floro Miraldi from Charles A. Casto dated June 13, 2012

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

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