

April 8, 2011

Mr. Douglas O'Banion, President
O'Banion Laboratories Corporation
P.O. Box 416
Trenton, Michigan 49930

SUBJECT: NRC INSPECTION REPORT NO. 030-38285/11-01(DNMS) AND NOTICE OF VIOLATION – O'BANION LABORATORIES CORPORATION

Dear Mr. O'Banion:

On March 22, 2011, the U.S. Nuclear Regulatory Commission (NRC) conducted an initial inspection as it related to your NRC license at 20090 West Road, Woodhaven, Michigan, with continued NRC in-office review through April 1, 2011. The in-office review was related to the evaluation of transporting an asphalt content gauge containing a sealed source of americium-241:berrilium that was not certified as Special Form. A telephone exit meeting between yourself and Andrew Bramnik of my staff was conducted on April 1, 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 inspected 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 one Severity Level IV violation of NRC requirements occurred. The violation was 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 violation involved the failure to comply with U.S. Department of Transportation (DOT) requirements for transporting hazardous materials contained in Title 49 of the Code of Federal Regulations (CFR) related to package marking and shipping papers. The NRC staff discussed corrective actions to address the above violation with you at the conclusion of the onsite inspection and during the telephonic exit meeting.

The root cause of this violation was a lack of awareness of the requirements in 10 CFR 71.5(a) to adhere to DOT requirements in 49 CFR for marking and shipping papers related to transporting packages containing radioactive materials. Specifically, you were not aware that the correct identification number for asphalt content gauging devices containing sealed sources of americium-241:berrilium was UN 3332, instead of UN 2974. As corrective actions, on March 23, 2011, you contacted Troxler Electronic Laboratories to order a new marking sticker

with the correct identification number. Additionally, on April 1, 2011, you stated that you will amend your shipping papers to include the correct identification number. These actions will be completed by April 30, 2011.

The violation is cited in the enclosed Notice of Violation (Notice). The violation is being cited because the NRC inspector identified it. 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 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 addition, one violation was identified involving the failure to maintain a survey meter for use in the event of an incident. The root cause of this violation was a misunderstanding of the requirement to maintain a survey meter for use. Specifically, you stated that because your asphalt content gauge had not been used, you believed that a survey meter was not required. Prior to the inspection, you had ordered a survey meter from Troxler Electronic Laboratories. On April 1, 2011, you informed the NRC that the survey meter had arrived and that you were now in compliance regarding this item. Because this violation represented an isolated failure to implement a requirement with insignificant safety impact, this failure constitutes a violation of minor significance and is not subject to formal enforcement action.

In accordance with 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.

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

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch

Docket No. 030-38285
License No. 21-32794-01

Enclosure:
Notice of Violation

cc w/ encl: State of Michigan

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Tamara E. Bloomer, Chief
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Enclosure:
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cc w/ encl: State of Michigan

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DATE	4/08/11	4/08/11		

NOTICE OF VIOLATION

O'Banion Laboratories Corporation
Trenton, Michigan

Docket No. 030-38285
License No. 21-32794-01

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on March 22, 2011, with continued NRC in-office review through April 1, 2011, one violation of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the Code of Federal Regulations (CFR) Section 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 107, 171-180, and 390-397. Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material.

Title 49 CFR 172.301 requires that each person who offers a hazardous material for transportation in a non-bulk packaging must mark the package with the proper shipping name and identification number (preceded by "UN" or "NA" as appropriate) for the material as shown in the 49 CFR 172.101 Table.

Title 49 CFR 172.202(a) and (b) require in part, with exceptions not applicable here, that the shipping description of a hazardous material on the shipping paper include, in the following sequence: (1) the proper shipping name prescribed for the material in 172.101 (2) the hazard class prescribed for the material as shown in Column 3 of the 172.101 Table, and (3) the identification number prescribed for the material as shown in Column 4 of the 49 CFR 172.101 Table

Contrary to the above, on March 22, 2011, the licensee transported outside the confines of its plant an asphalt content gauging device containing a sealed source of americium-241:berrilium and failed to comply with the DOT requirements for transporting hazardous materials contained in 49 CFR, with two examples:

- a. The licensee failed to mark the package with the proper identification number. Specifically, the licensee transported the device in a package marked with the identification number UN 2974, instead of the correct identification number UN 3332; and
- b. The shipping description on the shipping paper that accompanied the shipment did not include the correct identification number. Specifically, the shipping description listed the identification number UN 2974, instead of the correct identification number UN 3332.

This is a Severity Level IV violation (Section 6.8.d.4).

The NRC has concluded that information regarding the reasons for the violation, the corrective actions taken and planned to be taken 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 letter transmitting this Notice of Violation (Notice). 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," 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.

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 8th day of April 2011.