

January 5, 2012

Ms. Barbara Robarge  
Office Manager  
Lapeer County Surgery Center  
1546 Callis Road  
Lapeer, Michigan 48446

SUBJECT: NRC REACTIVE INSPECTION REPORT 03037853/11-001(DNMS) – LAPEER  
COUNTY SURGERY CENTER

Dear Ms. Robarge:

On November 14, 2011, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted a reactive inspection at your Lapeer, Michigan facility, with continued in-office review through December 30, 2011. The in-office review was to evaluate eight prostate permanent seed implant procedures conducted at your facility between November 2009 and December 2010.

On October 28, 2011, you faxed a letter to the NRC requesting the termination of your NRC license. During this inspection, the NRC staff examined whether your facility possessed licensed materials that would prevent the NRC from terminating your license. Additionally, the staff reviewed your compliance with the Commission's rules and regulations, and with the conditions of your license. Within these areas, the inspection consisted of selected examination of representative records and interviews with personnel.

The enclosed report presents the results of this inspection, which were discussed with you during a final telephonic exit meeting held on December 30, 2011. Based on the results of this inspection, an open item was identified; because the inspector could not fully evaluate the level of management oversight of licensed activities during this inspection. The NRC will continue to review this Open Item and you will be advised by separate correspondence of the results of our deliberations on this matter.

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 and its enclosure 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>.

B. Robarge

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If you have any questions concerning this matter, please contact Andrew Bramnik of my staff at (630) 829-9543.

Sincerely,

*/RA/*

Tamara E. Bloomer, Chief  
Materials Inspection Branch  
Division of Nuclear Materials Safety

Docket No. 030-37853  
License No. 21-32718-01

Enclosure:  
Inspection Report 03037853/11-001(DNMS)

cc w/encl: State of Michigan

B. Robarge

-2-

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cc w/encl: State of Michigan

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U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.: 030-37853

License No.: 21-32718-01

Report No.: 03037853/11-001(DNMS)

Licensee: Lapeer County Surgery Center

Facility: 1546 Callis Road  
Lapeer, Michigan 48446

Inspection Dates: November 14, 2011  
Continued in-office review through  
December 30, 2011

Preliminary Exit Meeting: November 14, 2011

Inspection Procedure: IP 87132

Final Exit Meeting: December 30, 2011

Inspector: Andrew M. Bramnik, Health Physicist

Approved By: Tamara E. Bloomer, Chief  
Materials Inspection Branch  
Division of Nuclear Materials Safety

Enclosure

## **EXECUTIVE SUMMARY**

### **Lapeer County Surgery Center NRC Inspection Report 03037853/11-001 (DNMS)**

On November 14, 2011, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted a reactive inspection at the licensee's Lapeer, Michigan facility, with continued in-office review through December 30, 2011. The in-office review was to evaluate eight prostate permanent seed implant procedures conducted at the licensee's facility between November 2009 and December 2010. The inspector determined that the licensee possessed 35 iodine-125 seeds that had been added to the licensee's inventory between March 2009 and December 2010. The licensee's Office Manager committed to dispose these seeds and provide documentation to the NRC in support of the company's license termination request. The inspector identified one Open Item regarding the management oversight of licensed activities and will be documented under separate correspondence.

## Report Details

### **1 Program Overview**

#### Licensed Activities and Inspection History

The NRC License No. 21-32718-01 authorized Lapeer County Surgery Center (licensee) to implant sealed sources of iodine-125 and palladium-103 in manual brachytherapy procedures permitted by Title 10 of the Code of Federal Regulations (CFR) 35.400. The licensee operated a freestanding "same-day" outpatient surgery center that performed prostate permanent seed implant procedures between March 19, 2009 and December 17, 2010. The licensee did not conduct any other activities involving byproduct material. No violations were identified during the previous initial inspection on November 18, 2009.

### **2 Possession of Licensed Materials**

#### **2.1 Inspection Scope**

The inspector reviewed selected records, toured the licensee's facility, and conducted independent surveys to determine whether the licensee possessed licensed materials.

#### **2.2 Observations and Findings**

On October 28, 2011, the licensee faxed a letter to the NRC Region III office with a request to terminate their NRC license. The letter stated that no seed implant procedures had been performed since December 2010, but did not indicate whether or not the licensee possessed any radioactive materials.

On November 14, 2011, a Region III inspector conducted a reactive inspection at the licensee's facility in Lapeer, Michigan. The inspector reviewed selected records including the licensee's current "Seed Inventory," "Quarterly Seed Inventory Radiation Survey," and surveys of incoming packages of radioactive materials dated between November 2009 and December 2010. Based on these records, the inspector determined that the licensee possessed 35 iodine-125 seeds that were unused or recovered after surgical procedures and were added to the licensee's inventory between March 2009 and December 2010.

Additional records indicated that the most recent iodine-125 seed was added to the licensee's inventory on April 6, 2010, and all of the other seeds stored in the licensee's inventory were significantly older. The licensee's Medical Physicist had documented that the newest seed would complete ten physical half-lives in December 2011. The remaining 34 seeds had all completed more than ten physical half-lives prior to the NRC reactive inspection.

Members from the licensee's nursing staff provided the inspector with a tour of the licensee's facility. The licensee maintained a secured room where the decayed seeds were stored. The seeds were kept in two shielded containers that were stored in a locked cabinet within the storage room. The area was posted and labeled in accordance with the appropriate regulations. Licensee staff members were aware of the need to

secure this room, only selected individuals had keycard access to the room, and less than four individuals had keys to the locked cabinet.

The licensee possessed a calibrated and operational SE International Monitor 4 survey meter (serial number 70318, calibrated on February 1, 2011) in the storage room. Independent and side-by-side area surveys with the licensee's survey meter and an NRC Ludlum Model 2403 survey meter (serial number 161599, calibrated on June 14, 2011) were all indistinguishable from background in the locked cabinet, the storage room, and the adjacent operating room where seed implant procedures had previously occurred.

The inspector informed the licensee's Office Manager that the NRC could not terminate the license while the licensee possessed iodine-125 seeds. The Office Manager stated that she would consult with the licensee's Medical Physicist regarding the best way to dispose of the seeds. Specifically, the Office Manager agreed to pursue either returning the seeds to the vendor or disposing of the seeds in accordance with the requirements in 10 CFR 35.92. The inspector stated that the NRC would need documentation of either method as well as the information in an NRC Form 314 "Certificate of Disposition of Materials" in order to terminate the NRC license.

### 2.3 Conclusions

The inspector determined that the licensee possessed 35 iodine-125 seeds that had been added to the licensee's inventory between March 2009 and December 2010. The licensee's Office Manager committed to dispose the seeds and provide documentation to the NRC in support of the facility's license termination request. Specific to these items, no violations were identified.

## **3 Evaluation of Implant Procedures**

### 3.1 Inspection Scope

The inspector reviewed selected records and interviewed personnel to evaluate eight prostate permanent seed implant procedures conducted between November 2009 and December 2010.

### 3.2 Observations and Findings

The inspector reviewed written directives and post-plan "VariSeed Study Summary" reports for eight prostate permanent seed implant procedures conducted between November 2009 and December 2010. The licensee's written directives contained all of the appropriate information required by 10 CFR 35.40. The procedure dates and numbers of seeds implanted correlated with the licensee's current "Seed Inventory" record.

Members of the licensee's nursing staff explained during interviews how they employed time, distance, and shielding when prostate seed implant procedures were conducted. The staff also explained how they worked with a Medical Physicist to survey the patient and the room after implant procedures.

During a telephone interview conducted on December 30, 2011, the licensee's Medical Physicist provided additional details about the written directives and post plan dosimetry reports. Specifically, the Medical Physicist described patient identification techniques, radiation safety operations, and how procedures were evaluated for medical events. Based on the records review and interviews, the inspector did not identify any medical events and, specific to the discussion above, no violations were identified.

The inspector contacted the Radiation Safety Officer (RSO) listed on the license by telephone on December 1, 2011, and was told that he had not worked for or had contact with the licensee since roughly October 2009. The inspector was not able to interview any of the licensee's authorized users or meet in person with the licensee's RSO or Medical Physicist. Because of this, the inspector could not fully evaluate the level of management oversight of licensed activities during the inspection. The licensee's management oversight is considered an Open Item, and the NRC will continue to review this item.

### 3.3 Conclusions

Specifically, no violations were identified regarding prostate seed implant procedures conducted by the licensee between November 2009 and December 2010. One Open Item was identified regarding the level of management oversight of licensed activities and will be documented under separate correspondence.

## 4 **Exit Meeting**

At the completion of the on-site inspection on November 14, 2011, the inspector discussed the preliminary inspection finding in this report with the licensee's Office Manager. A final telephone exit meeting was conducted with the licensee's Office Manager on December 30, 2011. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.

ATTACHMENT: SUPPLEMENTAL INFORMATION

## **SUPPLEMENTAL INFORMATION**

### **PARTIAL LIST OF PERSONS CONTACTED**

- \* Barbara Robarge – Office Manager
- Shelly Wiegele – Nurse Manager
- Mary Cherry – Registered Nurse
- Jacek Wierzbicki, Ph.D. – Radiation Safety Officer
- Scott Symington, M.S. – Medical Physicist
- Arthur Ewald, M.S. – Medical Physicist

\* Individuals present at November 14, 2011 preliminary exit meeting  
& Individuals present at December 30, 2011, telephone exit meeting

### **LIST OF ACRONYMS USED**

CFR	Code of Federal Regulations
ADAMS	Agencywide Documents Access and Management System
DNMS	Division of Nuclear Materials Safety
NRC	U.S. Nuclear Regulatory Commission
RSO	Radiation Safety Officer