

August 27, 2014

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

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION ON THE FINAL STATUS
SURVEY REPORTS FOR THE PHASE II DECOMMISSIONING PLAN.
MALLINCKRODT COLUMBIUM-TANTALUM PLANT, SOURCE MATERIAL
LICENSE STB-401

Dear Ms. Burke:

The U.S. Nuclear Regulatory Commission (NRC) staff has completed its technical review of all Final Status Survey Reports for the Mallinckrodt Columbiu-m-Tantalum Plant, Phase II Decommissioning Plan [Agencywide Document Access and Management System (ADAMS) Accession Number ML14177A180].

Based on the review of the Final Status Survey Report Chapters 1 through 33, the NRC staff has identified technical deficiencies that require the submittal of additional information. The request for additional information (RAI) is provided in Enclosure 1 of this letter. Please note that the NRC requests that the licensee provide written responses to the RAIs by September 30, 2014.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of the NRC's ADAMS. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

K. Burke

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If you have comments or questions regarding this letter, please contact the project manager, Yolande Norman at 301-415-7741 or via email at Yolande.norman@nrc.gov.

Sincerely,

/RA/

Lydia W. Chang, Branch Chief
Special Projects Branch
Decommissioning and Uranium Recovery
License Directorate
Division of Waste Management
and Environmental Protection
Office of Federal and State Materials
and Environmental Management Programs

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

Enclosure:
Request for Additional Information

cc: Mallinckrodt Distribution List

K. Burke

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If you have comments or questions regarding this letter, please contact the project manager, Yolande Norman at 301-415-7741 or via email at Yolande.norman@nrc.gov.

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**U.S. Nuclear Regulatory Commission
Request for Additional Information on the Reports Entitled
“Phase II Final Status Survey Report, Chapters 1 through 33,
Mallinckrodt Columbian-Tantalum Plant, St Louis, Missouri”
Source Materials License No. STB-40-1475, Docket No. 40-6563**

General Comments

- 1) **Comment:** In several survey units (e.g. SU1, SU2, SU4, SU5, SU6, SU10), Mallinckrodt was unable to remove all contaminated soil due to the close proximity to structural foundations. Demonstrate that any residual contamination beneath these structural foundations will meet the U.S. Nuclear Regulatory Commission’s (NRC) unrestricted release criteria stated in Title 10, Code of Federal Regulations (CFR), Part 20, Subpart E, 20.1402.
- 2) **Comment:** The dose assessment performed for SU22 is not adequately supported and may underestimate the potential dose from the residual contamination in this survey unit.
 - a) In Chapter 28, Section 28.5.3.1 states that the Residual Radioactivity models (RESRAD) used to calculate this dose were identical to those used to develop the derived concentration guideline level (DCGLs). However, the DCGLs were based on probabilistic RESRAD calculations, while the dose assessment for SU22 was a deterministic calculation. Justification is needed for the use of the deterministic model and its associated parameters or a dose assessment that is identical to the one performed for the DCGLs should be provided.
 - b) The dose assessment for SU22 only includes the dose from the survey unit average and Elevated Area (EA) #3. The dose from the other elevated areas in this survey unit should also be included in this dose assessment.
 - c) Mallinckrodt should provide justification for the area and thickness of the elevated areas identified in SU22 (1a, 1b, 2, and 3).
 - i. For EA#1, Figure 28-12 shows locations of samples and the delineated elevated area. However, samples 0333 and 0337 both have significantly elevated concentrations [sum of fractions (SOF) 22 and 7, respectively] but the delineated elevated area does not encompass these samples. Data from the samples 0333 and 0337 have not been included in estimating the Index values in Section 28.3.1.1. Thus, there does not appear to be clear rationale for the delineation of EA#1A and EA#1B as shown and the area of contamination.
 - ii. For EA#2 and EA#3, Figure 28-11 shows the delineated elevated areas, but does not show the sampling and boring locations that were used to justify the delineation. It also appears that there were not biased borings inside building 240 along the side

Enclosure

of the building. Thus, there does not appear to be clear justification for the delineation of EA#2 and EA#3 and the area of contamination.

- iii. Section 28.3.1 includes description of the size of the elevated areas, but the bases for the sizes are not provided. In particular, basis for determining that contamination does not extend laterally beyond the delineated areas has not been provided.
 - iv. Regarding the thickness of the contamination, the dose modeling in Section 28.5 indicates a thickness of 0.3 m, based on Section 28.5.2.1. However, Section 28.5.2.1 simply states that contamination was limited to approximately the top 1 ft of soil under the building foundation. This statement is not supported.
 - d) Mallinckrodt should provide justification that radionuclide concentrations used in the dose modeling for the elevated areas are representative or conservative. It appears the current concentrations used are based on a very small number of samples.
 - e) The total time in the trench assumed for the excavation scenario (0.5 hours per year) is not justified. If the worker were to spend more time in the trench, the dose would be higher than the dose that was calculated. The dose from the excavation scenario may be bounded by the dose from the *in situ* model since the worker in the *in situ* model spends more time on site. Either provide justification for the time assumed in the excavation scenario or provide a justification for how the dose from the excavation scenario is bounded by the dose from the *in situ* model.
- 3) **Comment:** In Chapter 28, Section 28.2.1 (page 8), states that the gamma walk-over survey (GWS) was not performed inside buildings 240 and 250. A GWS is expected for Class 1 survey units. SU22 is a Class 1 survey and thus should have received a 100% scan survey. Mallinckrodt did not provide justification for not performing the survey. Perform the gamma walk-over survey of 100% of the survey unit or provide justification for how the final status survey is sufficient without the GWS.
- 4) **Comment:** Please provide an update on the status of the Delineation Agreement between Mallinckrodt and the U.S. Army Corp of Engineers (USACE) to address that contamination located in Plant 7. Plant 7 contains two aboveground concrete wastewater neutralization basins which were used during Columbium –Tantalum (C-T) operations. Although USACE acknowledges that soil contamination in Plant 7 will be cleaned up under the Formerly Utilized Remedial Action Program (FUSRAP) and, Mallinckrodt has surveyed the basins and found them to be clean, the Delineation Agreement remains an outstanding issue.

Please note that the NRC's approval letter for the Phase II Decommissioning Plan (ADAMs Accession No. ML091960087) states, "It should be noted that NRC will not terminate Mallinckrodt's license until decommissioning in Plant 7 is complete consistent with a delineation agreement".

Specific Comments

- 1) **Comment:** Chapter 1, Section 1.4 states that Mallinckrodt extracted columbium and tantalum compounds under NRC License No. STB-401 from 1961 to 1989. Please note that the NRC was not established until 1974, the license was likely initially issued by the Atomic Energy Commission.

Technical Basis: N/A

Path Forward: Suggest providing accurate “licensing” information prior to 1974.

- 2) **Comment:** Tables 4-1 and 4-2 seem to contradict each other. The reason for the contradiction results from an inadequate definition of the terms Investigation Level and Action Level. Table 4.1 states that the Investigation Level for all survey units (SUs) is a SOF greater than 0.5. In table 4-2, the Action Level is stated as above a SOF of 1 for Class 1 and Class 2 SUs and greater than 0.5 for Class 3 SUs.

Technical Basis: Although NUREG-1575, Revision 1, Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) dated August 2000, to a certain extent, interchange the two terms of Investigation Level and Action Level. Section 2.2 of MARSSIM provides a specific definition for Investigation Level as “...a radionuclide-specific level based on the release criterion that, if exceeded, triggers some response such as investigation or remediation” (ADAMS Accession No. ML111730514). This definition infers a quantitative result from, for example, a sample analytical result. The Action Level term is generally used to indicate a qualitative result such as an elevated gamma radiation count rate that results in collecting a judgmental sample. Therefore, although conservative, it is unclear why a SOF >0.5 would be selected as the Investigation Level for Class 1 and 2 survey units as stated in Table 4-1. Typically, the respective Investigation Levels would be greater than the derived concentration guideline level used for the elevated measurement comparison ($>DCGL_{EMC}$) in a Class 1 survey unit and greater than the derived concentration guideline level used for the statistical test ($>DCGL_W$) in a Class 2 survey unit. For Class 3, the Investigation Level would be some fraction of the $DCGL_W$ agreed upon with the regulator, such as the 0.5 provided in the table. Relative to Table 4-2, the document states that the Table 4-2 Action Levels were established “...to cause further evaluation of locations identified by scans or stationary measurements...” This agrees with the expected definition as stated earlier in this technical basis. However, the reported Action Levels are indicated as a function of the SOF rather than what is typically a function of scan minimum detectable concentration (MDC) relative to the $DCGL_W$. The SOF reported is indicative of quantitative results.

Path Forward: Define the terminology in the document and modify Tables 4-1 and 4-2 as applicable.

- 3) **Comment:** Chapter 4, Section 4.1.3 indicates the impacted media were of two types: surface slab material or soil and bulk materials. What specifically is meant by bulk materials?

Technical Basis: If bulk material includes items that are other than soil-like media the application of the soil DCGLs is not likely appropriate.

Path Forward: Please define what is meant by bulk materials. Additionally, if these items were not soil-like media, include information on how they were assessed to ensure they meet the DCGLs.

- 4) **Comment:** Chapter 4, Section 4.1.4, Step 4 of the data quality objectives (DQO) process, Define the Study Boundaries, states the sewer spatial boundaries included "...the **internal surfaces** of the impacted sewer lines remaining in use downstream of Building 238..." However, Chapter 29, which addresses the sewerage, does not present any static measurement data. Only sediment samples were statistically assessed. Furthermore, Section 4.4 also indicates scans were performed on the sewer survey units SUs although it is also not presented in Chapter 29. If these data were collected, were the data qualitative or quantitative?

Technical Basis: All applicable data required and utilized to assess a SU for release should be included as part of the final status survey (FSS) data release package.

Path Forward: Please update applicable sections to accurately describe the data requirements for the sewerage SUs and present all data collected and utilized in release decisions in Chapter 29. Additionally, see comment 9 below for additional concerns associated with the sewerage.

- 5) **Comment:** Chapter 4, Section 4.6.1 states that samples were sieved and the plus material was removed. The section also states the material was "...analyzed separately to verify residual radioactivity was consistent with sample results," then seems to immediately contradict saying "...it was radiologically screened to ensure significant levels of radioactivity, if present, were investigated." The section further states that none [significant levels] were present. This does not seem likely, regardless of whether the slag was part of the C-T process or not in comparison to the ORAU/ORISE findings. Also, if the plus material was analyzed separately via gamma spectroscopy analysis, then the results should be presented in the applicable SU chapters.

Technical Basis: The Oak Ridge Associated Universities\Oak Ridge Institute of Science and Education (ORAU/ORISE) confirmatory survey report entitled, "Final Report - Independent Confirmatory Survey Results for Survey Units 1 and 3 Within the Plant 5 Footprint at the Mallinckrodt Inc. Site, St. Louis, Missouri dated September 1, 2011" (ADAMS Accession No. ML112640373), identified significant contamination associated with the plus material. The confirmatory samples were sieved and both portions were analyzed via gamma spectroscopy.

Path Forward: Provide data supporting the conclusion that the plus material was not in excess of the guidelines.

- 6) **Comment:** Chapter 4, Section 5.5.1.1 states that "...no screening or sifting of material was performed in the field." This statement is made in other Chapters as well.

Technical Basis: The ORAU\ORISE confirmatory survey team observed sifting of samples during sample collection in the field during the May 2011 site visit (ADAMS Accession No. ML112640373). The plus material was discarded back into the SU.

Path Forward: If procedures were updated following the confirmatory site visit, please accurately indicate the sequence of events. Additionally, see Specific Comment No. 8. Were all the samples from these SUs recollected following the ORAU May 2011 site visit using a revised procedure?

- 7) **Comment:** Detector efficiencies should be included in Chapter 5 along with a more detailed discussion of calibration procedures. It is not clear how survey instrumentation was calibrated. For example, was instrumentation calibrated in accordance with ISO-7503 methods?

Technical Basis: Section 6.5.4 of MARSSIM discusses instrument efficiencies. NUREG-1507 entitled "Minimum Detectable Concentration with Typical Radiation Survey Instruments for Various Contaminants and Field Condition, August 1995" (ADAMS Accession No. ML003676046) also provides information on source efficiencies for surface materials.

Path Forward: Instrument efficiencies could be added to Table 5-1. Expand Section 5.4 of Chapter 5 to better discuss calibration methods and procedures.

- 8) **Comment:** Chapter 5, Section 5.4.2 provides typical MDCs for various survey instrumentation. The conclusion section of each SU chapter simply states "...the instruments used to collect the data were capable of detecting the radiation type at or below the release criteria."

Technical Basis: MARSSIM recommends that when feasible, survey instrumentation should be capable of detection limits that are 50% of the DCGL.

Path Forward: Demonstrate that, at a minimum, SU-specific MDCs were below 50% of the DCGL for Class 2 and 3 SUs and below the DCGL_{EMC} in Class 1 SUs.

- 9) **Comment:** Chapter 5, Section 5.8 – Two confirmatory survey trips were made; one in May 2011 and the other in June 2011 (ADAMS Accession No. ML112640373). When were FSS samples collected relative to confirmatory surveys? During the initial site visit, FSS activities were being completed in SUs 1 and 3. It was apparent that remediation was performed on those SUs in between the two site visits.

Technical Basis: At the time of the first confirmatory survey in May 2011, the licensee was completing FSS and collecting FSS samples. During the first site visit ORAU\ORISE identified several areas in excess of the DCGL.

Path Forward: Confirm and clarify that the FSS samples presented in the FSSR are representative of the final survey unit conditions.

- 10) **Comment:** Chapter 6: Underestimation of surface activity is a concern when using such a large area detector (821cm^2) for measurements. This is indicated as footers to Tables 6-1 and 6-2 where the potential “worst-case” values were presented if in fact all contamination would have been concentrated in a 100 cm^2 area of the detector. Since this is a valid concern, why were the higher values not used in the retrospective data analysis for the SU (Tables 6-5 and 6-6)?

Technical Basis: Underestimation of surface activity can result when using large area detectors with an active area greater than 100 cm^2 .

Path Forward: Provide justification for using the lower, non-conservative values in the data assessment.

- 11) **Comment:** Chapter 7, Section 7.2.2 states that, “The on-site laboratory, by design, reported conservative sample results.” However, the Th-232 on-site results are not conservative in Table 7-1. Additionally, Section 5.6.3.1 states that the on-site laboratory consistently under-reported the concentration of Th-232 and as a result added 0.051 to the Th-232 >DCGL_w fraction.

Technical Basis: N/A

Path Forward: Update appropriate chapters/sections as necessary to reflect the on-site lab did not produce conservative sample results for Th-232.

- 12) **Comment:** Chapter 7, Section 7.2.2 Soil Sampling, Figure 7-4 and Table 7-2 present data for the gamma walkover surveys (GWS) biased samples. As clearly evident in Figure 7-4, these four locations exhibited the highest GWS count rates although the sample results did not reflect the expected elevated concentrations.

Technical Basis: N/A

Path Forward: Perhaps the responses to previous Comments 7 and 8 (i.e., timing and change in sampling procedure) will address this comment. This could also be an issue with AECOM Technical Services (AECOM) surveyors not listening to the audible response during bias soil sample collection. If simply given a coordinate after post-processing of the GWS data, the most elevated location may not have been sampled.

- 13) **Comment:** Chapter 7, Section 7.3.2.4 elevated measurement comparison (EMC) Limit, 20 m^2 was used in the EMC screening test result calculation when they stated the elevated area was 21 m^2 .

Technical Basis: N/A

Path Forward: Update the calculation using the correct area.

- 14) **Comment:** Table 12-5 presents the EMC Limit Test Value = 0.25; however, section 12.4.2.4 presents the value = 0.33.

Technical Basis: N/A

Path Forward: Update the table to reflect the accurate value and ensure this error did not affect anything else.

- 15) **Comment:** Table 12-9 states that the receptor is expected to remain in the trench for 1 hour each modeled year. How was this time selected?

Technical Basis: Justification for receptor inputs should be presented so that reviewers can assess the level of conservatism used—the target is prudently conservative.

Path Forward: Provide the basis for the outdoor time fraction of 0.00011 hours found in Table 12-9 RESRAD Excavation Scenario Model Parameter Values.

- 16) **Comment:** Chapter 16, Section 16.2.1, states that 100% of the excavation was not surveyed due to standing water. Section 16.2.1 states, “This area was excavated to the clay layer and was surveyed as much as possible with no elevated readings noted by the surveyor.” It is unclear what this previous statement means.

Technical Basis: Per MARSSIM, Class 1 survey units are to receive 100% scan coverage.

Path Forward: Provide justification for not removing water in order to scan, or sampling soil under water.

- 17) **Comment:** Sample 0624 from Chapter 17 was not sent to the off-site laboratory. What is the threshold for not sending elevated samples to the off-site laboratory? Nothing was mentioned regarding not sending Sample 0624 to the off-site lab for analysis.

Technical Basis: Chapter 4, Section 4.6.2 states that exceptions were noted when not sending samples to the off-site lab for analysis.

Path Forward: Provide the criteria or threshold for not sending elevated samples to the off-site laboratory for analysis. Sample 0624 from S07 in Table 17-1, Gamma Spectroscopy Systematic Sample Analytical Results, shows elevated results from the on-site laboratory but notes that the sample was not sent to the off-site laboratory, presumably due to the elevated on-site results.

- 18) **Comment:** The header of Chapter 18 is labeled as Chapter 26. The text appears to all be related to Chapter 18.

Technical Basis: N/A

Path Forward: Revise heading as necessary.

- 19) **Comment:** Figure 18-14 in Chapter 18 is hand-drawn.

Technical Basis: N/A

Path Forward: Suggest revising with a computer generated figure or provide explanation for figure being hand-drawn.

- 20) **Comment:** Bias samples were not collected as a result of gamma survey #0326 in SU 19 (Chapter 25). Instrument response for survey #0326 were similar to the bottom of the excavation where bias samples were collected. The justification provided in the text that these results were due to geometry, however this cannot be verified because scan results of soils next to the excavation wall are not shown on Figure 25-3.

Technical Basis: Bias samples should be collected at areas where instrument response shows the potential to exceed the DCGL.

Path Forward: Provide a comparison of these survey results (#0326) with background and explain any impact the 50–70k counts per minute (cpm) readings may have on the survey unit. Assuming the gamma walkover surveys were performed with a NaI detector, background should have been on the order of 10k cpm. Please address readings that appear to be 5–7 times background.

- 21) **Comment:** Chapter 29 presents the FSS results for the C-T plant sewage lines, which were classified as a Class 3 SU. As shown in Figure 29-1 and Table 29-1, four characterization samples were above the SOF DCGL. Based on the characterization data, the sewer SU should have been a Class 1, understanding that portions of the sewer above the DCGL were remediated during cleanup of other SUs.

Technical Basis: Per MARSSIM, Class 1 SUs are areas where residual activity above the DCGL can be expected, as demonstrated in sediment samples collected during characterization.

Path Forward: Provide rationale as to why the sewer system was surveyed as a Class 3.

- 22) **Comment:** Throughout the various chapters, post-remediation samples referred to as “At-Depth (Auger) Sampling” were collected. What is meant by at-depth?

Technical Basis: N/A

Path Forward: Provide more information on how the samples were collected and the depth interval at which the sample submitted for analysis was selected.

- 23) **Comment:** Several areas of the final status survey report (FSSR) relating to laboratory analysis and procedures are vague. It is unclear as to why there was such a difference between the on-site and off-site laboratory results for individual radionuclides. Perhaps this difference was explained in Appendix G of the AECOM Preliminary FSSR for Plant 5 Subsurface Survey Units. However, it seems important that these differences be discussed in the FSSR, especially the rationale for adding 0.051 to the Th-232 DCGL fraction. It is also unclear which photopeaks were used to quantify individual radionuclides.

Technical Basis: The report should contain enough information so the reader can understand the complete process and be able to independently assess the work.

Path Forward: Provide further, more detailed, explanation on why the on-site laboratory reported SOF results were about 45% higher relative to the off-site laboratory results as stated in chapter 5.6.3.2, the rationale for addition of 0.051 to the Th-232 DCGL fraction, and the photopeaks used to quantify individual radionuclides.

- 24) **Comment:** It is unclear from the FSSR how the EMC limit is applied. The EMC limit screening, as calculated in Equation 14-7 in the Phase II DP, compares the residual dose from the SU to the release criterion. However, it is unclear why the contamination area is, essentially, accounted for twice in the calculation (i.e., once in the area factor and once by weighting each term in Equation 14-7 by the respective area).

Technical Basis: Equation 8-2 in MARSSIM provides the inputs to ensure SU meets the release criteria when hot spots are present.

Path Forward: Provide an explanation as to why Equation 14-7 in the Phase II DP is more applicable than Equation 8-2 in MARSSIM. This explanation would probably fit best in the early chapters (4 or 5) and would not need to be added to each chapter.

Additionally, ORAU/ORISE determined that when using Equation 8-2, the SOF value exceeds one for several SUs. If justification cannot be provided for using Equation 14-7, some sort of added dose assessment will be necessary to ensure the average for those survey units do not exceed 25 mrem/yr.

- 25) **Comment:** How were the contractors for laboratory analysis selected?

Technical Basis: NUREG-1575, Revision 1 (MARSSIM) discusses criteria for selecting radioanalytical laboratories in Section 7.4.

Path Forward: Provide for the inclusion of inter- and intralaboratory performance analyses as part of the laboratory quality control (QC) checks under the measurement quality objectives of Chapter 4, Section 4.1.8. Please ensure that all quality assurance QA program objectives listed in Section 7.4 of MARSSIM are addressed.

- 26) **Comment:** Per Section 14.4.3.8 of the decommissioning plan (DP), screening software will be used to perform the data analysis. However, as stated in the FSSR, a spreadsheet was used in lieu of the analysis software. This could potentially lead to QC issues. For example, the software could be developed, reviewed, and approved—thereby assuring that all subsequent calculations are correct. How were the spreadsheets controlled so that data quality objectives were met?

Technical Basis: This is needed to assess the validity of the use of the spreadsheet and hand calculations in lieu of the screening software required in the DP.

Path Forward: Provide an example of an Excel spreadsheet and hand calculations for a survey unit data set used in lieu of the screening software required in the C-T Phase II DP.

