



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

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

October 19, 2012

EA-12-159

Dr. D. V. Ramana  
Lapeer County Surgery Center  
1546 Callis Road  
Lapeer, Michigan 48446

**SUBJECT:** NOTICE OF VIOLATION AND RESULTS OF NRC INVESTIGATION –  
LAPEER COUNTY SURGERY CENTER; NRC INSPECTION REPORT  
NO. 03037853/2011001(DNMS); NRC INVESTIGATION REPORT  
NO. 3-2012-009

Dear Dr. Ramana

On December 12, 2011, the U.S. Nuclear Regulatory Commission's Office of Investigations (OI) Region III Field Office initiated an investigation to determine whether employees at the Lapeer County Surgery Center willfully conducted licensed activities without having a radiation safety officer or willfully failed to perform safety activities through a radiation safety officer. The investigation was completed on July 20, 2012, and was documented in OI Report No. 3-2012-009.

Based on the evidence developed during the investigation, the NRC did not substantiate that employees at the Lapeer County Surgery Center willfully conducted licensed activities without having a radiation safety officer or willfully failed to perform safety activities through a radiation safety officer. Therefore, this investigation is closed. The NRC is also closing the open item from NRC Inspection Report 03037853/2011001(DNMS).

Specifically, our review concluded that the radiation safety officer on the Lapeer County Surgery Center license continued to have some very limited involvement with certain activities, specifically an NRC inspection in November 2009, and the final termination survey in December 2011, when required. Therefore, the NRC concluded that there was not a violation of your previous license condition 11 for failure to have a radiation safety officer. However, based on the information obtained during the OI investigation, the radiation safety officer was not aware that the office manager had added additional authorized users to the NRC license, despite the NRC sending letters to Lapeer County Surgery Center addressed to the radiation safety officer. Additionally, based on the results of the NRC investigation, it appeared that the radiation safety officer was also not aware that Lapeer County Surgery Center was continuing to conduct prostate seed implants using the new authorized users. The NRC also determined that there was a basic failure by Lapeer County Surgery Center, when establishing its license, to specify the authority, duties, and responsibilities of the radiation safety officer in writing as required by Title 10 of the Code of Federal Regulations (10 CFR) 35.24(e). This failure to establish the authority, duties, and responsibilities of the radiation safety officer led both the office manager and the radiation safety officer to believe that someone else could accomplish those duties and responsibilities.

The failure to specify the authority, duties, and responsibilities of the radiation safety officer in writing led the NRC to be concerned as to whether Lapeer County Surgery Center was allowing the radiation safety officer the authority, organizational freedom, time, resources, and management prerogative as required by 10 CFR 35.24(g). In the end, the NRC chose not to pursue such a violation because of the voluntary efforts of both the radiation safety officer who participated in the NRC inspection and final license termination and an authorized user who performed routine surveys. The NRC concluded that, overall, the duties and responsibilities of the radiation safety officer were adequately accomplished.

Based on the results of the investigation, 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 current Enforcement Policy is included on the NRC's Web site at [http://www.nrc.gov/about\\_nrc/regulatory/enforcement/enforce\\_pol.html](http://www.nrc.gov/about_nrc/regulatory/enforcement/enforce_pol.html).

The violation is cited in the enclosed Notice of Violation (Notice). The violation is being cited in the Notice because it was identified by the NRC as a result of information identified during the investigation. The NRC determined that this basic failure to establish the authority, duties, and responsibilities of the radiation safety officer was at the root of the communication breakdown between the radiation safety officer and the office manager that resulted in the NRC suspecting that Lapeer County Surgery Center employees were willfully violating NRC requirements.

The NRC notes that Lapeer County Surgery Center has terminated its NRC license. As such you are not required to respond to this violation or to take any further corrective actions. If, in the future, you decide to apply again for an NRC license, the NRC will expect you to address this issue as part of your application. The NRC will also expect that you will ensure that you will allow whomever is your radiation safety officer to have the authority, organizational freedom, time, resources, and management prerogative to perform his or her duties and that any future license will accurately reflect the individual who is performing the duties and responsibilities of the radiation safety officer.

If you contest the violation, you should provide a response within 30 days of the date of this letter, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Regional Administrator, Region III, and (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response, if any, will be available electronically for public inspection in the NRC Public Document Room or from the Agencywide Document Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. You should note that final NRC documents, including the final OI report, may be made available

to the public under the Freedom of Information Act (FOIA) subject to redaction of information pursuant to the FOIA. Requests under the FOIA should be made in accordance with 10 CFR 9.23, "Request for Records." The instructions for making a request for information under the FOIA are accessible at <http://www.nrc.gov/reading-rm/foia/foia-request.html>.

If you have any questions, you may contact Mr. Steven Orth at 630-810-4373.

Sincerely,

***/RA by P. Loudon for/***

Anne T. Boland, Director  
Division of Nuclear Materials Safety

Docket No. 030-37853  
License No. 21-32718-01 (terminated)

cc w/encl: State of Michigan

## NOTICE OF VIOLATION

Lapeer County Surgery Center  
Lapeer, MI

Docket No. 030-37853  
License No. 21-32718-01 (terminated)  
EA-12-159

As a result of a U.S. Nuclear Regulatory Commission (NRC) investigation conducted from December 12, 2011 through July 20, 2012, a 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 (10 CFR) 35.24(e) states that a licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

Contrary to the above, from January 28, 2009 through December 29, 2011, Lapeer County Surgery Center did not establish the authority, duties, and responsibilities of the Radiation Safety Officer on NRC License No. 21-32718-01 in writing. Specifically, the Lapeer County Surgery Center, who was a licensee at the time of the violation, did not document the specific actions for which the Radiation Safety Officer was responsible to complete in order to implement the radiation protection program.

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 the date when full compliance was achieved, is already adequately addressed by termination of license 21-32718-01. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description above 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-12-159," 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, 2443 Warrenville Road, Suite 210, Lisle, IL 60532, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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.

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 19<sup>th</sup> day of October, 2012

to the public under the Freedom of Information Act (FOIA) subject to redaction of information pursuant to the FOIA. Requests under the FOIA should be made in accordance with 10 CFR 9.23, "Request for Records." The instructions for making a request for information under the FOIA are accessible at <http://www.nrc.gov/reading-rm/foia/foia-request.html>.

If you have any questions, you may contact Mr. Steven Orth at 630-810-4373.

Sincerely,

**/RA by P. Loudon for/**

Anne T. Boland, Director  
Division of Nuclear Materials Safety

Docket No. 030-37853  
License No. 21-32718-01 (terminated)

cc w/encl: State of Michigan

**DISTRIBUTION:**

Cynthia Pederson  
Nick Hilton  
Leela Sreenivas  
OEMAIL Resource  
Mary Spencer  
Michael Clark  
Michele Burgess  
Robert Goetz  
Nancy Hane  
Scott Kryk

Anne Boland  
Tamara Bloomer  
MIB Inspectors  
Steven Orth  
James Lynch  
Patricia Loughheed  
Paul Pelke  
Magdalena Gryglak  
Sarah Bakhsh  
Tammy Tomczak

**SEE PREVIOUS CONCURRENCE**

FILE NAME: G:\ORAI\IICS\ENFORCEMENT\Cases\Enforcement Cases 2012\IA-12-049 Lapeer County Office Manager\IA-12-049 Lapeer County Office Manager FINAL.docx

OFFICE	RIII	RIII	D:OI	D: FSME	D:OE	D:OGC	RIII	RIII
NAME	Loughheed	Bloomer	Goetz	Satorius <sup>1</sup>	Zimmerman <sup>2</sup>	Spencer <sup>3</sup>	Orth	Boland PLoudon for
DATE	09/21/12	09/21/12	09/21/12	10/17/12	10/16/12	10/16/12	09/18/12	09/19/12

**OFFICIAL RECORD COPY**

1 FSME concurrence received via e-mail from M. Burgess on October 17, 2012.

2 OE concurrence received via e-mail from L. Sreenivas on October 17, 2012.

3 OGC "No Legal Objection" received via e-mail from M. Clark on October 17, 2012.