

February 7, 2014

Mr. Clinton J. Gregg  
Radiation Safety Officer  
Aptuit, LLC  
10245 Hickman Mills Drive  
Kansas City, MO 64137

SUBJECT: NRC INSPECTION REPORT NO. 03009415/2013001(DNMS) – APTUIT, LLC.

Dear Mr. Gregg:

On December 2, 2013, the U.S. Nuclear Regulatory Commission (NRC) completed inspection activities at Aptuit, LLC in Kansas City, Missouri. The purpose of this inspection was to determine whether decommissioning activities were conducted safely and in accordance with NRC requirements. Specifically, during the onsite inspection on December 2 through 4, 2013, the inspectors evaluated your decommissioning performance in the areas of quality assurance, radiation protection, and procedural adherence. At the conclusion of the onsite inspection the inspectors discussed the onsite inspection results with you and members of your staff. An in-office inspection of licensee shipping documents was conducted until January 9, 2014. At the conclusion of the in-office review, a telephone exit meeting was conducted on January 9, 2014, to discuss the final inspection results with you.

This inspection consisted of an examination of decommissioning activities at the site as they relate to safety and compliance with the Commission's rules and regulations. Areas examined during the inspection are identified in the enclosed inspection report. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations of activities in progress, and interviews with personnel.

Based on the results of this inspection, 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>).

The violation is cited in the enclosed Notice of Violation (NOV) and the circumstances surrounding it are described in detail in the subject inspection report. The violation is being cited because it was identified by NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. 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>. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements."

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and 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>. 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 may have regarding this inspection.

Sincerely,

*/RA/*

Robert J. Orlikowski, Chief  
Materials Control, ISFSI, and  
Decommissioning Branch  
Division of Nuclear Materials Safety

Docket No. 030-09415  
License No. 24-15595-01

Enclosures:

1. Notice of Violation
2. Inspection Report No. 03009415/2013001(DNMS)

C. Gregg

- 2 -

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Docket No. 030-09415  
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## NOTICE OF VIOLATION

Aptuit, LLC  
Kansas City, Missouri

Docket No. 030-09415  
License No. 24-15595-01

During a U.S. Nuclear Regulatory Commission (NRC) inspection at Aptuit, LLC in Kansas City, Missouri, conducted between December 2, 2013 and January 9, 2014, one 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* (CFR) 31.5(c)(8) states that “any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in paragraph (a) of this section: Shall transfer or dispose of the device containing byproduct material only by export as provided by paragraph (c)(7) of this section, by transfer to another general licensee as authorized in paragraph (c)(9) of this section, or to a person authorized to receive the device by a specific license issued under parts 30 and 32 of this chapter, or part 30 of this chapter that authorizes waste collection, or equivalent regulations of an Agreement State, or as otherwise approved under paragraph (c)(8)(iii).”

Contrary to the above, on June 11, 2013, the licensee transferred a Beckman Liquid Scintillation Counter LS6500, a generally licensed device, containing 30  $\mu$ Ci of Cesium-137. This transfer was made to a person who did not hold a specific license pursuant to 10 CFR parts 30 and 32 or from an Agreement State to receive the device, and the exception in 10 CFR 31.5(c)(9) did not apply. Specifically, the device was transferred to American Radiolabeled Chemicals (ARC) which was unlicensed to receive the device.

This is a Severity Level IV violation (Section 4.0).

Pursuant to the provisions of CFR 2.201, Aptuit, LLC 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; IR 03009415/2013001(DNMS)" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or 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 previous 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. 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 1

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, 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 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 of receipt.

Dated this 7<sup>th</sup> day of February 2014.

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No. 030-09415

License No. 24-15595-01

Report No. 03009415/2013001(DNMS)

Licensee: Aptuit, LLC

Facility: Pharmaceutical Research and Development

Location: 10245 Hickman Mills Drive  
Kansas City, MO 64137

Dates: December 2 through 4, 2013 with continuing  
NRC review through January 9, 2014

NRC Inspectors: Navid N. Tehrani, Health Physicist  
Michael M. LaFranzo, Senior Health Physicist

Approved by: Robert J. Orlikowski, Chief  
Materials Control, ISFSI, and  
Decommissioning Branch  
Division of Nuclear Materials Safety

**EXECUTIVE SUMMARY**  
**Aptuit, LLC**  
**Inspection Report 03009415/2013001(DNMS)**

Aptuit, LLC (Aptuit), a pharmaceutical research and development facility located in Kansas City, Missouri, is in the process of performing decontaminations and decommissioning activities described in the decommissioning plan (DP). Aptuit intends to release the facilities currently licensed by the Nuclear Regulatory Commission (NRC) from radiological controls and to terminate the license.

Radioactive material has been used at Aptuit facility for research purposes since the issuance of the license in the spring of 1973. The original license included tritium (Hydrogen-3) and nickel (Nickel-63) detector cells for use in chromatographs. By 1980, Nickel-63 had been eliminated from the license, but the list of radionuclides that could be possessed had grown to seven: Carbon-14, Hydrogen-3, Phosphorus-32, Sulfur-35, Iodine-125, Iodine-131 and Cesium-137. The License has been amended 32 times, primarily to address changes in company ownership and changes in the radiation safety officer (RSO). The most significant amendment was amendment 27 in 2008, which substantially increased License limits for Hydrogen-3 and Carbon-14 and authorized synthesis of radiolabeled organic compounds.

**Radiation Protection**

- The licensee established and maintained its radiation protection program in accordance with applicable Title 10 of the Code of Federal Regulations (CFR) Part 20 and the License. (Section 1.0)

No violations of NRC requirements were identified during this inspection.

**Radioactive Waste Management**

- The licensee maintained its radioactive waste management program in accordance with NRC requirements. (Section 2.0)

No violations of NRC requirements were identified during this inspection.

**Management Organization and Controls**

- The licensee maintained its management organization and controls in accordance with NRC requirements. (Section 3.0)

No violations of NRC requirements were identified during this inspection.

**Transportation of Radioactive Material**

- The inspectors identified one Severity Level IV Violation of very low safety significance of Title 10 CFR 31.5(c)(8), in that the licensee failed to follow the transfer requirements in 10 CFR 31.5(c)(8). (Section 4.0)

## Report Details

### **1.0 Radiation Protection (83822)**

#### a. Inspection Scope

The inspectors interviewed licensee staff involved in radiation protection activities to determine if the licensee had adequate knowledge to ensure safety and compliance with NRC requirements. Radiation protection program procedures were reviewed to determine if they were consistent with regulatory requirements and included appropriate limits, precautions and controls.

#### b. Observations and Findings

The inspectors observed wipe sampling activities and interviewed staff associated with performing the activities. The inspectors found that the staff performed wipe samples and analysis activities with adequate knowledge to ensure radiological safety. The activities observed were performed adequately and in accordance with sound radiation safety practices. The inspectors observed licensee staff performing personal radiological surveys exiting radiological controlled areas and found licensee staff were performing surveys adequately to ensure radiological control of radioactive material.

No findings of significance were identified.

#### c. Conclusions

The inspectors noted that the licensee staff worked safely and in compliance with NRC regulations and licensee procedures.

### **2.0 Radioactive Waste Management (88035)**

#### a. Inspection Scope

The inspectors reviewed the licensee's radioactive waste program to determine compliance with NRC requirements.

#### b. Observations and Findings

The inspectors observed the proper packaging and removal of radioactive waste in regards to the removal of the heat exchanger. The inspectors verified the location and disposal process of liquid waste (scintillation cocktail) from the licensee's liquid scintillation counter (LSC). No deficiencies were identified. The licensee estimates they have disposed of 43,101 lbs of solid waste and approximately 50 gallons of liquid waste. The removal, packaging, and disposal of radioactive waste were completed in accordance with NRC requirements.

No findings of significance were identified.



c. Conclusion

The inspectors noted that the licensee handled and disposed of radioactive waste in compliance with NRC regulations and licensee procedures.

**3.0 Management Organization and Controls (88005)**

a. Inspection Scope

The inspectors reviewed the licensee's management oversight program to determine if management observations of work in the field were identifying issues and areas for improvement and if so, that adequate corrective actions were being taken as a result. The inspectors reviewed a selection of internal audits and self-assessments and interviewed individuals associated with the documents reviewed.

b. Observations and Findings

During the review the inspectors noted the adequate detail in the licensee's audits and self-assessments. It was noted that when a self-assessment identified an issue the licensee corrected the issue in a timely manner. The inspectors reviewed the licensee's management oversight program and it was determined that the licensee maintained their organization and controls in accordance with NRC requirements.

No findings of significance were identified.

c. Conclusion

The inspectors determined that the management oversight, controls, and corrective actions adequately addressed and corrected any issues that arose. In addition, the inspectors did not identify any negative trends in the audits and self-assessments during this inspection.

**4.0 Transportation of Radioactive Material (86730)**

a. Inspection Scope

The inspectors reviewed the licensee's program that encompasses the transportation of radioactive material to determine whether or not the licensee was transporting radioactive material in accordance with NRC requirements. The inspectors reviewed a selection of shipping and packaging documents, license amendments, and interviewed individuals associated with the documents reviewed.

b. Observations and Findings

During the inspection of the licensee's shipment and packaging documents on December 3, 2013, the inspectors identified one Severity Level IV Violation of very low safety significance of 10 CFR 31.5(c)(8), for failing to following proper shipment requirements.

The violation occurred on June 11, 2013, when the licensee shipped a Beckman LS6500 LSC (S/N 7069065 and Inst ID 305112) with a 30  $\mu$ Ci Cesium-137 source (P/N A22684) to American Radiolabeled Chemicals Inc. (ARC), who was not licensed to receive the above stated item.

Aptuit LLC shipped a LSC with a 30  $\mu$ Ci Cesium-137 source to ARC as a generally licensed device. The inspectors reviewed documents related to License Amendment No. 27 (ML081010124, ML081010616, ML080990744, ML080930598, ML081010557, ML081010568, and ML081010564) which added cesium-137 to be used in a Beckman LSC LS6500 to the license. The inspectors reviewed these documents to determine whether the licensee had at any point in the past transferred the LSC from a general license to their own specific license in accordance with 10 CFR 31.5(8)(iii). The inspectors determined that no documentation exists which supported the device being transferred to their specific license under the provisions of 10 CFR 31.5(8)(iii). Therefore, although the device was listed in their license, it remained a generally licensed device under the provisions of 10 CFR 31.

The inspectors determined that the failure to transfer or ship general licensed material to another licensee that was authorized to receive the device by a specific license issued under 10 CFR part 30 and 32 is a violation of NRC requirements.

The inspectors utilized the NRC Enforcement Policy to determine if the violation was more than minor. The NRC inspectors determined that the violation was more than minor because the violation had a potential safety or security consequence and impacted the ability of the NRC to perform its regulatory oversight function by not informing the NRC of the previously stated transfer. The level of individuals involved in the failure and the reason why the failure occurred given their position and training also contributed in the determination of a more than minor violation. The agency will normally cite a licensee for a failure to report a condition or event if the licensee knew of the information to be reported but did not recognize that it was required to make a report.

Title 10 CFR 31.5(c)(8) states that "any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in paragraph (a) of this section: Shall transfer or dispose of the device containing byproduct material only by export as provided by paragraph (c)(7) of this section, by transfer to another general licensee as authorized in paragraph (c)(9) of this section, or to a person authorized to receive the device by a specific license issued under parts 30 and 32 of this chapter, or part 30 of this chapter that authorizes waste collection, or equivalent regulations of an Agreement State, or as otherwise approved under paragraph (c)(8)(iii)."

Contrary to the above, on June 11, 2013, the licensee transferred a Beckman LSCLS6500 containing 30  $\mu$ Ci of Cesium-137. This transfer was made to a person who did not hold a specific license pursuant to 10 CFR parts 30 and 32 or from an Agreement State to receive the device, and the exception in 10 CFR 31.5(c)(9) did not apply. Specifically, the device was transferred to ARC which was unlicensed to receive the device. (VIO 0309415/2013001-001)

As part of the corrective actions, the licensee has ceased all shipments and transfers to ARC or any other licensee.

c. Conclusion:

The inspectors identified one Severity Level IV violation of low safety significance of 10 CFR 31.5(c)(8), in that the licensee failed to follow the transfer requirements in 10 CFR 31.5(c)(8).

## **5.0 Exit Meeting Summary**

The inspectors presented the inspection results to licensee management at the conclusion of the onsite inspection on December 4, 2013. The inspectors presented the in-office inspection results to the RSO at the conclusion of the in-office review on January 9, 2014. The licensee acknowledged the results presented and did not identify any of the documents reviewed by the inspectors as proprietary.

ATTACHMENT: SUPPLEMENTAL INFORMATION

## **SUPPLEMENTAL INFORMATION**

### **LIST OF PERSONS CONTACTED**

#### Licensee

<sup>1,2</sup>C. Greg, Radiation Safety Officer  
<sup>1</sup>P. Barton, Director, Facilities  
<sup>1</sup>R. Greene, Contractor  
<sup>1,2</sup>Z. Peckham, Health Physicist  
<sup>1</sup>G. Coffman, District Manager  
<sup>1</sup>M. Dimare, Senior Director

<sup>1</sup>Indicates presence at the exit meeting held on December 4, 2013.

<sup>2</sup>Indicates presence at the telephonic exit meeting held on January 9, 2014.

### **LIST OF PROCEDURES USED**

IP 83822	Radiation Protection
IP 84101	Radioactive Waste Management
IP 88005	Management Organization and Controls
IP 86730	Transportation of Radioactive Material

### **ITEMS OPENED, CLOSED, AND DISCUSSED**

Opened	VIO 03009415/2013001-001 (Transportation violation)
Closed	None
Discussed	None

### **LIST OF ACRONYMS USED**

ADAMS	Agencywide Documents Access and Management System
ARC	American Radiolabeled Chemicals, Inc.
CFR	Code of Federal Regulations
DNMS	Division of Nuclear Materials Safety
DP	Decommissioning Plan
LSC	Liquid Scintillation Counter
NOV	Notice of Violation
NRC	U. S. Nuclear Regulatory Commission

### **DOCUMENTS REVIEWED**

AWI 001 – Surface Contamination Surveys for Decommissioning Activities at Aptuit, LLC  
AWI 002 – Operations and Use of Portable Radiation Survey Instruments at Aptuit, LLC

AWI 003 – Liquid Scintillation Counter Procedure for Beta Radiation Screening of Surface Wipe Samples  
AWI 004, rev 1 – General Decontamination & Decommissioning Activities at Aptuit, LLC  
Decommissioning Plan Aptuit Scientific Operations rev 1, February 2013  
Original Bill of Lading dated April 11, 2012 (Radioactive material – Carbon-14 and Hydrogen-3)  
Original Bill of Lading dated December 18, 2012 (Radioactive material – Carbon-14, Hydrogen-3, and laboratory equipment)  
Original Bill of Lading dated March 7, 2013 (Radioactive material – Carbon-14, Hydrogen-3, and laboratory equipment)  
Original Bill of Lading dated June 6, 2013 (LSC with Cesium-137 source)  
Packing Slip dated June 6, 2013  
Materials License No. 24-15595-01, Aptuit, LLC, Amendment No. 36  
Materials License No. 24-21362-01, American Radiolabeled Chemicals, Amendment No. 50