



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

REGION III  
2443 WARRENVILLE RD. SUITE 210  
LISLE, IL 60532-4352

May 7, 2015

Dr. Richard S. Longley, M.D.  
Radiation Safety Officer  
Thyroid and Diabetes Management Center  
8939 Broadway  
Merrillville, IN 46410

**SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03035963/2015001(DNMS) AND  
NOTICE OF VIOLATION – THYROID AND DIABETES MANAGEMENT CENTER**

Dear Dr. Longley:

On March 16, 2015, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Merrillville, Indiana clinic with continued in-office review through April 30, 2015. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review of your immediate corrective actions and the status of your program. Ms. Deborah A. Piskura of my staff conducted a final exit meeting with you by telephone on April 30, 2015, 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 examined your compliance with the Commission's rules and regulations as well as the conditions of your license. 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 four 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 website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations concerned the licensee's failures to: (1) calibrate the survey meter; (2) perform sealed source leak tests; (3) perform sealed source physical inventories; and (4) conduct an annual review of the radiation protection program. The violations are cited in the enclosed Notice of Violation (Notice). The NRC is citing the violations in the Notice because the inspector identified the violations.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the Information Notice on the NRC website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

R. Longley, M.D.

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In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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 publicly available without redaction.

Please feel free to contact Ms. Piskura of my staff if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

Sincerely,

*/RA/*

Aaron T. McCraw, Chief  
Materials Inspection Branch  
Division of Nuclear Materials Safety

Docket No. 030-35963  
License No. 13-32380-01

Enclosure:  
Notice of Violation

cc w/encl: State of Indiana

R. Longley, M.D.

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Sincerely,

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Aaron T. McCraw, Chief  
Materials Inspection Branch  
Division of Nuclear Materials Safety

Docket No. 030-35963  
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Enclosure:  
Notice of Violation

cc w/encl: State of Indiana

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## NOTICE OF VIOLATION

Thyroid and Diabetes Management Center  
Merrillville, Indiana

License No. 13-32380-01  
Docket No. 030-35963

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on March 16, 2015, four violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Title 10 of the *Code of Federal Regulations* (CFR) 20.1101(c) requires the licensee to periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, between November 6, 2013, and April 28, 2015, the licensee failed to review the radiation protection program content and implementation, an interval that is greater than annually.

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

- B. Title 10 CFR 35.61(a) requires, in part, that a licensee calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 before first use, annually, and following a repair that affects the calibration.

Contrary to the above, as of March 16, 2015, the licensee was using a Bicron Surveyor 2000 survey instrument to show compliance with 10 CFR Parts 20 and 35, and the survey instrument had not been calibrated since December 12, 2013, a period greater than annually.

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

- C. Title 10 CFR 35.67(b)(2) requires, in part that a licensee in possession of a sealed source shall test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

Contrary to the above, between November 6, 2013, and April 28, 2015, the licensee failed to test a barium-133 sealed source for leakage at intervals that did not exceed 6 months, and no other interval was approved.

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

- D. Title 10 CFR 35.67(g) requires, in part that a licensee in possession of a sealed source shall conduct a semi-annual inventory of all sources in its possession.

Contrary to the above, between November 6, 2013, and April 28, 2015, physical inventories were not performed semi-annually of all sources in the licensee's possession as required.

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

Enclosure

Pursuant to the provisions of CFR 2.201, Thyroid and Diabetes Management Center is hereby required to submit a written statement or explanation 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 (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; NRC Inspection Report No. 03035963/2015001(DNMS)" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or its severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, 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 reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Your response will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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 publicly available without redaction.

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, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Dated this 7<sup>th</sup> day of May 2015.