

June 29, 2005

Mr. Jim Grant
C -T Decommissioning Project Manager
Mallinckrodt Chemical, Inc.
Mallinckrodt & Second Streets
P.O. Box 5439
St. Louis, MO 63147

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR THE REVIEW OF THE
DRAFT C-T PHASE II DECOMMISSIONING PLAN (TAC. NO. L51568)

Dear Mr. Grant:

By letter dated May 14, 2003, Mallinckrodt, Inc. (Mallinckrodt) submitted an amendment request to the U.S. Nuclear Regulatory Commission (NRC) to amend Materials License No. STB-401, to authorize Phase II Columbium-Tantalum decommissioning for a proposed license termination. On July 29, 2003, you were notified that NRC staff had completed its acceptance review of your application and that it contained sufficient information for staff to perform a detailed technical review. On December 16, 2004, NRC staff members met with representatives of Mallinckrodt to discuss NRC's draft health physics and dose modeling comments on the Phase II Decommissioning Plan (DP) (Enclosure 1). NRC understands that Mallinckrodt is now addressing these comments and plans to submit its responses to NRC shortly.

In addition to the above NRC comments, the staff has determined that further information is needed to complete its technical review of the Phase II DP. The information requested is found in Enclosure 2. Additional information, requested by this letter, as well as your responses to the December 16, 2004, draft health physics and dose modeling comments, should be submitted in the form of revised pages of the Phase II DP. To help us schedule staff review time of your response, we request that you provide this information by August 1, 2005. If you are unable to provide a response by that date, you must notify us in writing, at least 2 weeks in advance, of both your new response submittal date and the reasons for the delay. The staff will then assess the impact of the new submittal date and notify you of a revised schedule.

Please reference Docket No. 40-6563 and TAC No. L51568, in future correspondence related to this licensing action. If you have any questions, please contact me at (301) 415-8580.

Sincerely,

/RA/

Amy M. Snyder, Senior Project Manager
Office of Nuclear Material Safety
and Safeguards
Division of Waste Management
and Environmental Protection

License No. STB-401
Docket No. 40-6563

Enclosures: 1. "Meeting Report for the December 16, 2004, Meeting with Mallinckrodt, Inc."
2. Request for Additional Information

cc: Mallinckrodt distribution list

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*See previous concurrence

OFFICE	DWMEP:PM	DWMEP	DWMEP:DD
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DATE	05/23/05	05/29/05	06/29/05

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REQUEST FOR ADDITIONAL INFORMATION
MATERIALS LICENSE NO. STB-401
MALLINCKRODT INC., DOCKET NO. 40-6563

By application, dated May 14, 2003, Mallinckrodt, Inc. (Mallinckrodt) submitted an amendment request to the U.S. Nuclear Regulatory Commission (NRC) to amend Materials License No. STB-401 to authorize the Phase II Columbium - Tantalum (C-T) decommissioning for the purpose of license termination. On December 16, 2004, NRC staff members met with representatives of Mallinckrodt to discuss NRC's draft health physics and dose modeling comments on the Phase II C-T Decommissioning Plan (DP). Mallinckrodt is now addressing these draft comments. This request identifies additional information needed by NRC staff to determine whether Mallinckrodt has demonstrated compliance with regulatory requirements. The requested information is organized by the following areas: (a) License Termination; (b) Planned Decommissioning Activities and Remediation; (c) Environmental Monitoring and Controls; (d) Radiation Safety for Workers; (e) Final Status Survey; (f) Waste Management; and (g) Organization. The staff used NUREG [NRC technical report designation]-1757, "Consolidated NMSS [Office of Nuclear Material Safety and Safeguards] Decommissioning Guidance," Volumes 1 and 2, to conduct its evaluation.

License Termination:

The following information is needed to assure compliance with Title 10 of the Code of Federal Regulations (10 CFR) 20.1401-1402:

1. It is unclear how Mallinckrodt will comply with 10 CFR 20.1402, regarding estimated dose to the average member of the critical group from residual radioactive material at the completion of decommissioning. Residual radioactivity is defined, in 10 CFR 20.1003, to include radioactivity from all licensed material and unlicensed sources used by the licensee, but excludes background radiation. For example, on page 1-2 of the DP, Mallinckrodt's decommissioning goal only includes licensed material. Furthermore, the non-licensed source material is not addressed in Chapter 5, "Dose Modeling," of the DP. Specifically, Mallinckrodt states, regarding delineation of responsibility, that ". . . Mallinckrodt intends that its responsibility for any remediation of C-T residue in those areas in question, aside from waste water basins, will be addressed in a separate license amendment request to remove that source material."

- A. Identify all contaminated areas on site, to include former burials and potential inaccessible contamination, so that NRC staff can determine how to proceed with its Environmental Assessment, under 10 CFR 51.21, 51.30, and 51.45:
1. Identify all areas (structures, systems, equipment, and matrices) of the Mallinckrodt site that are contaminated or potentially contaminated. Provide radiological and non-radiological characterization data. Identify potential remediation strategies and potential waste volumes for each medium/matrix, so that NRC staff can evaluate all potential impacts under the National Environmental Policy Act.
 2. Identify whether any offsite contamination (attributable to Mallinckrodt operations) was found and/or cleaned up on the properties adjacent to the Mallinckrodt site.
 3. Identify any contaminated utilities, such as sewerage lines, that extend beyond the site boundary or extend to the levee.
- B. Identify and reference, in the DP, the documents that define the United States Army Corps of Engineer's (USACE's) authority and cleanup scope of work at Mallinckrodt. Identify areas and environmental media that are still in question, regarding cleanup responsibilities between Mallinckrodt and USACE. [See page 8-1 of DP.]
- C. Identify, by site area, the schedule for the Formerly Utilized Sites Remedial Action Program (FUSRAP) cleanup and explain how it relates to the proposed Mallinckrodt Phase II decommissioning activities. Explain how Mallinckrodt will ensure that areas that have been cleaned will not be cross-contaminated from ongoing remediation activities.
- D. Identify all other activities that might impact the DP Phase II schedule. [See page 8-8 in the DP.] "NRC verification that residual radioactivity limits have been met will occur concurrently with other activities and not impact the length or the Phase II schedule."
- E. Update Figure 8-1, "Conceptual Decommissioning Schedule for Phase II."
- F. For license termination, explain how Mallinckrodt will include residual radioactivity concentration from the FUSRAP cleanup in its dose assessment.
- G. Explain why "Contaminated Structures are not in the scope of the C-T Phase II Decommissioning Plan (Phase II Plan)," when Mallinckrodt will be addressing building slabs and foundations.

Planned Decommissioning Activities and Remediation:

The following information is needed to ensure compliance with 10 CFR Part 20, Subpart E, requirements. NRC staff needs the following kinds of information to evaluate potential safety issues associated with remediation of subsurface material: (1) whether remediation activities and radiation control measures proposed by Mallinckrodt are appropriate for the type of radioactive material present; (2) whether Mallinckrodt's waste management practices are appropriate; and (3) whether Mallinckrodt's cost estimates are plausible, given the amount of contaminated material that will need to be remediated.

1. Explain how Mallinckrodt will determine whether below-grade systems are contaminated (surface vs. volumetrically) and how those systems will be remediated or removed if necessary. Provide an estimate of the volume of waste expected for all potential contaminated systems [see page 4-2 of the DP]: "Systems that are below grade are within the scope of the Phase II Plan. These systems include the utility systems used to support operations at the site. These utilities are water, electric, gas, sewer, and communications. The utilities, with the exception of the sewer, will be relocated or worked around as necessary to facilitate remediation of surrounding soils."
2. Explain how Mallinckrodt will verify that the soil under the sealed pavement is not contaminated at unacceptable levels. Mallinckrodt states, on page 8-3 of the DP, that floor slabs of process and support buildings that were removed during Phase I of decommissioning have been sealed.
3. Explain how Mallinckrodt will address the waste water neutralization basins, regarding remediation and verification of acceptable levels of subsurface contamination. On page 8-3 of the DP, Mallinckrodt proposes flexibility to leave the waste water neutralization basins in place. If Mallinckrodt decides to leave the waste water neutralization basins, explain how Mallinckrodt will verify that no volumetric contamination is present in these structures and that no subsurface contamination beneath these structures exists at unacceptable levels. Also, if decontamination of the basins is necessary, what derived concentration guideline levels (DCGLs) will be used? Explain how Mallinckrodt will verify that these porous concrete structures are not volumetrically contaminated. If volumetrically contaminated, explain how Mallinckrodt will proceed.
4. Identify all C-T target radionuclides and explain how they differ from other Manhattan Engineering District/Atomic Energy Commission material used on site and how they can be distinguished among each other in the field and in the laboratory.
5. Explain how Mallinckrodt will identify if sewerage must be remediated. Explain the potential remediation strategies and techniques that Mallinckrodt may use for this purpose. [See page 8-2 of the DP.] "During Phase II, Mallinckrodt will, as may be necessary, ... c) remediate sewerage."
6. Describe the criteria Mallinckrodt will use to determine when further remediation in an area is not necessary or when Mallinckrodt will know that it has been remediated, sufficiently.

7. Explain Mallinckrodt's strategy for addressing contamination that is found to be outside of the site boundary.
8. Identify the release limits referred to on page 8-2 and page 12-2 of the DP and what they apply to. It is unclear what Mallinckrodt is referring to: waste limits or survey unit DCGLs. [see page 8-2 of the DP]: "The Phase II Plan is based on the following preferences: . . . decontaminate or removal of selected contaminated areas or pavement and subsurface material to reduce the average mass concentration activities below release limits and therefore minimize the cost of disposal."
9. Explain when backfilling and compaction of excavated areas may occur in relationship to the final status survey. Explain how Mallinckrodt plans on addressing final status survey of the survey units that had subsurface contamination (subsurface soil).
10. Provide a statement of commitment, in the DP, that Mallinckrodt will provide NRC, on request, an updated schedule on a periodic basis that reflect progress and work completed. [See page 8-8 of the DP.]
11. Reference or list the procedures that will be used for Phase II decommissioning. Identify those not yet developed, by topic. For those that are not developed yet, make a commitment to have the procedures in place and personnel trained before the Phase 2 decommissioning will be conducted.
12. Explain the method that Mallinckrodt proposes to use for plugging drains. Explain when drain remediation will be conducted in relationship to soil, building slab, and building foundation remediation.
13. Describe when and how Mallinckrodt will determine the radioactivity concentration for excavated soil that it proposes to return to an excavation pit. [See page 8-6 of the DP.] Also, explain how this applies to the waste disposition strategy identified on page 12-4 of the DP. The strategies appear to be inconsistent with each other.

Environmental Monitoring and Controls:

The following information is needed to ensure compliance with 10 CFR 20.1101(b) and (d); 20.1301(a) and (d), 20.1301(a) and (b); 20.1501; 20.2001(a); 20.2003(a); 20.2003(b); 20.2107(a); 20.2202(a); and 20.2203(a). Also, the staff needs this information to assess whether Mallinckrodt's environmental monitoring program and control measures are commensurate with the risks associated with the proposed actions.

Provide or reference information that will allow NRC staff to fully evaluate Mallinckrodt's environmental monitoring and control program:

1. Identify the radiation controls Mallinckrodt plans to use for in-place debris size reduction, loading, and transportation to staging areas, to include in-place staging and activities at material management areas. [See page 12.3 of the DP.]

2. Identify the soil techniques that will be used to control excavation, loading, transport, and handling of contaminated soil. [See page 8-6 of the DP.]
3. During excavation, explain how Mallinckrodt will address any groundwater infiltration, accumulation of rain water, or surface runoff in the excavation. [See page 8-7 of the DP.]
4. Identify whether Mallinckrodt will monitor the groundwater during soil remediation and/or after soil remediation.
5. Describe the air sampling program that Mallinckrodt will use under routine conditions and under emergency conditions. Explain why gross activity measurements are sufficient and when analytical analyses would be required. [See page 11-3 of the DP.]

Radiation Safety for Workers:

The following information is needed to ensure compliance with 10 CFR 20.1204, 20.1501 (a)-(b), and 20.1703(a)(3), because Mallinckrodt may use respiratory protection.

Provide or reference information that will allow NRC staff to fully evaluate Mallinckrodt's air-sampling program:

1. Specify the respiratory protection practices and compliance requirements of NRC. [See page 10-2 of the DP.]
2. Describe the criteria to determine when respirators are required and when they will be issued. [See page 10-2 of the DP.]
3. Describe or reference the criteria that Environmental Safety and Health staff will use for selection of respirators. [See page 10-2 of the DP.]
4. Identify Mallinckrodt's plans to administratively control dose from air, using an administrative limit of one Derived Air Concentration (DAC). One DAC equates to an airborne radioactivity area. [See page 10-1 of the DP.]

Final Status Survey:

The following information is needed to ensure compliance with 10 CFR 20.1401-1402:

As part of the final status survey design, provide the following information: [See page 14-1 of the DP.]

1. Provide a description of how the samples, which will be analyzed in the laboratory, will be collected, controlled, and handled.
2. Describe Mallinckrodt's plans to conduct the final status survey for subsurface structures that have been remediated, to include sewerage.

3. Explain why Mallinckrodt will be performing a final status survey in each remediation area as opposed to each survey unit. [See page 8-4 of the DP.]
4. Clarify when analytical data would be used for compliance purposes. Explain why Mallinckrodt plans to only analyze the subsurface material. If there is no fixed ratio among the concentrations of radionuclides, it is necessary to evaluate the concentration of each radionuclide. If ratios have been established before the final status survey is implemented, then Mallinckrodt must verify that the ratios are still valid to use during the final status survey. [See page 14-4 of the DP.]
5. Explain how residual source material in an area of imported fill will be quantified. [See page 3-6 of the DP.] Identify if this fill will affect scanning and field-measurement instrumentation.
6. Provide, or make a commitment to provide, a summary of direct measurements or sample data used to both evaluate the success of remediation and to estimate the survey unit variance.
7. Provide, or make a commitment to provide, a summary of any significant additional residual radioactivity that was not accounted for during site characterization.
8. Provide a commitment to submit a Final Status Survey Report(s) that covers all survey units and includes all areas of the site that contain residual radioactive material.

Waste Management:

The following information is needed for NRC staff to fully understand the types, volumes, and activities of radioactive waste generated during decommissioning operations and the manner in which Mallinckrodt intends to manage and dispose of such wastes. Evaluation criteria: Part 20, Subpart K, 10 CFR 61.55, 10 CFR 61.56, 10 CFR 61.57, and 10 CFR 71.5.

1. Reference the Radioactive Waste Management Plan. [See page 12-1 of the DP.]
2. Provide a waste estimate for all subsurface materials identified. [See page 12-1 of the DP.]
3. Explain why Mallinckrodt does not plan on assessing the radiological status of the loose material generated during excavation. [See page 12-1 of the DP.]
4. Define non-impacted material. How does it differ from soils and materials less than the DCGLs for soil? How will Mallinckrodt make this determination? Will a statistical survey plan be developed and implemented? If it is determined that soil DCGLs do not apply to all materials, then the definitions presented in the DP may have to be modified.
5. Identify whether 10 CFR 40.13 will be used as the decommissioning criteria. [See page 12-4 of the DP.]

Organization:

The following information is needed for NRC staff to verify that Mallinckrodt has a management organization and the personnel resources to ensure that the decommissioning of the facility can be completed safely and in accordance with NRC requirements. Acceptance criteria [10 CFR 30.36(g)(4)(ii); 10 CFR 40.42(g)(4)(ii); 10 CFR 30.33(3); and 10 CFR 40.32(b)]

1. Provide clarification of Mallinckrodt's decommissioning organization. Descriptions on page 9-2 and Figure 9-1 are not consistent. Furthermore, there is no "SSRO" on the organization chart in the description section. [See page 9-4 of the DP.]
2. Reference and describe the "Administrative Control Plan." How does it differ from the DP? Mallinckrodt states that activities will be implemented under this DP and the Administrative Control Plan. [See page 9-4 of the DP].
3. Explain what equivalent means with respect to qualifications. Equivalent qualifications are not defined by NRC. [See page 9-5.]
4. As defined in the DP, the qualifications of the Radiation Safety Officer (RSO) do not meet the qualifications in NUREG - 1757. [See page 9-5 of the DP.] NUREG - 1757 states that the radiation safety officer (RSO) must be qualified by training and experience for the types and quantities of radionuclides that will be encountered during decommissioning operations, as well as the operations that will be undertaken to decommission the facility. In addition, the RSO must be authorized to implement the radiation protection program.
5. Identify Mallinckrodt's methodology to issue, modify (after appropriate review and approval), and terminate, plans, procedures, and work permits, as well as programs for ensuring that individuals performing the tasks are informed and trained in the procedures.
6. Provide a description of the management interfaces that will be in place between Mallinckrodt's management and onsite supervisors, and contractor management and onsite supervisors.
7. Provide a description of the oversight responsibilities and authority Mallinckrodt will exercise over contractor personnel.
8. Provide a description of the training that will be provided to contractor personnel by Mallinckrodt. Provide a description of the training that will be provided by the contractor.
9. Provide a commitment that the contractor will comply with all radiation safety and license requirements at the facility.

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