

February 8, 2013

Ms. Karen Burke, Director  
Environmental Remediation  
Covidien  
Mallinckrodt, Inc.  
675 McDonnell Boulevard  
St. Louis, MO 63134

SUBJECT: NRC INSPECTION REPORT NO. 04006563/12001(DNMS) —  
MALLINCKRODT, INC., ST LOUIS, MO

Dear Ms. Burke:

On January 23, 2013, the U.S. Nuclear Regulatory Commission (NRC) completed an inspection of decommissioning activities performed under your license by your decommissioning contractor, *EnergySolutions*, at the Columbium-Tantalum (C-T) Plant 5 area, located within the Mallinckrodt St. Louis Plant, at 3600 North Second Street, St. Louis, Missouri. Two on-site inspections and an in-office review of laboratory sample analysis results were completed during the inspection period between June 1, 2012, and January 23, 2013. The purpose of the inspections was to determine whether decommissioning activities were conducted safely and in accordance with your NRC approved C-T Phase II Decommissioning Plan (DP) and NRC regulations. On August 28, 2012, and December 11, 2012, the NRC inspectors discussed the results of the on-site inspections with you and your contractor; and on January 23, 2013, the NRC inspectors conducted a telephonic re-exit meeting with you to discuss the conclusion of the NRC's in-office review of the laboratory results of samples collected from the December 11, 2012, on-site confirmatory surveys.

This inspection examined decommissioning activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Specifically, the on-site inspections examined decommissioning activities conducted under your site-specific work plans and NRC approved DP, and included an examination of decommissioning documentation and representative records, observations of activities, and interviews with personnel. In addition, the NRC reviewed the transition plan regarding the change in decommissioning contractors; and performed independent confirmatory radiological surveys of Survey Unit (SU) 11.

Based on the results of the on-site inspections, the NRC did not identify any violations.

K. Burke

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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 and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Document Access and Management system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

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

Sincerely,

***/RA By Michael M. LaFranzo Acting  
For/***

Christine A. Lipa, Chief  
Materials Control, ISFSI, and  
Decommissioning Branch  
Division of Nuclear Materials Safety

Docket No. 040-06563  
License No. STB-401

Enclosure:  
Inspection Report No. 04006563/12001(DNMS)

cc w/encl: Mallinckrodt Service List

K. Burke

-2-

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U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.: 040-06563

License No.: STB-401

Report No.: 04006563/12001(DNMS)

Licensee: Mallinckrodt, Inc.

Location: C-T Plant 5 area within the  
Mallinckrodt St. Louis Plant  
3600 North Second Street  
St. Louis, MO

Inspection Dates: June 1, 2012 through January 23, 2013  
(period included two on-site inspections and  
an in-office review)

Inspectors: E. Bonano, Health Physicist  
P. Lee, Health Physicist, PhD, CHP  
N. Tehrani, Nuclear Safety Professional  
Development Program Participant

Approved by: Christine A. Lipa, Chief  
Materials Control, ISFSI, and  
Decommissioning Branch  
Division of Nuclear Materials Safety

Enclosure

## EXECUTIVE SUMMARY

### **Mallinckrodt, Inc. Phase II C-T Decommissioning Project NRC Inspection Report 04006563/12001(DNMS)**

During this decommissioning inspection period, between June 1, 2012, and January 23, 2013, regional inspectors completed two on-site inspections on August 28, 2012, and December 11, 2012; and completed on January 23, 2013, an in-office review of laboratory analytical results of samples collected from the December 11, 2012, on-site confirmatory survey.

The inspectors reviewed the licensee's change in decommissioning contractors, and the licensee's transition plan which described how this change-over would not affect the Decommissioning Plan (DP), site-specific work plans and procedures, and all work completed for the project; the change-over from AECOM-Environment to EnergySolutions was completed on July 10, 2012 (ML12201A084).

During the December 11, 2012, on-site inspection, the U.S. Nuclear Regulatory Commission (NRC) inspectors performed confirmatory radiological surveys of Survey Unit (SU)-11; and collected three soil samples for analysis by the NRC's contract laboratory, Oak Ridge Institute for Science and Education (ORISE) for the isotopes of concern. Inspectors also reviewed the final status survey packages of survey units 10, 11, and 19 to ensure the licensee conducted the survey in accordance with the requirements as stated in the DP; and reviewed the comparative analysis of on-site gamma spectroscopy with ORISE confirmatory sampling results to ensure the accuracy of the on-site laboratory.

#### **Decommissioning Inspection Procedure for Materials Licensees (IP 87104)**

Following the transition to a new contractor, the inspectors determined that decommissioning activities continued to be conducted in accordance with the NRC license, approved DP, work plans, procedures, and NRC regulations. (Section 1.0)

#### **Closeout Inspection and Surveys (IP 83890)**

The inspectors concluded, based on inspection reviews of completed survey units and independent confirmatory surveys, that the licensee conducted the final status survey activities in accordance with the DP and license requirements. (Section 2.0)

## Report Details<sup>1</sup>

### **1.0 Decommissioning Inspection Procedure for Materials Licensees (IP 87104)**

#### a. Inspection Scope

During the August 28, 2012, on-site inspection, the inspectors reviewed the licensee's change in decommissioning contractors from AECOM-Environment to EnergySolutions, and the licensee's transition plan CS-PM-PN-056, "Transition Plan, Phase II Decommissioning, Mallinckrodt C-T Plant, St. Louis, Missouri," Revision 0, dated July 13, 2012, which described how this change-over would not affect the DP, site-specific work plans and procedures, and all work completed for the project. The inspectors interviewed the licensee's and contractor's management and technical staff to determine if this change would affect the DP, site-specific work plans and procedures, and all work completed for the project; and to ensure that EnergySolutions (License: 06-20775-01; Docket: 030-22060) was in compliance with their NRC radioactive material license requirements as an out-of-state decommissioning contractor.

#### b. Observations and Findings

The change-over from AECOM-Environment to EnergySolutions was completed on July 10, 2012 (ML12201A084). The licensee and its new decommissioning contractor, EnergySolutions, completed a thorough review of all work plans and procedures developed and used by the outgoing contractor, AECOM-Environment, and compared them to EnergySolutions procedures to ensure compliance with the approved DP; CS-RS-PN-035, "AECOM SOP Equivalency Review, Phase II Decommissioning Project, Mallinckrodt C-T Plant, St. Louis, Missouri," Revision 0, dated July 25, 2012; and determined that the EnergySolutions procedures were equivalent to the AECOM SOPs. As a result, EnergySolutions implemented the licensee's suite of operating procedures to meet the requirements of the DP; specifically, Sections 10 and 11 of the DP. The inspectors also determined that the out-of-state decommissioning contractor, EnergySolutions, had complied with the Temporary Job Site Notification requirements of their NRC license; and both licensees had an agreement in effect that described EnergySolutions would be conducting activities under the Mallinckrodt decommissioning license.

No findings of significance were identified regarding the licensee's change in contractors or decommissioning activities.

#### c. Conclusions

Following the transition to a new contractor, the inspectors determined that decommissioning activities continued to be conducted in accordance with the NRC license, approved DP, work plans, procedures, and NRC regulations.

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<sup>1</sup>A list of acronyms used in these "Details" are provided at the end of the report.

## 2.0 Closeout Inspection and Survey (IP 83890)

### a. Inspection Scope

During the December 11, 2012, on-site inspection, the NRC inspectors reviewed the final status survey packages of survey units 10, 11, and 19 to ensure the licensee conducted the survey in accordance with the requirements as stated in the DP. The inspectors also reviewed the comparative analysis of on-site gamma spectroscopy with ORISE confirmatory sampling results to ensure the accuracy of the on-site laboratory. The inspectors conducted confirmatory radiological surveys of SU-11 and collected three soil samples for analysis by the NRC's contract laboratory, ORISE, for the isotopes of concern.

### b. Observations and Findings

The inspectors noted that the licensee's contractor, EnergySolutions, conducted final status surveys in accordance with NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)," the DP, Field Sampling Plan (FSP), Quality Assurance Project Plan (QAPP); and determined that the quality assurance program for the on-site laboratory and the data quality objectives for sample collection and analysis was adequate. The inspectors used a calibrated Ludlum 2241-2 survey meter with a 44-10 NaI detector to survey SU-11; collected three biased soil samples at locations where the highest surface radiation levels were identified, which were also below the licensee's action level of remediation. In the January 2, 2013, letter from ORISE to the NRC (ML13008A125); ORISE reported the results for the soil samples to be consistent with the licensee's on-site laboratory analytical sample results, and less than the derived concentration guideline levels (DCGLs) as stated in the DP.

Regarding SU-11, the Sum-of-Fractions (SOF) of the radionuclides of concern from the licensee's systematic sampling were all less than one; with the exception of borehole sample #7 which had a SOF greater than one in the third and fourth meter section of the bore hole. All biased sampling locations in SU-11 were remediated to SOFs less than one; except the area of sewer pipe. The licensee plans to conduct additional core boring around borehole #7 to determine if additional remediation is required; and the area of sewer pipe with SOFs exceeding one will be remediated at a later date prior to completion of the project.

No findings of significance were identified.

### c. Conclusions

The inspectors concluded, based on inspection reviews of completed survey units and independent confirmatory surveys, that the licensee conducted the final status survey activities in accordance with the DP and license requirements.

### **3.0 Exit Meetings**

The inspectors presented the inspection results to Ms. Karen Burke, Director of Environmental Remediation, and contractor personnel, at the conclusion of the on-site inspections on August 28, 2012, and December 11, 2012; and during the telephonic final re-exit meeting on January 23, 2013. The inspectors confirmed that none of the potential report input discussed was considered proprietary.

ATTACHMENT: SUPPLEMENTAL INFORMATION



## **SUPPLEMENTAL INFORMATION**

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

P. Anderson, Engineer, Missouri Department of Natural Resources (MDNR)  
K. Burke, Project Manager, RSO, Mallinckrodt  
M. Cambra, Project Manager, EnergySolutions  
M. Carr, Site RSO, EnergySolutions

### **LIST OF PROCEDURES USED**

IP 87104      Decommissioning Inspection Procedure for Materials Licensees  
IP 83890      Closeout Inspection and Survey

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

None

### **DOCUMENTS REVIEWED**

Documents reviewed during the inspection are listed in the body of the report.

### **LIST OF ACRONYMS USED**

ADAMS	Agencywide Documents Access and Management System
CFR	Code of Federal Regulations
C-T	Columbium-Tantalum
DCGL	Derived Concentration Guideline Level
DNMS	Division of Nuclear Materials Safety
DP	Decommissioning Plan
FSP	Field Sampling Plan
IP	Inspection Procedure
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
NaI	Sodium Iodide
NRC	U.S. Nuclear Regulatory Commission
ORISE	Oak Ridge Institute for Science and Education
QAPP	Quality Assurance Project Plan
SOF	Sum-of-Fractions
SU	Survey Unit