

June 29, 2012

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

SUBJECT: NRC INSPECTION REPORT NO. 040-06563/11-003(DNMS) –  
MALLINCKRODT, INC. ST LOUIS, MO

Dear Ms. Burke:

On May 31, 2012, the U.S. Nuclear Regulatory Commission (NRC) completed an inspection of decommissioning activities performed under your license by your decommissioning contractor, AECOM Environment, at the Columbian-Tantalum (C-T) Plant 5 area, located within the Mallinckrodt St. Louis Plant, at 3600 North Second Street, St. Louis, Missouri. Two onsite inspections were completed during the inspection period between December 15, 2011 and May 31, 2012. 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 December 16, 2011 and April 26, 2012, the NRC inspectors discussed the results of the onsite inspections with you and your contractor. On May 31, 2012, the NRC inspectors conducted a telephonic final exit meeting with you to discuss the findings from this inspection period.

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 onsite 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 performed confirmatory and independent radiological surveys of Survey Units (SU) 9 and 17.

During the inspection, the NRC noted that your decommissioning contractors had changed. It is our understanding that you will submit a transition plan to the NRC specifically describing how this changeover will not affect the DP, site-specific work plans and procedures, and all work completed for the project. If this is not your understanding, please contact Gene Bonano at 630-829-9826.

Based on the results of the onsite 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/*

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. 040-06563/11-003(DNMS)

cc w/encl: Mallinckrodt Service List

K. Burke

-2-

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Mallinckrodt Chemical Inc. Service List – Project Manager, John Buckley

Henry Morton  
Morton Associates  
10421 Masters Terrace  
Potomac, MD 20854

Sharon Cotner, Program Manager  
U.S. Army Corps of Engineers  
FUSRAP  
8945 Latly Avenue  
Berkley, MO 63134

Dennis Chambers  
U.S. Army Corps of Engineers  
FUSRAP  
8945 Latly Avenue  
Berkley, MO 63134

Jacqueline Mattingly, Program Manager  
U.S. Army Corps of Engineers  
FUSRAP  
8945 Latly Avenue  
Berkley, MO 63134

Ms. Pat H. Duft  
Vice President, Legal  
Covidien  
Mallinckrodt Inc.  
675 McDonnell Boulevard  
Hazelwood, MO 63042

Branden B. Doster  
Missouri Department of Natural Resources  
Hazardous Waste Program  
P.O. Box 176  
Jefferson City, MO 65102-0176

Patrick Anderson, Environmental Engineer  
Missouri Department of Natural Resources  
1730 E. Elm St.  
Jefferson City, MO 65101

Karen Burke  
Director, Environmental Remediation  
Covidien  
Mallinckrodt Inc.  
675 McDonnell Boulevard  
Hazelwood, MO 63042

H. Floyd Gilzow, Deputy Director  
Policy and Intergovernmental Cooperation  
Department of National Resources  
State of Missouri  
P.O. Box 176  
Jefferson City, MO 65102

Honorable Doyle Childers  
Director  
Department of National Resources  
State of Missouri  
P.O. Box 176  
Jefferson City, MO 65102

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.: 040-06563

License No.: STB-401

Report No.: 040-06563/11-003(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: December 15, 2011 through  
May 31, 2012 (period included two onsite  
inspections)

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 040-06563/11-003(DNMS)**

During this decommissioning inspection period, between December 15, 2011 and May 31, 2012, two onsite inspections were completed on December 16, 2011 and April 26, 2012 by regional inspectors. The inspections included an independent confirmatory survey of Survey Units (SU) 9 and 17, and in-process inspector reviews of the licensee's decommissioning activities and final status survey packages of completed survey units.

The licensee's routine decommissioning activities consisted of: (1) excavating contaminated soil, placing it into large polypropylene bags (super sacks), transporting the bags from the Plant 5 area to a railhead within the Mallinckrodt St. Louis Plant, temporarily storing onsite, and then shipping the waste for disposal; (2) conducting final status surveys (FSS); (3) water removal from excavated trenches and pits, and processing for disposal; and (4) operating an onsite laboratory in support of backfill activities.

During the inspection period, the licensee completed final status surveys and backfilled eleven survey units (SUs: 4 through 9, 14 through 17, and 20) within the Plant 5 area. The inspectors reviewed the final status survey packages of SUs 5, 6, 7, and 20 to ensure the licensee conducted the surveys in accordance with the U.S. Nuclear Regulatory Commission (NRC) approved Decommissioning Plan (DP) and work plans. The inspectors also reviewed the comparative analysis of onsite gamma spectroscopy with off-site confirmatory laboratory results to ensure the accuracy of the onsite laboratory; and did not identify any problems with the results. The licensee backfilled the survey units based on the screening results from the onsite laboratory.

Water, collected from the excavated trenches and pits, was removed and passed through a six stage filtration system; then analyzed and placed in large mobile tanks for disposal. The inspectors verified the activity per unit volume concentrations of radioactivity in the filtered water was less than the Title 10 of the Code of Federal Regulations (CFR) Part 20, Appendix B effluent release concentrations for the isotopes of concern; and the licensee ensured effluent release concentrations also did not exceed the Missouri Department of Natural Resources (MDNR) release limits.

As a result of legal and contract issues, the project's decommissioning schedule was significantly delayed due to a change in decommissioning contractors. The changeover from AECOM Environment to EnergySolutions is planned for June of 2012; the licensee committed to submit a transition plan to the NRC before the new contractor begins work, specifically describing how this changeover would not affect the DP, site-specific work plans and procedures, and all work completed for the project.

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

The licensee conducted decommissioning activities in accordance with the NRC approved DP, work plans, procedures, and NRC regulations. (Section 1.0)

### **Radiation Protection (IP 83822)**

The licensee and its contractor maintained strict adherence to the Health and Safety Plan (HASP), safety procedures and 10 CFR Part 20 safety requirements. (Section 2.0)

### **Closeout Inspection and Surveys (IP83890)**

The inspectors determined the licensee conducted the final status surveys in accordance with the requirements stated in the DP. (Section 3.0)

### **Low-Level Radioactive Waste Storage (IP 84900)**

The inspectors determined that the licensee is temporarily storing excavated material in accordance with the DP, work plans, procedures, and NRC regulations. (Section 4.0)

### **Effluent and Environmental Monitoring (IP 84750)**

The inspectors determined that the licensee's effluent releases did not exceed the 10 CFR, Part 20, Appendix B release limits. (Section 5.0)

### **Inspection of Transportation Activities (IP86740)**

The inspectors determined shipments of excavated material was completed in accordance with the DP, work plans, procedures, NRC and Department of Transportation (DOT) regulations. (Section 6.0)

### **OSHA Interface Activities (IP 93001)**

The inspectors did not identify any violations of Occupational Safety and Health Administration (OSHA) regulations during decommissioning work. (Section 7.0)

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

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

#### a. Inspection Scope

The inspectors observed the licensee's decommissioning activities pertinent to the completion of their C-T Phase II Decommissioning Project; and verified their compliance with the NRC approved DP, Master Project Plan (MPP), Work Plan (WP), Health and Safety Plan HASP, Field Sampling Plan (FSP), Quality Assurance Project Plan (QAPP), procedures, and NRC regulations to protect the health and safety of workers and the general public. The inspectors reviewed the licensee's Audit Report Number: 2011-002 Project 6016412, "Mallinckrodt C-T Project Annual Radiation Safety Program Audit" report dated December 13, 2011. The inspectors interviewed select licensee and contractor staff regarding their roles, responsibilities, and knowledge related to the decommissioning project and safety.

#### b. Observations and Findings

Decommissioning activities were conducted in accordance with the DP, work plans, procedures, and NRC regulations. The licensee's contractor completed an audit of their radiation safety program for the C-T Phase II Decommissioning Project and identified two findings and six observations of low safety significance, which were corrected and preventative actions taken. No violation of NRC requirements was identified in regards to the audit.

Radiation work permits were appropriately maintained and followed by work crews. Site HP staff maintained constant oversight of activities, and briefed personnel of radiation safety concerns daily. The licensee's quality assurance program for the onsite laboratory and the data quality objectives for sample collection and analysis was adequate. Management and staff were knowledgeable and cognizant of their roles and responsibilities regarding the project and safety. No findings of significance were identified.

#### c. Conclusions

The licensee conducted decommissioning activities in accordance with the NRC approved DP, work plans, procedures, and NRC regulations.

### **2.0 Radiation Protection (IP 83822)**

#### a. Inspection Scope

The inspectors reviewed the licensee's radiation protection program in regards to posting, labeling and notices, air sampling and monitoring in regards to occupational exposures, the use of dosimeters, use of personal protective equipment and clothing, surveys and monitoring (i.e., use of frisk stations, performing periodic surveys of restricted and unrestricted areas), controlling and containing the spread of contamination

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



from workers, heavy equipment and the super sacks that are filled with excavated contaminated soil.

b. Observations and Findings

The licensee and its contractor audited their radiation protection program to ensure compliance with their HASP, safety procedures, and 10 CFR Part 20 requirements. Posting, labeling, and notices were appropriately placed throughout the site. During the inspection period, air sampling results did not exceed the 10 CFR Part 20 Appendix B occupational limits. Workers wore their dosimetry and serviceable Personal Protective Equipment (PPE) while working in the excavated trenches and pits, and used frisk stations before leaving the excavation site. Radiation protection staff periodically surveyed trucks, loaders, and the exterior of the super sacks to ensure contamination do not go beyond the boundary of the restricted areas. No findings of significance were identified.

c. Conclusions

The licensee and its contractor maintained strict adherence to the HASP, safety procedures and 10 CFR Part 20 safety requirements.

**3.0 Closeout Inspection and Survey (IP 83890)**

a. Inspection Scope

The inspectors performed side-by-side surveys with the licensee's contractor, and conducted independent confirmatory surveys of SU-9 and 17. The inspectors collected soil and water samples from SU-9 and 17 and submitted them for analysis to the NRC's contract laboratory, Oak Ridge Institute for Science and Education (ORISE) for the isotopes of concern.

During the April 26, 2012 onsite inspection, the inspectors reviewed the final status survey packages of survey units 5, 6, 7, and 20, 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 onsite gamma spectroscopy with off-site confirmatory results to ensure the accuracy of the onsite laboratory.

The inspectors reviewed the sampling results of core boring from survey unit 11, 15, and 21; which are Class 2 areas.

b. Observations and Findings

Side-by-side measurement comparisons with the licensee were adequate. During side-by-side walkover surveys in SU-9 and 17, the NRC inspectors' measurements, using a calibrated Ludlum 2241-2 survey meter with a 44-10 NaI 2 by 2 detector, were consistent with the licensee's contractor survey results.

In the January 12, 2012 (ML120240777) and May 21, 2012 (ML12146A229) letter reports from ORISE to the NRC; ORISE reported the results for soil and water samples collected by the inspectors. The results were found to be consistent with the licensee's

laboratory analytical sample results, and less than the derived concentration guideline levels (DCGLs) as stated in the DP.

The licensee conducted final status surveys in accordance with NUREG-1575 Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) guidance. The onsite soil analytical results were consistent with the off-site laboratory; and the survey units were backfilled based on the screening results from the onsite laboratory. The confirmatory sampling results from the off-site laboratory required a 30-day waiting period; therefore, to support the project timeline, the licensee relied on the onsite sampling results to mitigate the risk of backfilling.

The sum of fractions (SOF) of the radionuclides of concern from systematic sampling laboratory results was less than one. A few SOFs of biased sampling in survey units 5 and 6 exceeded one. The licensee plans to document in their final status survey report how the survey units with elevated areas will meet the release criteria in accordance with NUREG-1575, MARSSIM.

The sampling results data from core boring in the Class 2 areas will be treated as final status survey. Most of the sampling results indicated SOF below one.

No findings of significance were identified.

c. Conclusions

The inspectors determined the licensee conducted the final status surveys in accordance with the requirements stated in the DP.

**4.0 Low-Level Radioactive Waste Storage (IP 84900)**

a. Inspection Scope

The inspectors verified the licensee is temporarily storing near the railhead super sacks containing excavated soil from the Plant 5 area safely and in accordance with the DP, work plans, procedures, and NRC regulations.

b. Observations and Findings

Super sacks staged for shipment to an authorized radioactive waste disposal site were cordoned off and labeled with radioactive material postings/placards and secured to prevent unauthorized removal. The material was properly controlled to meet the licensee's radiation control requirements, and the radiation levels from the super sacks were properly monitored. No findings of significance were identified.

c. Conclusions

The inspectors determined that the licensee is temporarily storing excavated material in accordance with the DP, work plans, procedures, and NRC regulations.

## **5.0 Effluent and Environmental Monitoring (IP 84750)**

### a. Inspection Scope

The inspectors reviewed the air monitoring data results collected from the air monitors stationed around the Plant 5 area, and waste water discharge from survey unit 15 during calendar year (CY) 2012. The inspectors verified that the concentrations of radioactivity from the air sampling data and in the filtered water analytical results were less than the 10 CFR Part 20, Appendix B effluent release concentrations for the isotopes of concern.

### b. Observations and Findings

During the inspection period, air sampling results did not exceed the 10 CFR, Part 20 Appendix B release limits for air effluent concentrations.

Prior to discharge, waste water generated from rainstorm and below surface streams was collected from the excavated trenches and pits, passed through a six stage filtration system then analyzed and placed in large mobile tanks for disposal. The activity per unit volume concentrations of radioactivity in the filtered water was less than the 10 CFR, Part 20, Appendix B effluent release concentrations for the isotopes of concern. The licensee ensured effluent release concentrations also did not exceed the MDNR release limits. No findings of significance were identified.

### c. Conclusions

The inspectors determined that the licensee's effluent releases did not exceed the 10 CFR, Part 20, Appendix B release limits.

## **6.0 Inspection of Transportation Activities (IP 86740)**

### a. Inspection Scope

The inspectors reviewed two records of non-hazardous waste shipments: CTNH-0140-AECOM, and CTNH-0161-AECOM completed in accordance with the contractor's procedure CT-AECOM-RP-24, "Radioactive Protection Procedure, Classification and Shipment of Radioactive Materials," Revision 0.

### b. Observations and Findings

All waste was shipped as non-hazardous unimportant quantities since the activities were below the DOT threshold for what is defined as radioactive materials, and therefore not regulated by DOT. No findings of significance were identified.

### c. Conclusions

The inspectors determined shipments of excavated material were completed in accordance with the DP, work plans, procedures, and NRC and DOT regulations.

## **7.0 OSHA Interface Activities (IP 93001)**

### a. Inspection Scope

The inspectors observed and verified decommissioning work activities performed by the licensee and contractor personnel were done in compliance with OSHA regulations.

### b. Observations and Findings

No findings of significance were identified.

### c. Conclusions

The inspectors did not identify any violations of OSHA regulations during decommissioning work.

## **8.0 Exit Meetings**

The inspectors presented the inspection results to Ms. Karen Burke, Director of Environmental Remediation, and contractor personnel, at the conclusion of the onsite inspections and during the telephonic final exit meeting on May 31, 2012. The inspectors confirmed that none of the potential report input discussed was considered proprietary.

ATTACHMENT: SUPPLEMENTAL INFORMATION

## **SUPPLEMENTAL INFORMATION**

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

K. Burke, Project Manager, RSO, Mallinckrodt  
J. Cooper, Project Technical Manager, AECOM  
M. Cushman, Site RSO, AECOM  
R. Larrabee, Field Operations Manager, AECOM

### **LIST OF PROCEDURES USED**

IP 87104	Decommissioning Inspection Procedure for Materials Licensees
IP 83890	Closeout Inspection and Survey
IP 83822	Radiation Protection
IP 84900	Low-Level Radioactive Waste Storage
IP 84750	Radioactive Waste Treatment, and Effluent and Environmental Monitoring
IP 86740	Inspection of Transportation Activities
IP 93001	OSHA Interface Activities

### **LIST OF ACRONYMS USED**

ADAMS	Agency Document and Management System
CFR	Code of Federal Regulations
C-T	Columbium-Tantalum
DCGL	Derived Concentration Guideline Level
DNMS	Division of Nuclear Materials Safety
DOT	Department of Transportation
DP	Decommissioning Plan
FSP	Field Sampling Plan
FSS	Final Status Survey
HASP	Health and Safety Plan
HP	Health Physics
IP	Inspection Procedure
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
MPP	Master Project Plan
MDNR	Missouri Department of Natural Resources
NaI	Sodium Iodide
NRC	U.S. Nuclear Regulatory Commission
ORISE	Oak Ridge Institute for Science and Education
OSHA	Occupational Safety and Health Administration
PPE	Personal Protective Equipment
QAPP	Quality Assurance Project Plan
RSO	Radiation Safety Officer
SU	Survey Unit
WP	Work Plan

## **DOCUMENTS REVIEWED**

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

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

None