

**SUMMARY AND RESPONSE TO COMMENTS
DRAFT PART I PERMIT
MALLINCKRODT LLC
ST. LOUIS, MISSOURI
EPA ID# MOD096726484**

The Missouri Department of Natural Resources (hereafter the Department) issued a final Missouri Hazardous Waste Management Facility Part I Permit to Mallinckrodt LLC (hereafter the Permittee). The final Part I Permit requires the Permittee to continue to perform corrective action activities at the site. The Permit also contains contingencies that may be exercised in the event there is a newly identified release to the environment from a new- or previously-identified solid waste management unit or area of concern.

The Department conducted the public participation activities for the draft Part I Permit, as outlined in Code of State Regulations 10 CSR 25-8.124(1)(A)10. The Department invited the public to review and offer written comments on the draft permit during a 45-day public comment period. The public comment period began on August 9, 2013, and ended September 23, 2011.

All written comments received during the public comment period concerning the draft Part I Permit are listed below. The Department's response to each comment and an explanation of how each comment was addressed in the final Part I Permit is also included. The Department changed certain requirements in the final Part I Permit based on technical or legal issues brought up by the comments. All changes made in the final Part I Permit are identified in the responses. This Summary and Response to Comments was prepared according to the requirements in 10 CSR 25-8.124(1)(A)17.

COMMENT FROM THE PERMITTEE DURING THE 10-DAY REVIEW PERIOD BEFORE BEING PUBLIC NOTICED:

GENERAL PERMIT CONDITIONS: I. Identification of SWMUs and AOCs [40 CFR 264.101]

Comment #1:

Paragraph D should be added regarding the attached Class I Permit Modification (see modification language in attachment). This modification addresses the coordination with USACE and/or DOE to avoid duplication of efforts in the investigation and remediation of the site under the FUSRAP program and the RCRA corrective action program.

Response #1:

The language from the Class I Permit Modification without Director's Approval dated April 20, 1999, has been added to the final Part I Permit. Corrective Action Condition I.D. has been added to the final Part I Permit and reads,

“D. *The Permittee shall be responsible for working with the DOE and/or the USACE to avoid duplication of efforts in the development of site investigation and remediation criteria at FUSRAP and other areas of the site. The Permittee will attempt to resolve any disputes over its responsibility while the Permittee shall be responsible for performing corrective action necessary to protect human health and the environment for any releases of hazardous waste, including hazardous constituents to the environment attributable to SWMUs or AOCs at the facility which are not the responsibility of DOE/USACE pursuant to the Federal Facilities Agreement between DOE and EPA dated June 26, 1990.*

Further, the Department acknowledges that there should be minimal, if any, duplicative regulatory effort in investigating and remediating the FUSRAP areas. The Department will allow DOE/USACE to discharge its investigation and remediation obligations as fully as possible pursuant to the Federal Facilities Agreement prior to requiring any additional corrective action in the FUSRAP areas by the Permittee. The Department will decide whether additional site investigation and/or site remediation are necessary as quickly as possible once the appropriate data to make a decision are available to the Department.”

COMMENTS FROM THE PERMITTEE:

INTRODUCTION

Comment #2:

Please change “Mallinckrodt, LLC” throughout the document to “Mallinckrodt LLC.”

Response #2:

The final Part I Permit language has been changed to incorporate the language above.

DEFINITIONS, page 10. “Release” means any spilling, leaking, pouring, emitting, emptying, discharging, injecting, pumping, escaping, leaching, dumping, or disposing of hazardous wastes or hazardous constituents into the environment (including the abandonment or discarding of barrels, containers, and other closed receptacles containing hazardous wastes or hazardous constituents).

Comment #3:

Mallinckrodt recommends the definition of “release” be revised to the presence of hazardous constituents above de minimis levels or relevant risk-based screening levels.

Response #3:

The term “release” is not specifically defined in RCRA or the federal or state regulations. The above definition of “release” is used to more specifically describe the act of a hazardous substance, pollutant or contaminant escaping from confinement or control and applies regardless of whether it exceeds a reportable quantity or “de minimis” level. Reportable quantity regulations are contained as part of the Superfund Amendments and Reauthorization Act of 1986, also titled the Emergency Planning and Community Right-To-Know Act (EPCRA) of 1986. The EPCRA reportable quantity regulations are

separate and distinct from the hazardous waste regulations and requirements of this Part I Permit. The response to a release cannot be determined until an assessment is made as to whether the quantity released threatens human health or the environment.

The usage of a risk-based threshold in the “release” definition implies that there would be sampling and analysis conducted to determine if a release had occurred and that is not a requirement of the applicable regulations or this Permit. Under all MHWMF Part I Permits, any new spill or release would be considered to be a new AOC in accordance with the definition in the Permit. All newly-identified spills or releases (AOCs) are subject to the corrective action provisions of the Permit unless and until these areas are evaluated, investigated/sampled and/or remediated such that no further action, as determined by the Department, is needed to address actual or potential threats to human health and the environment.

The final Part I Permit language will remain the same as the draft Part I Permit language.

GENERAL PERMIT CONDITIONS, II. Notification of an Emergency Situation, page 14.
“The Permittee shall, at the earliest practical moment upon discovery of an emergency involving the hazardous waste under the Permittee 's control, notify the Department’s emergency response hotline at (573) 634-2436 and the National Response Center at 1-800-424-8802.”

Comment #4:

Per 40 CFR 264.51(b), the contingency plan is implemented “whenever there is a fire, explosion, or release of hazardous waste or hazardous waste constituents which could threaten human health or the environment.” Mallinckrodt recommends revising the above notification as follows: *“The Permittee shall, at the earliest practical moment upon discovery of an emergency involving the hazardous waste under the Permittee’s control, implement the facility contingency plan, including notify the Department’s emergency response hotline at (573) 634-2436 and the National Response Center at 1-800-424-8802.”*

Response #4:

The final Part I Permit language has been changed to incorporate the language above.

SPECIAL PERMIT CONDITIONS, II. Seismic Evaluation Requirements, page 16.

Comment #5:

Mallinckrodt demonstrated that the permitted Hazardous Waste Storage Area (HWSA) was in compliance with the seismic requirements. However, as the HWSA is undergoing closure (has been demolished), this requirement is no longer applicable.

Response #5:

Special Permit Condition II of the Draft Part I Permit has been removed from the final Part I Permit in response to the above comment.

CORRECTIVE ACTION CONDITIONS, I. Identification of SWMUs and AOCs, page 17. Section A., Second paragraph. “Following further evaluation of the SWMUs and the AOC identified as requiring additional investigation in the RFA Report and a review of other relevant site specific information, the Department determined that a total of seven SWMUs and two AOCs would require further action. These SWMUs and AOCs are listed below. Figure 3 shows the approximate locations of these SWMUs and AOCs at the facility.”

Comment #6:

Please revise the first sentence as follows to clarify the basis for further action for the subject SWMUs and AOCs: “... *seven SWMUs and two AOCs would require further action as required in the Part B Permit dated 1997.*”

Response #6:

The final Part I Permit language has been changed to read,

“Following further evaluation of the SWMUs and AOC identified as requiring additional investigation in the RFA Report and a review of other relevant site-specific information, the Department determined that a total of seven SWMUs and two AOCs would require further action as required in the previous Missouri Hazardous Waste Management Facility Part I Permit dated September 19, 1997. These SWMUs and AOCs are listed below. Figure 3 shows the approximate locations of these SWMUs and AOCs at the facility.”

CORRECTIVE ACTION CONDITIONS, I. Identification of SWMUs and AOCs, page 19. Section A., Eighth paragraph. “The Permittee provided notice to the Department on August 25, 2008 regarding the discovery of some laboratory bottles at the north end of the Plant 6W area, which were found during the excavation of Unreacted Ore (URO) burials that were being removed by USACE under FUSRAP. The labels on the laboratory bottles identified the material as Arsenic Acid Powder, a type of pesticide. A total of 40 bottles were removed from the excavation by hand, cleaned and released from radiological restriction, and lab packed for hazardous waste disposal. The Permittee reported that there was no visual evidence of released arsenic acid powder within the excavation. The newly-identified SWMU was identified as “URO Burial #5, Plant 6W”. The Permittee indicated that any further investigation or corrective action for this SWMU would be addressed in the CA725 Environmental Indicator evaluation and in the supplemental RFI Work Plan.”

Comment #7:

Please note that Mallinckrodt, not the USACE, removed the laboratory bottles from the URO excavations. As such, revise the first sentence to read “...*Unreacted Ore (URO) burials that were being removed by Mallinckrodt under a license amendment with the US Nuclear Regulatory Commission.*”

Response #7:

The final Part I Permit language has been changed to incorporate the language above.

CORRECTIVE ACTION CONDITIONS, I. Identification of SWMUs and AOCs., page 20. Section A., Ninth paragraph. “The Permittee provided notice to the Department on December 1, 2009, regarding an incident where a drum of waste chloroform was punctured by a fork truck in an asphalt paved area located immediately east of Building 250 and within the Phase II Columbian-Tantalum Area (CT Area) on November 19, 2009. The incident released approximately eight gallons of chloroform waste. Once the spill cleanup activities were complete, the asphalt pavement was found to be compromised within the footprint of the spill area. The asphalt pavement and gravel layer, approximately 5 feet square in size, were removed for proper disposal and an intact concrete pad was found beneath the gravel layer. This newly-identified release was identified as “AOC K”.”

Comment #8:

Please note that the chloroform was spilled onto a paved surface. As such, revise the second sentence as follows: *“The incident released approximately eight gallons of chloroform waste onto asphalt pavement.”*

Response #8:

The final Part I Permit language has been changed to incorporate the language above.

CORRECTIVE ACTION CONDITIONS, II. Notification Requirements for, and Assessment of, Newly-Identified SWMUs and AOCs, page 20. Section A. “The Permittee shall notify the Department and EPA, in writing, no later than 15 calendar days after discovery or after discovery should have been made, of any new SWMU(s) or AOC(s) identified after issuance of this Permit.”

Comment #9:

Mallinckrodt recommends the definition of “discovery” include visual observations, laboratory test results or information not previously available.

Response #9:

The final Part I Permit language has been changed to read,

“A. *The Permittee shall notify the Department and EPA, in writing, no later than 15 calendar days after discovery (e.g., visual observations, laboratory test results, or information not previously available) or after discovery should have been made, of any new SWMU(s) or AOC(s) identified after the issuance of this Permit.*”

Comment #10:

Mallinckrodt recommends removing the phrase “*or after discovery should have been made*” throughout the permit as this is a subjective requirement.

Response #10:

The “*after discovery should have been made*” language in Corrective Action Condition II.A. is standard language that is used in all Part I Permits and is intended to safeguard

human health and the environment and ensure due diligence on the part of the Permittee with respect to inspection of its operations in accordance with established operating procedures and other applicable regulatory requirements and prompt identification and reporting to the Department of new SWMUs, AOCs and releases. If applicable internal inspection schedules or procedures are delayed or not followed and a “discovery” should have been made earlier, then the 15 day window for reporting to the Department is diminished by any time that has passed since the SWMU, AOC or release should have been discovered.

The final Part I Permit language will remain the same as the draft Part I Permit language.

CORRECTIVE ACTION CONDITIONS, III. Notification Requirements for, and Assessment of, Newly-Identified Releases from Previously-Identified SWMUs and AOC, page 23. Section A. “The Permittee shall notify the Department and EPA, in writing, no later than 15 calendar days after discovery or after discovery should have been made, of any newly-identified releases(s) of hazardous wastes or hazardous constituents from previously-identified SWMU(s) or AOC(s) discovered during the course of groundwater monitoring, field investigations, environmental auditing, or other activities undertaken after issuance of this Permit.”

Comment #11:

Mallinckrodt recommends focusing this requirement to previously-identified SWMUs and AOCs that aren’t currently being investigated and reported as part of the RCRA Corrective Action process. Otherwise, notification could be triggered based on the results of routine monitoring.

Response #11:

The above language in Section A of Corrective Action Condition III. in the draft Part I Permit is standard language used in all Part I Permits and this requirement is not just limited to those SWMUs/AOCs identified for further action. The draft Part I Permit language was modified in the final Part I Permit to provide further clarification of this issue. The final Part I Permit language has been changed to read,

“A. *The Permittee shall notify the Department and EPA, in writing, no later than 15 calendar days after discovery or after discovery should have been made, of any newly-identified release(s) of hazardous wastes or hazardous constituents from any previously-identified SWMU(s) or AOC(s) at the facility including those being investigated and reported as part of the corrective action process that are discovered during the course of groundwater monitoring, field investigation, environmental auditing, or other activities undertaken after issuance of this Permit. The Department may examine the Facility’s inspection records to determine if the Permittee should have known such a release has occurred.*”

Comment #12:

Please remove “*environmental auditing*” from the sentence as audit results are subject to attorney-client privilege.

Response #12:

The “environmental auditing” language in Corrective Action Condition III. is standard language that is used in all Part I Permits and is included to ensure due diligence on the part of the Permittee with respect to prompt identification and reporting to the Department of new SWMUs, AOCs, and releases. Including “environmental auditing” allows the Department to evaluate compliance of the Permittee with the terms and conditions of the Permit, which is required under RSMo 260.395.12. Excluding the environmental audits from the Final Part I Permit could lead to the Permittee not reporting new SWMUs, AOCs, and releases identified by the environmental audit to the Department due to attorney-client privilege. In addition, the reference to “environmental auditing” is identical to the reference contained in the September 19, 1997, MHWMF Part I Permit previously issued to Mallinckrodt, to which no objection was expressed.

The final Part I Permit language will remain the same as the draft Part I Permit language.

CORRECTIVE ACTION CONDITIONS, III. Notification Requirements for, and Assessment of, Newly-Identified Releases from Previously-Identified SWMUs and AOC, page 23. Section B-1. “A discussion of the hazardous waste/chemical management practices related to the release(s);”

Comment #13:

Mallinckrodt suggests removing “/chemical management practices” from the sentence as this would appear to extending beyond the original intent of RCRA.

Response #13:

The above language in Section B of Corrective Action Condition III. in the draft Part I Permit is standard permit language used in all Part I Permits. Areas where chemicals (products) are released to the environment may become subject to corrective action requirements as an AOC, if appropriate.

The final Part I Permit language will remain the same as the draft Part I Permit language.

CORRECTIVE ACTION CONDITIONS, IV. Historical and Contingent Interim/Stabilization Measures, pages 25-26.

Comment #14:

Mallinckrodt recommends adding *Interim/Stabilization Measures (ISM)* to the Definitions section of the permit, and that the definition be focused to SWMUs and AOCs.

Response #14:

The “*Stabilization*” term in the Definitions section has been revised in response to the above comment. The final Part I Permit language has been changed to read,

“Interim Stabilization Measures means actions to control or abate threats to human health and/or the environment from releases at RCRA facilities and/or to prevent or

minimize the further spread of contamination while long-term remedies are pursued”

Comment #15:

Please add the following information in Section A, related to the work performed for SWMUs in the CT area.

“4. SWMUs 20, 39 and 42 are located within the footprint of the remedial excavations performed for the Columbian-Tantalum (CT) Decommissioning project. This resulted in the removal of affected soils in these areas.”

Response #15:

The final Part I Permit language has been changed to incorporate the language above.

Comment #16:

Section B indicates: *“Should the Permittee become aware of a situation that may require any additional ISMs that may be necessary to protect human health or the environment, the following conditions shall apply:”*

ISMs are potentially relevant in the context of SWMUs and AOCs. As such, Mallinckrodt suggest that the sentence be revised as follows: *“... aware of a situation with respect to identified SWMUs or AOCs that may require any additional ISMs...”*

Response #16:

The final Part I Permit language has been changed to incorporate the language above.

CORRECTIVE ACTION CONDITIONS, VII. Corrective Measures Study (CMS) Work Plan, page 33. Section C. “Within 45 calendar days of receipt of the Department’s request to conduct a CMS, the Permittee shall prepare and submit a CMS Work Plan to the Department and EPA for review and approval.”

Comment #17:

Mallinckrodt recommends the schedule be changed to 90 days. A 45 day schedule is usually not realistic when such a request can come several months/years after an RFI report is submitted.

Response #17:

The final Part I Permit language has been changed to read,

“C. *Within 90 calendar days after receipt of the Department’s request to conduct a CMS, the Permittee shall prepare and submit a CMS Work Plan to the Department and EPA for review and approval. The CMS Work Plan shall be consistent with the EPA document entitled, RCRA Corrective Action Plan (Final), OSWER Directive 9902.3-2A, May 1994, or the most recent version. At a minimum, the CMS Work Plan shall provide the following information and a proposed schedule for implementing the CMS Work Plan.*”

In addition, to the above revision, the corresponding Contingent Corrective Action Submittal Requirements on Table 2 of the final Part I Permit was also modified from 45 calendar days to 90 calendar days.

CORRECTIVE ACTION CONDITIONS, XII. Activity and Use Limitations (AULs), pages 37-38. A.1. Soil or Other Media Disturbance at the Facility. “The Permittee shall notify the Department at least 30 calendar days before any planned construction, excavation, or maintenance and repair activities that may disturb existing contamination at any SWMUs, AOCs, or other areas subject to AULs. The Permittee shall, in coordination with the owner(s) of any off-property areas impacted by soil and/or groundwater contamination originating from SWMUs and AOCs at the facility, assess the potential hazards associated with activities that potentially disturb or expose any contaminated environmental media and ensure that necessary precautions are taken, including protective and/or remedial measures, prior to performing the activity. In situations where advance notice is not feasible (i.e., emergency utility service or repair) notice shall occur as soon as practical. Future construction, excavation activities, or land use changes may necessitate further evaluation of conditions at SWMUs or AOCs having residual levels of contamination that exceed applicable regulatory thresholds.”

Comment #18:

Mallinckrodt has procedures in place to assess and mitigate potential hazards prior to conducting intrusive work in any area of the facility. This would appear to meet the intent of this permit condition. Mallinckrodt suggests the condition for prior notification be focused on the corrective action SWMUs and AOCs. As such, we recommend revising the first sentence as follows: “*The Permittee shall notify the Department at least 30 calendar days before any planned construction, excavation, or maintenance and repair activities that may disturb existing contamination at any corrective action SWMUs or AOCs requiring further action.*”

Response #18:

The first sentence of Corrective Action Condition XII.A.1. of the final Part I Permit language has been changed to read,

“The Permittee shall notify the Department at least 30 calendar days before any planned construction, excavation, or maintenance and repair activities that may disturb existing contamination at any SWMUs or AOCs subject to AULs.”

CORRECTIVE ACTION CONDITIONS, XII. Activity and Use Limitations (AULs), pages 39. C. Change in Use of Property. “The Permittee shall notify the Department at least 30 calendar days before any proposed change in the use of the facility property, of any applications for building permits for work on the facility property, or proposals for work potentially affecting the contamination on the facility property and/or compliance with the requirements of this Permit, in accordance with 40 CFR 270.30(h).”

Comment #19:

Mallinckrodt requests condition be focused on changes in the use of property that would be affected by residual contamination at a corrective action SWMU or AOC. Suggested revisions to the permit language are as follows: *“The Permittee shall notify the Department at least 30 calendar days before any proposed change in the use of the facility property, of any applications for building permits for work on the facility property, or proposals for work that could potentially be affected by contamination from a corrective action SWMU or AOC, in accordance with 40 CFR 270.30(h).”*

Response #19:

The final Part I Permit language has been changed to read,

“The Permittee shall notify the Department at least 30 calendar days before any proposed change in the use of the facility property, of any applications for building permits for work on the facility property, or proposals for work that could potentially be affected by contamination from a SWMU or AOC, in accordance with 40 CFR 270.30(h).”

CORRECTIVE ACTION CONDITIONS, XVI. Closure and Corrective Action Cost Estimates and Financial Assurance, B.9.a. Financial Assurance, Performance Failure, page 52.

Comment #20:

The last paragraph of this section says, *“The Department may issue a written notice (“Performance Failure Notice”) of the Permittee 's failure to perform to both the Permittee and the financial assurance provider. The notice shall specify the grounds upon which it was issued and shall provide the Permittee a period of ten calendar days to remedy the circumstances. ”*

Mallinckrodt believes ten days provides limited ability to remedy a situation, therefore is suggesting the condition specify ten days to develop and submit to the Department a plan to remedy the circumstances.

Response #20:

It has always been and will continue to be, the Department’s intention to work with the Facility and the financial assurance provider to resolve any corrective action activities performance failures as described Corrective Action Condition in XVI.B.9.a. before the Department would draw on the financial assurance to address such a situation. The above 10 calendar day language in Corrective Action Condition XVI.B.9.a. is standard language that is used in all Part I Permits. It is intended to provide the Facility and the financial assurance provider with formal notice before a draw on the financial assurance instrument(s) to address a failure to perform corrective action activities described by Corrective Action Condition in XVI.B.9.a. as required by the Part I Permit and applicable regulatory requirements as a last resort should it become necessary.

The final Part I Permit language will remain the same as the draft Part I Permit language.

FACILITY SUBMISSION SUMMARY, Page 61.

Comment #21:

Mallinckrodt recommends the ability to combine information required in the Quarterly and Semi-Annual and Corrective Action Progress Reports, for efficiency.

Response #21:

The “Quarterly Reports” and the “Semi-Annual Corrective Action Progress Reports” are submitted for different purposes and are sent to different Sections of the Hazardous Waste Program. The quarterly reports being referred to by Standard Permit Condition I. are the quarterly hazardous waste generator reports that are required to be submitted pursuant to the referenced regulations to document the generation/shipment of hazardous waste from the facility. The “Semi-Annual Corrective Action Progress Reports” being referred to by Corrective Action Condition XIII. are required to be submitted to summarize all permitted corrective action activities undertaken during the previous calendar half-year at the facility. The quarterly reports are submitted to the Hazardous Waste Program/Budget & Planning Section, while the Semi-Annual Progress Reports are submitted to the Hazardous Waste Program/Permits Section. Combining these divergent submittals into a single report could well lead to confusion as to whether the Permittee is complying with all of the submittals required by the Part I Permit and the applicable regulatory requirements.

The final Part I Permit language will remain the same as the draft Part I Permit language.