

## **Responses to NRC 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 has addressed the request for additional information related to that meeting in a response previously sent to the NRC dated August 1, 2005. This response addresses additional information requested by NRC staff to determine whether Mallinckrodt has demonstrated compliance with regulatory requirements. The additional requested information is organized by the following areas: License Termination, Planned Decommissioning Activities and Remediation, Environmental Monitoring and Controls, Radiation Safety for Workers, Final Status Survey, Waste Management, and 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) Parts 20.1401-1404:

50. It is unclear how Mallinckrodt will comply with 10 CFR Part 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 Part 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, the 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. Additionally, it appears that the DP does not address all licensed material, as noted by the Mallinckrodt's comments on page 1-2 of the DP. Specifically, Mallinckrodt states regarding delineation of responsibility that "... Mallinckrodt intends that its responsibility for any C-T residue remediation in those areas in question, aside from waste water basins, will be addressed in a separate license amendment request to remove that source material."

#### Response:

Residue from C-T processing constitutes the remnant NRC-licensed material on-site. Other radioactive material on-site is subject to remediation under the Formerly-Utilized Site Remedial Action Program (FUSRAP). Whenever agreement on delineation to distinguish responsibility in site areas in Plant 6 and in Plant 7 is accomplished,

Mallinckrodt intends to provide supplemental information about those areas and describe how it will remove that material for which it is responsible.

Interest is expressed in how radiological dose to an average member of the critical group will be demonstrated to comply with the 25 mrem/yr standard on the site, including MED-AEC and C-T areas after both are decommissioned. The response to item 56 hereafter explains how radiological dose to an average member of the critical group will be considered on a site-wide basis. It shows that dose to a member of the critical group who may be present on both areas will experience no more than 25 mrem/yr provided compliance is demonstrated separately for each area. As a result, the following items propose to rely on USACE documentation to identify MED-AEC areas subject to the FUSRAP and to characterize their condition.

NRC RAI set 1, item 4 inquired whether dose from pavement and dose from soil beneath it in Plant 5 would be independent. Resolution of that allocation issue is described and provided in response to that item 4.

51. 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 Parts 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 media/matrix so that NRC staff can evaluate all potential impacts under the National Environmental Policy Act (NEPA).
  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.

Response:

It was Mallinckrodt's intention that the DP would answer most of the questions noted in the DP. These topics are essentially covered in sections 4 and 8 of the draft DP. Table 51 below summarizes and cross references some of this information. Mallinckrodt does not anticipate generating any mixed-waste.

Location of the URO burials can be found in Figure 2-5 in the draft DP.

Mallinckrodt does not believe there are any inaccessible areas. Figure 2-5 shows that Burial site 10 is located under the floor of an existing warehouse, but this burial will be remediated along with the other burials. Figure 4-17 indicates contamination adjacent to Building 240, but Mallinckrodt believes this is due to a sewer located in this area and that contaminated soil will be accessible.

**Table 51. Potentially Contaminated C-T Areas**

Item	Location	Reference to Decommission Plan	Remediation Strategy	Waste Volume Estimate (ft <sup>3</sup> )
Plant 5 pavement	DP Fig. 14-1A	CT 2 DP §4.8.3	Decontamination or removal and disposal off-site.	4100.
Plant 5 building slabs		CT 2 DP §4.8.3	Decontamination or removal and disposal off-site.	13000.
Plant 5 soil and subsurface material	DP Figs. 4-17,18,19	CT 2 DP §4.8.4	Excavation and disposal off-site.	42000.
Sewerage from Plant 5 to wastewater basins	DP Fig. 4-1	CT 2 DP §4.8.2	Expected to meet release criteria. Else, removal and disposal of sediment or removal of sewerage and disposal of debris.	0
Wastewater lift station	DP Fig. 4-5	CT 2 DP §4	Expected to meet release criteria. Else, decontamination, with waste disposal off-site	0
Wastewater Neutralization Basins in Plant 7W	DP Fig. 4-5	CT 2 DP §4	Expected to meet release criteria. Else, decontamination, with waste disposal off-site	0
URO buried in Plant 6W	DP Fig. 2-5	CT 2 DP §2.6	Excavation and disposal off-site	81500

Section 2.4.2 of the DP discusses the MED/AEC operations that occurred at the site during the 1940s and 1950s, and the FUSRAP remediation being implemented at the site by U. S. Army Corps of Engineers (USACE). There was significant MED/AEC processing in much of the plant outside of Plant 5 as shown in DP Figure 2-3. Significant remediation has been done in Plants 1, 2 and 10. USACE is now remediating Plants 6 and 7.

The USACE has done a comprehensive survey of vicinity properties and is doing characterization and remediation as required. Additional information is provided in response to item 64 herein.

Sections 8.4.1 and 8.4.6 discuss sewerage related to the MED/AEC operations, and Section 8.4.1 mentions the sewer line that passed through the Plant 6/7 area.

52. B. Identify and reference, in the DP, the document(s) that defines the United States Army Corps of Engineer's (USACE's) authority and clean-up scope of work at Mallinckrodt. Identify areas and environmental media that are still in question regarding clean-up responsibilities between Mallinckrodt and USACE. [See page 8-1 of DP.]

Response:

The following are documents that define USACE's authority and clean-up scope of work ( Refer to DP Section 2.4.2 for further discussion of these issues):

- The USACE is administering and executing cleanup at FUSRAP sites pursuant to a March 1999, Memorandum of Understanding with the Department of Energy and the provisions of the Energy and Water Development Appropriations Acts for Fiscal Years 1998-2001 (Public Laws 105-62, 105-245, 106-377, respectively). Section 611 of Pub. L. 106-60 requires the USACE to remediate FUSRAP sites, in accordance with, and subject to the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), 42 U.S.C. 9601 et seq., and the National Oil and Hazardous Substance Pollution Contingency Plan (NCP), Chapter 1, Part 300.
- USEPA Region VII. Federal Facility Agreement in the matter of the United States Department of Energy's FUSRAP Sites, St. Louis and Hazelwood, Missouri. Docket VII-90-F-0005. June 26, 1990
- U.S. Army Corps of Engineers, Record of Decision for the St. Louis Downtown Site, St. Louis, Missouri, July 1998.

The CERCLA process provides for a Record of Decision (ROD) of the selected remedial action for cleanup of the wastes related to the Manhattan Engineering District/Atomic Energy Commission (MED/AEC) on the Mallinckrodt Chemical Works Site and Vicinity Properties. A Record of Decision was agreed to by the USACE and the USEPA and was concurred to by the Missouri Department of Natural Resources (MDNR).<sup>1</sup>

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<sup>1</sup> USACE and USEPA. Declaration for the Record of Decision, August 1998, in U.S. Army Corps of Engineers, Record of Decision for the St. Louis Downtown Site, St. Louis, Missouri, July 1998.

This ROD applies to cleanup of MED/AEC wastes in accessible soils by excavation and off-site disposal, for monitoring ground water in the Mississippi River alluvial aquifer, and for periodic reviews to evaluate need for ground water remediation at the St. Louis Downtown Site.

Areas and environmental media for which responsibility for remediation remains completely unresolved between the USACE and Mallinckrodt are:

- Soils in Plants 6W, 7W, 7N, and 7S.

53. C. Identify, by site area, the schedule for the Formerly Utilized Sites Remedial Action Program (FUSRAP) clean-up 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 due to ongoing remediation activities.

Response:

Current early finish dates for the FUSRAP clean-up published by USACE on their web site are:

Area	Cleanup Schedule	Relation to C-T Phase II
Plant 1	Complete	None
Plant 2	Complete	None
Plant 6W <sup>C</sup>	July 30, 2010	C-T URO <sup>E</sup> is buried in Plant 6W
Plant 6E <sup>D</sup>	August 18, 2005	None
Plant 7N/S/E	July 17, 2007	None
Plant 7W	November 6, 2006	Equalization basins are located in Plant 7W
Plants 3,8,9,11	February 12 <sup>th</sup> 2007	None
Plant 10 <sup>A</sup>	Building removed; soil excavated and disposed offsite.	None
Building K1E	Complete.	None
Building 25	future CERCLA action	None
Building 101	future CERCLA action	None
Inaccessible soil <sup>B</sup>	future CERCLA action	None
Vicinity Properties and Roads	March 7, 2008	None

<sup>A</sup> former Plant 4

<sup>B</sup> Inaccessible soil is under portions of buildings in Plants 1, 6, & 7, and portions of the railroads

<sup>C</sup> Plant 6W includes Plant areas 6a & 6b listed in the USACE ROD

<sup>D</sup> Plant 6E is listed as Plant 6c in the USACE ROD

<sup>E</sup> URO = unreacted ore, or ore that did not dissolve in process.

The USACE has covered with pavement, gravel and or clean soil, every area it has remediated. Mallinckrodt will ensure that areas that have been cleaned will not be cross-contaminated due to ongoing remediation activities by:

- planning the progression of remedial actions involving decontamination and or excavation to minimize likelihood of cross-contamination;
- planning progression of final status surveys to improve likelihood of discovering inadvertent cross-contamination.
- establishing a controlled area boundary around a remediation location;
- employing water misting to suppress airborne dust if needed;
- implementing a contamination control procedure for haul vehicles;
- specifying and monitoring the haul route from excavation site to rail car loading site;
- routine surveillance of the haul route;
- establishing a controlled area boundary around the rail car loading area;
- surveying, and if necessary decontaminating rail car surfaces before shipment; and
- employing administrative controls, including procedures, field instructions, and safety work permits to control activities involving radioactive material.

54. 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.”

Response:

Conceivable contingencies that might substantially lengthen the time required to complete Phase II decommissioning include:

- inclement weather;
- railroad delays delivery of empty rail cars for loading waste and or removal of filled cars;
- inability to resolve delineation of responsibility with the USACE;
- public intervention delays approval of DP or other essential permit;
- delay in receiving all necessary permits;
- competition with USACE to use rail car loading station on-site;
- relocating utilities;
- excavate more than anticipated, *e.g.*, more contaminated soil than expected or more adjacent soil slope to control embankment caving;

55. E. Update Figure 8-1, Conceptual Decommissioning Schedule for Phase II.

Response:

CT 2 DP, §8.9 Schedule, including Figure 8-1 are being revised to provide a current, best estimate of the decommissioning schedule.

56. F. For license termination, explain how Mallinckrodt will include residual radioactivity concentration from the FUSRAP clean-up in its dose assessment.

Response:

Land on Mallinckrodt's site, including Plant 5 and the areas subject to the FUSRAP, will remain in industrial use for the foreseeable future; and industrial workers will be the critical group for potential radiological exposure.

The USACE Record of Decision, presents its selected remedial action for cleanup of wastes related to MED-AEC operations in accessible soils and ground water at Mallinckrodt's site, states that 10 CFR Part 20, Subpart E, standards are relevant and appropriate to any FUSRAP materials similar to licensable materials under the Atomic Energy Act.<sup>2</sup> The ROD also provides that a post-remedial action risk assessment will be performed to describe the level of risk remaining from MED-AEC contaminants after completing remedial actions.<sup>3</sup> In FUSRAP progress to date, after remediating areas and performing final status survey, potential radiological dose using the data in RESRAD was estimated by the USACE to be:

Area	Estimated Potential Annual Radiological Dose to Worker (mrem/yr)
Plant 1	Less than 2 mrem/yr
Plant 2	Less than 1 mrem/yr <sup>4</sup>

Since compliance with a 25 mrem/yr criterion will be demonstrated in areas of the site subject to FUSRAP remediation and independently in areas subject to C-T decommissioning, a question may be whether the 25 mrem/yr criterion should be apportioned between the separate areas, assuming the critical group of industrial workers may might work anywhere on the Mallinckrodt site.

In an industrial use scenario, the substantial pathways of potential radiological exposure are irradiation directly from the source in ground, ingestion of dust from contact, and inhalation of dust suspended in air. Such exposure would only occur proximate to the source. According to RESRAD modeling of nominal 3 U series + 1 Th series source in an industrial land use scenario, 0.91 of radiological dose would be caused by irradiation directly from the ground, 0.08 of dose would be caused by ingestion of soil, and less than 0.01 of dose would be caused by inhalation of airborne dust. Thus, more than 0.99 of radiological exposure occurs very near the source in ground.

The exposure by inhalation model assumes dust of contaminated soil within a 10,000 m<sup>2</sup> area becomes suspended as airborne dust where it could be inhaled. Atmospheric dispersion would dilute it and deposition would deplete it as wind blows it away from the survey unit or Plant 5. Prevailing wind would tend to blow dust in one direction at a time,

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<sup>2</sup> USACE. Record of Decision for the St. Louis Downtown Site, St. Louis, Missouri, pp. 76, July 1998

<sup>3</sup> USACE. ROD. p. 69. July 1998.

<sup>4</sup> USACE. *Post-Remedial Action Report for the St. Louis Downtown Site Plant 2 Property*, p. 37, June 2001.

exposing a person to dust in air from Plant 5 or from MED-AEC areas, but not both at the same time. Not only does dose modeling estimate inhalation to contribute < 0.01 of dose in an industrial scenario, the nature of atmospheric dispersion makes it unlikely that airborne dust from adjacent Plant 5 and MED-AEC areas, would add to increase airborne dust over that modeled proximate to the source.

Dose modeling assumes a member of the critical group wanders randomly on the area being modeled during their time on-site. Since a person can be in but one place at a time, they cannot be on an MED-AEC area and a C-T area at the same time. Reciprocally, sources of exposure in the separate areas cannot be in the same area. If exposure were to be apportioned by location in dose modeling, time of exposure, *i.e.*, nominal 2000 hour work year, would also be apportioned, thereby diminishing duration of exposure on each separate area.

In practical effect, a person will not suffer occupational exposure in two places, *i.e.*, C-T versus MED-AEC, at a time. Since C-T and MED-AEC areas will independently be demonstrated to achieve  $\leq 25$  mrem/yr by RESRAD modeling of an industrial land use, with industrial workers as the critical group, and with each evaluating final status survey data collected in accordance with the MARSSIM as a guide, the 25 mrem/yr criterion does not have to be apportioned between C-T and MED-AEC material and areas in order to assure that industrial workers on-site will not receive more than 25 mrem/yr in the foreseeable future.

57. 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.

Response:

C-T process and support buildings and other structures above ground were decommissioned during Phase I [ref. CT 2 DP §8.2]. In the Phase 2 Plan, *structure* is intended to refer to buildings and other structures above ground. CT 2 DP §8 describes what is subject to decommissioning during Phase II.

**Planned Decommissioning Activities and Remediation:**

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

58. 1. Explain how Mallinckrodt will determine whether below grade systems are contaminated (surface vs. volumetrically) and must be remediated or removed. Provide an estimate of all potential contaminated systems of the volume of waste expected [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."

Response:

Utility lines in-ground that might be contaminated radioactively could be those within contaminated soil that was beneath and adjacent to Building 238 or would have been contaminated within by effluent wastewater from process Building 238 or 246B, 247A&B, or 248.

Results of extensive soil core sampling and of sediment sampling taken via manholes in sewerage are reported in CT 2 DP §4.8.2 Sewers and §4.8.4 Subsurface Material. Interpretation of the manhole samples indicates radioactive contamination in sewerage to be confined to segments immediately southwest, west, and north of Building 238. [ref. CT 2 DP, §4.8.2] This main sewer lines segment beside Building 238 serving Building 238 or 246B, 247A&B, and 248 will be removed or plugged in the process of remediation of floor slabs and subsoil beneath them. If removed, about 400 linear feet of sewers and the sludge in them will be treated as radioactive waste, as described in Section 12 of the Phase II Plan, and will pose a minimal increment to the total volume of contaminated subsurface soil. Else, if plugged, they will be subject to a final status survey as described in the Phase II Plan, §14.

It is anticipated that sewers remaining downstream of Building 238, beginning about even with west ends of Buildings 236 and 245 and extending to the Waste Water Treatment Basin area, will remain in service after a Final Status Survey as described in Section 14 of the Phase II Plan and will be demonstrated eligible for unrestricted use. [ref. CT 2 DP, §8.4.2] Sediment in sewers remaining in use downstream of Building 238 extending to the Waste Water Treatment Basin area and other sewers in the Plant 5 area will be considered a separate Class 3 survey unit and will be subject to a final status survey as proposed in CT 2 DP §14.4.3.2.

Drains that served C-T support buildings and served C-T yard areas that may have been exposed to C-T materials will be identified and surveyed for radioactivity. If surveys of those drains and other at-grade locations do not identify the presence of radioactivity above criteria, sewerage downstream will reasonably be assumed to be uncontaminated. If these surveys do identify contamination, interior surveys, *i.e.*, sediment sampling, will be performed. [ref. CT 2DP §8.4.3 and §8.4.4.]

59. 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.

Response:

Where either a building slab or vintage pavement<sup>5</sup> is to remain atop soil, the soil beneath will be subject to final status survey by core sampling through the pavement, designed in accordance with CT 2 DP §14.4, Final Status Survey Design. Already extensive characterization survey by core sampling into soil through existing pavement and building slabs has provided data to classify soil for final status survey, identified in CT 2 DP Figure 14-2, and to estimate bounds where radioactivity in soil exceeds the proposed DCGL, indicated in Figures 4-17, 4-18, and 4-19. These extensive data show that less than 0.1 of the area of Plant 5 is a Class 1 survey area and should remain valid where the soil has remained covered by pavement or concrete slab.

Access to C-T process and support building floor slabs that were sealed by temporary pavement awaiting removal or final status survey is described in CT 2 DP, §14.4.3.2.

60. 3. Explain how Mallinckrodt will address the waste water neutralization basins regarding remediation and verification of no unacceptable level 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 no volumetric contamination is present in these structures and no subsurface contamination beneath these structures exists. Also, if decontamination of the basins are 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 precede.

Response:

During use and afterward, the wastewater neutralization basins were lined with a rubberized liner with seams sealed to prevent wastewater from contaminating the concrete.

Each of the two basins was surveyed by surface gamma walkover scan. At 26 locations, indicated in Figure 4-5, where gamma radiation was elevated the most, one-square-foot sections of the liner were removed and direct measurements for beta radiation were made. No beta measurement exceeded the proposed DCGL<sub>w</sub> for pavement or a concrete slab.

After the liner is removed, the entire surface of both wastewater neutralization basins will be exposed to allow a final status survey. DCGL proposed in CT 2 DP, §5.8.2 Industrial Work on Pavement (originally numbered §5.8.3), will be applicable to the concrete surface of the basins. As with a building floor slab, joints and cracks in the basins would be subject to judgment survey if immediately adjacent surfaces were to exhibit substantial contamination. If contamination requiring decontamination were found, it would be removed either by a traditional method such as water scavenging, scabbling, or chipping; or the affected section of concrete would be broken and the rubble disposed.

Characterization survey measurements on neutralization basin concrete surfaces are less

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<sup>5</sup> not the temporary pavement seal applied atop C-T process building slabs to protect against prospect of radioactive contamination transfer while awaiting Phase II decommissioning, which will be removed, surveyed, and disposed as described in CT 2DP §14.4.3.2

than 0.1 DCGL<sub>w</sub> proposed for outdoor surfaces. [ref. DP Figure 4-5]. When doing final status survey of the basins, Mallinckrodt will treat them as Class 2, will scan at least 0.1 of their area, and will do judgment measurements searching for evidence of embedded residual source material. If evidence of embedment or penetration into the concrete is discovered, Mallinckrodt will investigate by scabbling or chipping into the concrete and or other means of sampling for potentially embedded radioactive source material. Else, if the final status survey passes without evidence of embedment into concrete, Mallinckrodt will have reasonable confidence it has not occurred. CT Phase II Decommissioning Plan, §14 “Facility Radiation Surveys,” is being revised to state this intent.<sup>6</sup>

61. 4. Identify all C-T target radionuclides and explain how they differ from other Manhattan Engineering District/Atomic Energy Commission (MED/AEC) material used on site and how they can be distinguished among each other in the field and in the laboratory.

Response:

It is important to note that USACE’s charge is to remediate any residual MED/AEC contamination, radiological or chemical, even if it is commingled with other materials such as those from former C-T operations. So, it is the presence of MED/AEC materials that determines where USACE will remediate.

The target radionuclides associated with both the C-T and MED/AEC materials are the long-lived radionuclides in the uranium series: U<sup>238</sup>, U<sup>235</sup>, Th<sup>230</sup>, Ra<sup>226</sup>, and Pb<sup>210</sup> and in the thorium series: Th<sup>232</sup>, Ra<sup>228</sup>, and Th<sup>228</sup>. Thus, one cannot distinguish between the C-T and MED/AEC based only on the radionuclides that are present. However, other information can be used to make a reasonable determination of where residual MED/AEC contamination is located. Some of these factors are:

1. Most MED/AEC feed materials had higher uranium -to- thorium ratios than the tin slag ores that were C-T feed materials; although both were variable. Also, radionuclide equilibrium was disrupted during the processing. But, due to that fact that there was 200 to 260 times more radioactivity processed through the MED/AEC operation at the site than the C-T operation, as shown in the table below, Mallinckrodt believes that prominently higher uranium to thorium ratios are indicative of MED/AEC residue, taking into consideration the additional factors described below.

Operation	Total Amount of Material Processed		
	Uranium	Thorium	Uranium + Thorium
MED-AEC	42600 to 54000 tons 26330 to 33370 Ci	44 to 56 tons 9 to 11 Ci	42644 to 54056 tons 26339 to 33381 Ci
C-T	163 tons 101 Ci	148 tons 29 Ci	311 tons 130 Ci

<sup>A</sup> C-T includes euxenite

<sup>6</sup> Mallinckrodt: J. Grant “Responses to NRC Inquiries About the C-T Phase II Decommissioning Plan,” item 47, NRC RAI set 1, EPAD query g, to NRC: Amy Snyder Aug. 1, 2005.

2. The types of activities that took place in Plants 6 and 7 were significantly different for the MED/AEC and the C-T operations. There was major chemical processing of pitchblende ore during MED/AEC operations. This resulted in chemical separation of uranium, thorium, and radium into discrete product and waste streams that were potential sources of contamination. There was no C-T processing done in this area. Other than the C-T burials, C-T feed materials and URO were only stored on the surface in Plants 6 and 7. The C-T materials stored and buried in Plants 6 and 7 did not have the same degree of radionuclide disequilibrium as the MED/AEC product and waste streams.
3. USACE removed a significant amount of soil from under the former MED/AEC chemical processing areas in Plants 1 and 2 beneath areas where waste water had leaked and contaminated soil. Similar contamination occurred in Plants 6 and 7 due to the MED/AEC processing operations. For instance, the MED/AEC acid digestion processing took place in Plant 6W. We know from historical records that a new separate acid sewer was installed because the original sewer leaked. Similarly, the soil beneath the former MED/AEC Ionium processing Plant in Plant 7 is contaminated with separated Th-230.
4. The original MED/AEC D&D that was done in the 1960s focused on above-ground D&D. The buildings were decontaminated. Some were left in place and many were demolished, but the floor slabs and footings were left behind. One exception was the acid digestion processing building in Plant 6W where, according to the D&D protocol, four feet of soil was removed from under its footprint. But, in this area, one could have expected contamination to extend 10 to 20 feet into the subsoil. In the area under and around the URO burials, data show contamination with signatures of separated uranium and separated thorium. In contrast, samples believed taken from the burials have substantially less disequilibrium within the natural uranium and thorium series.

Based on these facts and others, Mallinckrodt believes that, except for the URO burials, the overwhelming majority of contamination that needs to be remediated in Plants 6 and 7 is from former MED/AEC processing.

62. 5. Explain [the] 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.”

Response:

Sewerage was characterized by sampling sediment via manholes as indicated in CT 2 DP Figure 4-1. The survey data indicate contamination in the sewerage is substantially confined to segments immediately southwest, west, and north of Building 238. [ref. CT 2 DP §4.8.2] Sewerage immediately to the west and north of Building 238 that served C-T process buildings (238, 246B, 247A&B, 248) will either be plugged to prevent use or will be removed during removal of building floor slabs and adjacent soil, if any. If removed,

the sewers and the sludge in them will be treated as potential radioactive waste, as described in Section 12 of the Phase II Plan. Else, if the sewers are plugged, they and their contents will be considered for FSS purposes a part of the subsurface survey unit in which they are located. As such, they may be released for unrestricted use if warranted by a Final Status Survey as described in Section 14 of the Phase II Plan.

On the basis of characterization survey data, Mallinckrodt does not anticipate that drains and subsurface sewerage that served C-T support buildings will contain C-T related contamination in excess of sewerage contamination criteria. Sewers remaining downstream of Building 238, beginning about even with west ends of Buildings 236 and 245 and extending to the Waste Water Treatment Basin area, are expected to remain in service after a Final Status Survey as described in Section 14 of the Phase II Plan and release for unrestricted use. [DP §8.4.2]

Sediment in sewers remaining in use downstream of Building 238 extending to the Waste Water Treatment Basin area and other sewers in the Plant 5 area will be considered a separate Class 3 survey unit. For classification and evaluation purposes, this sediment is considered no different from other subsurface soil at the equivalent depth. At each location, a single vertical average radionuclide concentration (as described in Section 14.4.3.1) in the sewer sediments and in soils located between the ground surface and the sewer, all taken as combined, has been used to establish the basis for comparison to limits for classification, and will be used for FSS evaluation. [DP §14.4.3.2]

Drains and other at-grade locations that may have been exposed to C-T materials will be identified and surveyed for radioactivity. Downstream sewerage will reasonably be assumed to be uncontaminated if surveys of drains and other at-grade locations do not identify the presence of radioactivity above criteria. If these surveys identify contamination, interior surveys, *i.e.*, sediment sampling, will be performed. Drains and subsurface sewerage that served C-T yard areas will be addressed in a manner similar to that employed for drains and subsurface sewerage that served C-T support buildings. [DP §8.4.3 & 8.4.4]

63. 6. Describe how Mallinckrodt will determine when further remediation in an area is not necessary or when Mallinckrodt will know that it has remediated, sufficiently.

Response:

The goal of remediation is to remove radioactive contamination until residual is < DCGL criteria. Where cleanup is necessary, Mallinckrodt's remediation contractor will perform remediation surveys as described in CT 2DP, §14.3 Remedial Action Support Surveys, to guide and decide remedial action. A survey technician will work actively with the decontamination worker or excavator operator to guide decontamination or excavation to decide when a location is decontaminated to meet the goal.

When remediating pavement, building slab, or foundation, a survey technician will:

- Perform beta or beta-gamma scanning;
- Then perform beta measurement at locations judged most likely to remain contaminated in excess of DCGL. Among radiations emitted, beta is most suitable to represent

contamination on a concrete slab or on pavement; for a low fraction of alpha rays escape a rough surface, while natural background gamma rays originating deeper in concrete or macadam would be detected.

- At joints or cracks, scraping, chipping, or scabbling may be used to collect a material sample to be analyzed by comparison with DCGL for a volumetric source, that derived for soil.

When remediating soil, a survey technician will:

- Rely on the extensive characterization survey data for guidance about where to begin.
- As excavation removes contaminated soil, remedial action surveys will decide whether that area has been decontaminated to the DCGL. Remedial survey measurements will be a combination of gamma scanning and point measurements on the surface or in shallow auger hole in the excavation cavity to measure the concentration of key radionuclides.
- Alternatively, sampling of soil and gamma spectrum analysis to measure the concentration of key radionuclides may be performed. This alternative would be especially useful in the event water accumulates in an excavation cavity.
- In the event caving is of concern, sampling of excavator bucket contents would enable an alternative means of measurement.

64. 7. Explain Mallinckrodt's strategy for addressing contamination that is found to go beyond the project boundary.

Response:

The USACE has done comprehensive surveys of vicinity properties around the St. Louis plant site. Where they have identified residual contamination, they have done further characterization, and remediation as required. USACE has been actively remediating vicinity properties to the south, southwest and north of the Mallinckrodt site (e.g., McKinley Bridge, PCS Metals, Thomas and Proetz, Gunther Salt, and BFI (south of Angelrodt)). Several Post Remedial Action Reports (PRAR) have been issued for vicinity properties.

65. 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."

Response:

The release limits mentioned are DCGL proposed in CT 2 DP §5.8.1 for soil and §5.8.2 for areal contamination. They apply to soil or to pavement, building slabs, and like surfaces that are subject to final status survey and are to remain in place on-site when the NRC license is terminated.

66. 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).

Response:

After excavation to remove contaminated soil, an excavation cavity will be subject to measurements, whether scanning, soil sampling, and or direct measurement, to fulfill final status survey requirements applicable to that location. Backfilling would be done afterward. In the event non-contaminated backfill soil were imported from off-site, its radioactivity would be subject to confirmation as natural background either by origin or confirmatory measurement, but would not be subject to final status survey. In the event backfill originates on-site, whether soil or other rubble, it would be subject to final status survey quality sampling and measurement before deposit in the excavation cavity. The undisturbed remainder of the survey unit would be surveyed later, or characterization survey data of recognized quality could be used to supplement it.

Characterization survey data were used to classify Plant 5 areas according to MARSSIM categories, identified in CT 2 DP Figure 14-2. One or more soil survey units will be delineated within each classified area and a final status survey will be designed for each survey unit in accordance with a final status survey design guide.

About 600 soil samples were analyzed during C-T characterization surveys. Where soil has remained undisturbed since their collection, analyses of these samples will be expected to fulfill data quality objectives to complement other final status survey measurements in the same survey unit and contribute prominently to assurance that land survey units satisfy decommissioning criteria. Where these data need to be complemented by new, systematic measurements, the final status survey design will so provide. Where subsoil contamination is reasonably suspected, final status survey design will be expected to include subsoil radioactivity measurement, either by soil core sampling and gamma spectrometry or in-ground, down-hole gamma spectrometry to measure key radionuclides.

67. 10. Provide a statement of commitment, in the DP, that Mallinckrodt will provide NRC, upon request, updated schedules that reflect progress and work completed. [See page 8-8 of the DP].

Response:

Upon request by the NRC, Mallinckrodt will provide an updated schedule that represents progress and work completed toward decommissioning. CT 2 DP §8.9 is being revised to include this statement.

68. 11. Provide reference to or list procedures that will be used for Phase II decommissioning. Identify those not yet developed. 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.

Response:

In CT 2 DP §9.2 Task Management, Mallinckrodt proposes to direct decommissioning activities by written instructions, including procedures, work plans, and safety work permits. In DP §9.2.1, Mallinckrodt proposes to develop and implement an Administrative Controls Plan that establishes guidelines for creation, use, and control of these administrative controls. An Administrative Controls Plan was submitted to the NRC staff as C-T Phase I Decommissioning Plan, Attachment 2, was accepted, and was used successfully to manage Phase I decommissioning. Training is described in CT 2 DP §9.4 Training. The Administrative Controls Plan specifies that each worker be instructed on the procedure, work plan, or safety work permit before being accepted to work on that task.

Traditionally, a licensee would agree to implement written procedures to direct compliance with regulations and license conditions, as is done in CT 2 DP §9 Project Management and Organization. NRC pre-approval of specific administrative control documents, or even commitment to a specific list of them, could hinder timeliness of creation, approval, revision, and implementation on the job when needed. Rather, Mallinckrodt proposes that procedures, work plans, and safety work permits will be available for NRC inspection on-site.

69. 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.

Response:

A contractor would access the drain or sewer via the drain opening, storm drain opening, or manhole into the sewer. In a manner similar to grouting a well to plug it, the contractor would pump cement or a cement-bentonite mixture into the drain or sewer to plug it at these strategic segments to preclude further use and to preclude further drainage of wastewater in the line.

Objectives of plugging sewerage would be to prevent future use, to contain sediment that might be in it, and to prevent backflow from sewers remaining in use downstream, especially at the juncture of a sewer line upstream to be removed. If sewerage north and west of Building 238 is to be removed, the juncture in sewerage will be plugged before sewer line upstream of the plug will be removed in order that sewerage downstream may remain in use. Any sewerage north and west of Building 238 to be plugged rather than removed would be plugged at strategic points before excavation to remove connected sewer lines in order to prevent backflow from downstream. Final status survey of sewerage downstream remaining in use would be done after plugging upstream and after building slab, foundation, and soil remediation.

70. 13. Describe when and how Mallinckrodt will determine the radioactivity concentration for excavated soil that the Mallinckrodt 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.

Response:

In order to qualify for deposition into an excavation pit, soil, concrete, or pavement rubble must be either be imported from a non-impacted source off-site, be indistinguishable from background radioactivity. Else, it must contain less than the DCGL for soil specified in DP §5 and be certified so by survey equivalent in quality to final status survey specifications in DP §14. Sampling or in-situ analysis of material originating on-site would be done in stockpile before deposition into an excavation pit. Measurement quality would be equivalent to that required for a final status survey to assure that the radioactivity concentration in backfill, when evaluated together with final status survey measurements of the excavation cavity, will satisfy the requirements of a final status survey of the combination.

The specifications in DP §8.5.1 and §8.5.2 on p. 8-6 and in DP §12.1.6 on p. 12-4 are compatible in that excavated material or debris containing less than the DCGL proposed in DP §5.8.1 may either be used as backfill deeper than 4 feet in an excavation cavity; or else would be disposed, up to an *unimportant quantity*, defined in 10CFR 40.13(a), in a facility off-site subject to NRC release and State acceptance; or at greater concentration, in an NRC-licensed disposal facility. That is, DCGL, proposed in DP §5, apply to what qualifies as decommissioned and remains on-site at license termination. Whereas, disposal criteria, the focus of DP §12.1.6, including application 10 CFR Part 40.13(a), apply to what may be authorized for disposition off-site. CT 2 DP §12.1.6, ¶4, is being revised to state its intent more clearly.

## **Environmental Monitoring and Controls**

The following information is needed to assure compliance with 10 CFR 20.1101(b) and (d), 10 CFR 20.1301(a) and (d), 20.1301(c) and (b), 20.1501, 20.2001(a), 20.2003(a), 20.2003(b), 20.2107(a), 20.2202(a), 20.2203(a) and 70.59. Also, the staff needs this information to assess whether the 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:

Response:

Mallinckrodt has evaluated potential risk associated with C-T decommissioning in order to gather perspective on the extent of radiological and environmental protection and monitoring that would be prudent to exercise during decommissioning activities.

An analysis of the potential for airborne radioactive particulate is summarized in Appendix 77 herewith. It finds that physical circumstances make it be unlikely that source material concentration in occupational air could be as much as one DAC, the 10 CFR Part 20 standard for maximum airborne concentration during chronic occupational exposure.

CT 2 DP Attachment 1 summarizes a conservative assessment of occupational radiation dose during Phase II decommissioning. Even if presumed to be exposed wholly to radioactivity concentration in soil that was observed in excess of the DCGL, a remediation worker would be

estimated to experience only about 120 mrem/yr, or less than 10% of the occupational dose standard.

CT 2 DP Attachment 2 summarizes analysis of an accident hypothesized to occur during Phase II decommissioning. Assuming spillage of contaminated soil were to cause a dust cloud, the maximum exposure to a nearby worker would be less than  $10^{-3}$  of the annual limit for occupational intake by inhalation, or ALI. The potential exposure of a person off-site would be even less than estimated for person on-site.

Together, these bounding exposure assessments demonstrate that even without active control, occupational exposure would be expected to remain well below the radiation protection standard, 10 CFR Part 20.

71. 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.]

Response:

Overall, radiation and environmental protection will be controlled in accordance with CT 2 DP §10 and §11. A project Radiation Safety Plan based on these DP sections will guide development of administrative directives, *e.g.*, field instruction, safety work permit, and or procedure, in accordance with an Administrative Controls Plan, to implement controls for radiation and environmental protection during these decommissioning activities.

Active controls will include water misting or similarly effective dust control methods as necessary to control release of airborne dust during the material handling operations of interest. In the event erosion or dispersion of staged or stockpiled soil were to become problematic, active confinement, *e.g.*, by straw bale berm or tarpaulin cover, would be considered.

Monitoring appropriate to the potential, may include direct radiation survey, personal dosimetry, area or personal lapel airborne particulate sampling, and or surface contamination survey to assess conditions in accordance with these administrative directives.

72. 2. Identify the soil techniques Mallinckrodt will use to control excavation, loading, transport and handling of contaminated soil? [See page 8-6 of the DP.]

Response:

These activities will be controlled administratively by directives, *e.g.*, field instruction, safety work permit, and or procedure, in accordance with an Administrative Controls Plan, to control operations and safety. Excavation will be done by conventional earth-moving bucket excavator, *e.g.*, backhoe, or front-end bucket loader. Sloping or shoring sides of an excavation cavity will be done to control sidewall stability. Excavation will be guided by radiation survey of the cavity bottom and side and or of soil as it is removed by excavation. Additional soil sampling for analysis or direct measurement will be done to determine for

which approved disposition it qualifies; that may necessitate sorting and short-term staging nearby the excavation.

73. 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.]

Response:

In the event water were to accumulate in an excavation cavity and impede remediation or radiation survey, Mallinckrodt would implement its water management plan to manage it in conformance with

- 10 CFR Part 20.2003
- C-T Phase II Decommissioning Plan, §12.2 Liquid Radwaste, and
- Mallinckrodt's Metropolitan St. Louis Sewer District (MSD) discharge permit no. 21120596-00

Water would be pumped from an excavation cavity into holding tanks or a tank on a truck. It would be transported to a water treatment system on-site where it would be filtered, sampled, and analyzed to verify compliance with 10 CFR Part 20, Appendix B, Table 2, column 2 effluent concentration limits and with the MSD permit before discharge into MSD sewer system.

If filtration were insufficient to assure the water discharged as effluent complies with the 10 CFR Part 20, Appendix B, effluent concentration limit, additional treatment, either by ion exchange or adding flocculant before filtration, would be done to achieve compliance. Similar practice has been used successfully by the FUSRAP contractor on-site. Used filters and treatment sludge, if any, would be managed as solid radioactive waste.

CT 2 DP §12.2 is being revised to include this information.

74. 4. Identify whether Mallinckrodt will monitor the groundwater during soil remediation and/or after soil remediation?

Response:

An appraisal of groundwater is described in CT 2 DP, Appendix A. It describes reasons why groundwater beneath the site is not a drinking water source and will not become one.

If enough water collects in an excavation to require its removal, that water will be sampled and analyzed as described in response to preceding item 73. That should represent an acute indicator of the radioactive quality of water affected by the remediation.

After remediation has been completed, Mallinckrodt does not plan to monitor groundwater since the magnitude and area of MED-AEC remedial action far exceeds that of C-T; MED-AEC areas are hydraulically down-gradient of Plant 5; and USACE plans to monitor groundwater and periodically evaluate whether ground water remediation may be needed.<sup>7</sup>

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<sup>7</sup> USACE and USEPA. Declaration for the Record of Decision, August 1998, in U.S. Army Corps of Engineers, Record of Decision for the St. Louis Downtown Site, St. Louis, Missouri, July 1998.

The Record of Decision (ROD) for the FUSRAP work specifies investigative limits for groundwater contaminants of concern. As a result, USACE issued a Regulatory Review Draft Phase 1 Groundwater-water Remedial Action Alternative Assessment ( GRAAA) at SLDS dated April 14, 2003.

75. 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.]

Response:

*Air Sampling Program:* Occupational air sampling is identified in CT 2 DP §10.1.1, “Air Sampling Program,” and environmental air sampling is identified in §11.2.5.2, “Environmental Air Monitoring.”

Mallinckrodt’s Radiation Safety Plan,<sup>8</sup> provides for airborne radioactive material surveys to be performed in work areas, in the breathing zone of workers, and in ambient air that may enter an unrestricted area. The Plan for air sampling is implemented in procedures for:

- Survey Requirements and Frequencies
- Environmental Monitoring
- Performance of Radiation, Contamination, and Airborne Radioactivity Surveys
- Air Sampler Operation
- Survey Documentation and Review, and
- Air sample analyzer calibration and operation.

An Internal Exposure Monitoring procedure specifies threshold airborne exposures (DAC· hours) above which evaluation of internal exposure by bioassay is required. Characteristics that are expected to cause airborne radioactive material to remain well below one DAC are evaluated in Appendix 77 herewith.

CT 2 DP Attachment 1 is an occupational dose evaluation and CT 2 DP Attachment 2 is an accident analysis of Phase 2 decommissioning. The potential radiological dose to representative remediation worker in occupational conditions was estimated to be 120 mrem/yr from exposure by ingestion, irradiation, and inhalation. The potential exposure to a remediation worker consequent to a dust cloud as a result of accidental spillage is estimated to be  $4 \times 10^{-4}$  of an Annual Limit of Intake (ALI) tolerated by 10 CFR Part 20, Appendix B. These analyses of occupational and accidental exposure indicate airborne exposure is unlikely to exceed a regulatory limit. Thus, air sampling equipment and evaluation procedures specified for remediation activity will be sufficient to evaluate an accidental occurrence.

*Gross Activity Measurements:* Measurement of gross activity on an air sample filter enables timely evaluation and has traditional precedent for airborne natural uranium and

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<sup>8</sup> Mallinckrodt. *Radiation Safety Plan*. CT-RS Plan. rev. 2. §3 Internal Exposure Protection, §3.2 Air Sampling, §8.3 Airborne Radioactive Materials and §9. Environmental Monitoring of §9.2 Air.

thorium particulate.<sup>9, 10</sup> A representative spectrum of the key, long-lived uranium series and thorium series radionuclides in soil in Plant 5 that would be the potential source of airborne radioactive particulate has been derived from soil characterization survey data. A DAC will be derived for that spectrum of key U-series and Th-series radionuclides. That spectrum is based on premises:

- thorium series is in approximate radioactive equilibrium and is assumed so;
- key, alpha-emitting, uranium series radionuclides, U<sup>238</sup>, Th<sup>230</sup>, and Ra<sup>226</sup>, and Th-series observed in excess of natural background
- ratio of geometric mean of U<sup>238</sup>-to-geometric mean of Th-series; ratio of geometric mean of Th<sup>230</sup>-to-geometric mean of Th-series; and ratio of geometric mean of Ra<sup>226</sup>-to-geometric mean of Th-series, when in excess of natural background.

### **Radiation Safety for Workers**

The following information is needed to assure compliance with 10 CFR 20.1204, 10 CFR 20.1501 (a)-(b), and 10 CFR 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:

76. 1. Specify the respiratory protection practices and compliance requirements of NRC. [See page 10-2 of the DP.]

Response:

Mallinckrodt has a well-developed respiratory protection program for airborne material other than radioactive material. Experience during C-T Phase I decommissioning demonstrated the low potential for airborne concentration of source material requiring respiratory protection. Nevertheless, CT 2 DP §10.1.2 outlines Mallinckrodt's respiratory protection program for radioactive material during CT Phase 2 decommissioning in the unlikely event it may be needed. References to the locations of specifications to implement a respiratory protection program are in Table 76 herewith.

Guidance for preparation of implementing procedures for the respiratory program is specified in the CT Radiation Safety Plan. It will be reviewed and revised to ensure the specifications for respiratory protection in 10 CFR Part 20, Subpart H are incorporated to guide preparation of implementing procedures.

CT 2 DP §10.1.2 is being revised to specify that in the event Mallinckrodt uses respiratory protection equipment to limit inhalation of radioactive material, it will maintain and implement a respiratory protection program as described in §10.1.2. [ref. 10 CFR Part 20.1703(a)(3)]

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<sup>9</sup> 10 CFR Part 20, Appendix B, Note 3, provides for gross alpha measurement of U series in ore dust prior to chemical separation.

<sup>10</sup> NRC Draft Regulatory Guide DG-8026, Sept. 2000. formerly Regulstory Guide 8.30.

Air sampling, which will also support a respiratory protection program, is specified in CT 2 DP §10.1.1. Therein, calibration of personal air sampler flow meters is specified. Calibration of air samplers is also specified in CT 2 DP §10.1.7. [ref. 10 CFR Part 20.1501(b).]

Determination of internal exposure to radioactive material is specified in CT 2 DP §10.1.3.

77. 2. Describe how Mallinckrodt will determine when respirators are required and when they will be issued. [See page 10-2 of the DP.]

Response:

Selection and prescription for use of respirators is made by health physics personnel based on:

- the current and or expected airborne radioactive material concentration in the work area,
- the protection factor of the respirator versus the peak concentrations of radioactive material concentration in the work area,
- the feasibility and or effectiveness of process or engineering control, and
- current environmental conditions in the work area.

A respirator may only be issued a person

- who is qualified by medical physical examination,
- who has passed a respirator fit test,
- has completed training for respiratory protection usage.

These provisions are prescribed in the CT project Radiation Safety Plan.

The source of regulated radioactive material in air during C-T decommissioning is mostly in soil that is to be removed by excavation. Whether that source material could cause airborne radioactivity as much as one Derived Air Concentration (DAC), a regulatory limit for chronic, occupational exposure has been considered. An evaluation on the basis of the dust loading model, the spectrum of uranium series and thorium series observed in soil during characterization surveys, and estimation of potential airborne dust loading during soil remediation is summarized in Appendix 77 herewith. The concentration in topsoil needed to yield one DAC in air would be greater than any measurement of  $U^{238} + Th^{232}$  observed in a soil sample during CT characterization surveys. Therefore, it would be unlikely that source material concentration in occupational air would be as much as one DAC, and unlikely that respiratory protection equipment will be needed during Phase II decommissioning.

78. 3. Describe or reference the criteria that ES&H staff will use for selection of respirators. [See page 10-2 of the DP.]

Response:

In concert with 10 CFR Part 20.1703(a)(1), the CT project Radiation Safety Plan specifies that only NIOSH/MSHA-approved respiratory protection equipment shall be used. CT 2 DP §10.1.2.3 is being revised to specify MSHA approval as well as NIOSH approval.

CT 2 DP §10.1.2.2 and the CT project Radiation Safety Plan also specify success in fit testing before a worker is authorized to use a respirator.

Potential or observed airborne radioactivity concentration would be considered when selecting the type of respirator and its protection factor to be issued for use.

79. 4. Identify what Mallinckrodt plans on administratively controlling using an administrative limit of one DAC. One DAC equates to an airborne radioactivity area. [See page 10-1 of the DP.]

Response:

Implementation procedures specify that the health physics technician who converts air sampling data and compares it with one DAC shall notify the Health Physics Supervisor or the contractor Radiation Protection, Health, and Safety Manager as the first action. In the event the data indicate airborne radioactivity concentration exceeds one DAC or could exceed 12 DAC· hr in a week, the second action is to post the area with wording, "Caution, Airborne Radioactivity Area" or "Danger, Airborne Radioactivity Area."

CT 2 DP §10.1.1.2 is being revised to clarify this response. The CT project Radiation Safety Plan, and implementing procedures will be reviewed and revised as needed to clarify the intended implementation.

**Final Status Survey:**

The following information is needed to assure compliance with 10 CFR 20.1401-1404:

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

80. 1. A description of how the samples, to be analyzed in the laboratory, will be collected, controlled, and handled.

Response:

Sampling depends on the material to be sampled. The method or reference to an applicable procedure will be specified in each final status survey design. If soil is to be sampled, collection may be by hand troweling of topsoil, by manual core-barrel augering, by split-spoon or equivalent core sampling, or by direct measurement of the sample *in-situ*. If concrete or macadam, sample collection alternatives include core sampling, drilling or augering a sample, scabbling or scraping a shallow sample, or collecting broken pieces of the bulk material.

Each sample will be put into a container, which will be then be closed and will be labeled in accordance with a formal Chain-of-custody procedure. Administrative control of final status survey samples, from initial packaging and labeling through laboratory and disposition, will be in accordance with the Chain-of-custody quality procedure. Health Physics technicians who collect and handle final status survey samples are subject to training to qualify each of them to perform the tasks and procedures that control sample collection and handling.

81. 2. Describe how Mallinckrodt plans on addressing final status survey for subsurface structures that have been remediated, to include sewerage.

Response:

*Plugged Sewerage.* A plugged sewer would not be usable and not be salvageable as they are clay or concrete and would break into pieces upon excavation. In the future, potential exposure as a consequence of inadvertent intrusion would be similar to that posed by other subsoil at that depth in the remainder of the survey unit. Thus, if plugged, sewers and their contents will be considered as part of the subsurface final status survey unit in which they are located.

*Sewerage Remaining in Use.* Characterization survey data indicate sewerage beginning about even with the west ends of Buildings 236 and 245 and extending downstream to the Wastewater Treatment Basins is expected to satisfy a final status survey and may remain in service. Applying criteria similar to other subsurface soil at the equivalent depth for classification and evaluation, sediment in this sewerage remaining in use will be considered a separate Class 3 survey unit.

Sediment in the sewerage remaining in use will necessarily be sampled through manholes and stormwater drain openings. At each sampling location, a vertical average radionuclide concentration in the sewer sediment and in soil between the ground surface and the sewer is evaluated. [DP 14.4.3.2]

*Drains and Sewerage that Served C-T Support Buildings and Yard Areas.* A final status survey will be designed to sample access points in drains and at-grade access locations in sewerage that served C-T support buildings and yard areas potentially exposed to C-T source material. If not contaminated, that will be accepted as confirmation that downstream sewerage is not contaminated. If contaminated, sediment in the sewer at accessible locations (manhole or surface drain opening) downstream will be sampled. [CT 2 DP §8.4.3 & §8.4.4]

*Building Foundation.* In the event the exposed portion of a foundation or adjacent portion of a slab in contact with it were contaminated above DCGL applicable to pavement, and an adjacent pathway to sub-grade exists, Mallinckrodt would investigate the possibly affected part of the foundation that is below grade. A foundation may be surveyed either by direct measurement or by collecting sample(s) of concrete from the foundation surface, e.g., by scabbling, scraping, or chipping. Residual source in that kind of sample would be measured, interpreted as areal contamination, and compared with the areal DCGL applicable to pavement. The rationale is described in response to NRC RAI set 1, item 10.

A subsurface part of a building foundation within a soil survey unit that requires remedial action adjacent the foundation and exposes it will be subject to measurement of radionuclide concentration in concrete samples from locations selected based on professional judgment. Results of those samples will be considered investigative or remedial action support survey data and will be evaluated to determine whether remedial action on the building foundation is necessary. In the event remediation is not necessary, those measurements on foundation below grade will be reported in the final status survey

as judgment measurements. In the event remediation is necessary, post-remediation, will be made and reported in the final status survey as judgment measurements. CT 2 DP §14.4.3.7 is being revised to clarify this element.

*Plant 7 Lift Station.* Interior surfaces, including exposed joints of a concrete enclosure of wastewater valving that is below grade, the Plant 7 Lift Station, will be surveyed. This final status survey will be done in the same manner as were building surfaces during CT Phase I final status surveys. DCGL proposed for surfaces in CT 2 DP §5.8.2 are applicable to the Lift Station interior surfaces.

*Revision of DP.* The CT 2 DP is being revised as needed to include this information.

82. 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.]

Response:

Referenced page 8-4 and related p 8-5 are intended mainly to address remedial actions.

§5, Dose Modeling, provides DCGL for soil and separately for exposed solid surfaces, including pavement. This logically differentiates some survey units.

Figures 14-1A and 14-1B identify the classification of paved areas, based on characterization survey results, within which survey units for pavement will be delineated during final status survey design. Figure 14-2 identifies the classification of soil, based on characterization survey results, within which survey units for soil will be delineated during survey design.

It is logical to assure that sediment in sewerage remaining in use does not exceed DCGL appropriate for subsoil. As such, it is also logical to designate it as a survey unit.

Thus, survey units will be designated more on the bases of applicability of DCGL, *i.e.*, soil or solid surface, and of common potential for residual source material, *i.e.*, within classification, and or within physical bounds, *e.g.*, within Lift Station or sewerage remaining in use.

83. 4. Clarify when Mallinckrodt would use analytical data for compliance purposes. Explain why Mallinckrodt plans on the possibility of analyzing only 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 final status survey. [See page 14-4 of the DP.]

Response:

- Mallinckrodt intends to survey surfaces, *i.e.*, pavement and slabs, as it did during C-T Phase I decommissioning and by methodology described in CT Phase I DP, Appendix D Therein, a beta radiation equivalent of the  $DCGL_w$  is derived on the basis of the spectrum, or ratio among concentrations of radionuclides observed in the characterization survey.

Mallinckrodt intends to measure key, long-lived radionuclides in soil, whether by in-ground gamma spectrometry or by core sampling and alpha or gamma spectrometry in a counting room. Quantitative measurement of key radionuclides would be *analytical* whether detection is in-ground or in-counting room. Thus, measurements of radionuclide concentration in soil will be *analytical*. [ ref. response to NRC RAI, set 1, item 38.]

- Practically all of Plant 5 is either covered by buildings or pavement, which pavement or remnant building slab will be subject to final status survey and comparison to CT 2 DP §5.8.2. Soil beneath pavement or building slab or absent pavement, whether called topsoil or subsoil, is subject to final status survey.
- The importance of a radionuclide is a function of either its areal density on a surface or its mass concentration in bulk material, its radiological dose factor, and presence of short-lived progeny. Radioactive equilibrium of short-lived progeny with parent is assumed. Dose modeling analyses of the range of relative concentration, or spectra, of the key, long-lived radionuclides in the uranium and thorium series observed in extensive soil characterization surveys are reported in response Appendix 45 to NRC RAI set 1, item 45. Within the envelope of radionuclide spectra observed in the soil characterization surveys, spectra that would produce maximum potential radiological dose during any year were determined and DCGL<sub>w</sub> in soil was derived on that basis.

Extensive soil characterization by soil core sampling and spectrum analysis was done. Considering the variability observed among the key, long-lived radionuclides and their radiological importance, compliance with the radiological criteria, represented by the DCGL for soil, can be determined with sufficient certainty by measuring

U<sup>238</sup> or a surrogate  
Ra<sup>226</sup> or a surrogate  
Th<sup>232</sup> or its surrogate, Ac<sup>228</sup>

Since it is impracticable to measure Th<sup>230</sup> by gamma spectrometry, it will be specified to be 1.1 times the measured concentration of U<sup>238</sup> as justified in CT 2 DP Appendix C, or else may be measured, *e.g.*, by  $\alpha$  spectrometry. This is reasonable in that the dose factor of Th<sup>230</sup> is about a factor of 2 less than that of U<sup>238</sup> and both dose factors are about 2 orders of magnitude less than that of Ra<sup>226</sup>. The large number of soil samples analyzed during characterization surveys should be expected to provide a more representative estimate of the spectrum of key radionuclides and likely variation therein than would fewer verification samples during final status survey. Moreover, since Ra<sup>226</sup> and the thorium series are the dominant contributors to radiological dose, and since Ra<sup>226</sup> and a surrogate of the thorium series, Ac<sup>228</sup>, will be measured, additional sampling to verify the radionuclide spectrum should not be needed.

84. 5. Explain how residual source material in an area of imported fill will be assessed. [See page 3-6 of the DP:] Residual source material addressed by the Phase II Plan is in an area of imported fill if the imported fill is naturally radioactive. Identify if this fill will affect scanning and field measurement instrumentation.

Response:

Sentences of interest appear to be, “The residual source material addressed by the Phase II Plan is in an area of imported fill. Material with concentrations greater than the approved release criteria will be removed.”<sup>11</sup> Mallinckrodt’s St. Louis Downtown Plant in general and Plant 5 in particular is on land historically filled with coal cinders and rubble.<sup>12</sup> The intent of the first sentence of interest is to represent that the land subject to CT decommissioning is imported cinder fill and rubble deposited well before the time of radioactive material processing, portions of which were later impacted by residual source material from CT processing. The second sentence should be interpreted to recognize that radioactivity in the imported cinder fill and rubble represents background and may be differentiated from release criteria, or DCGL. CT 2 DP Appendix B describes the measurement and interpretation of background uranium series and thorium series concentrations in the coal cinder and rubble fill.

Scanning and field measurement instrumentation will detect background radiation from the cinder fill in absence of or together with radiation from residual source material. Consequently, survey measurements will include background as well as residual source material, since both include the uranium series and the thorium series. Methods devised during CT characterization surveys and during Phase I decommissioning enable background and residual source material to be measured satisfactorily.<sup>13, 14, 15, 16</sup>

Final status survey data evaluation will account for differentiation of background and residual source material by statistical tests as described in CT 2 DP, §14.4.3.8, Data Analysis, and notably by screening tests and by Wilcoxon Rank Sum statistical testing.

85. 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.

Response:

Success of remediation of each survey unit will be demonstrated in the final status survey report. The report will include measurements data mentioned in CT 2 DP, §14.5, Final Status Survey Report, which the request seeks.

86. 7. Provide or make a commitment to provid[e], a summary of any significant additional residual radioactivity that was not accounted for during site characterization.

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<sup>11</sup> CT Phase II Decommissioning Plan, §3.5.1 Geology, p. 3-6, Feb. 28, 2003.

<sup>12</sup> CT Phase II Decommissioning Plan, §3, Figure 3-9, Hydrogeological Cross-Section.

<sup>13</sup> CT Phase I Decommissioning Plan, apx D, “Method of Interpreting Surface Radioactivity Limit and Gross Beta Limit in Comparable Units.

<sup>14</sup> CT Phase I Decommissioning Plan, Attach. 3, Energy Dependent Calibrations for the Bicron Model AB-100 Beta Ray Survey Probe.

<sup>15</sup> CT Phase II Decommissioning Plan, apx F. Radionuclide Analysis in Soil by In-ground Gamma Spectrometry.

<sup>16</sup> CT Phase II Decommissioning Plan, apx B. Interpretation of Natural Background Radioactivity Concentrations in Cinder/Fill for the Mallinckrodt Columbium-Tantalum Decommissioning Plan.

Response:

CT 2 DP, §4 Radiological Status of Facility, summarizes the radioactivity associated with CT Plant 5 and downstream sewerage, to and including the wastewater basins in Plant 7 West that are subject to CT Phase II decommissioning. In the event Mallinckrodt were to find substantial additional radioactive residue not accounted for in site characterization, it would provide a summary to the NRC

87. 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.

Response:

Survey units will be designated during final status survey design to include all areas subject to decommissioning as identified by historical site assessment and characterization surveys and so designated in the CT Phase II DP. Other areas of the site subject to the FUSRAP are not subject to final status survey by Mallinckrodt and thus will not be subject to a final status survey report by Mallinckrodt. At the conclusion of the Final Status Survey, a Final Status Survey Report will be prepared to demonstrate that the areas addressed in the Phase II Plan meet the radiological criteria for license termination.<sup>17</sup> CT 2 DP §14.5 will be revised to state that Mallinckrodt will submit this report to the NRC.

## **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 the Mallinckrodt intends to manage and dispose of such wastes. Evaluation criteria: 10 CFR Part 20, Subpart K, 61.55, 61.56, 61.57, and 71.5.

88. 1. Reference the Radioactive Waste Management Plan. [See page 12-1 of the DP.]

Response:

CT 2 DP §12 Radioactive Waste Management Program is the Radioactive Waste Management Plan from which administrative directives to manage waste will be prepared.

89. 2. Provide a waste estimate for all subsurface materials identified. [See page 12-1 of the DP.]

Response:

An estimate of the volume of material below grade that is potentially radioactive solid waste subject to removal and disposal off-site is 59100 ft<sup>3</sup> in Plant 5 and 81500 ft<sup>3</sup> of URO in Plant 6W. The basis of that estimate is described in revised DP §4.8.4 and the estimate is tabulated in revised Table 12-1. This corrects a misattribution in original DP §4.8.4 which is being revised in that text and in Table 12-1.

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<sup>17</sup> CT Phase II Decommissioning Plan, §14.5 Final Status Survey Report. p. 14-28. Apr. 15, 2003.

90. 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.]

Response:

The very small amounts of loose material of concern, *e.g.*, spillage while loading or removed from the exterior of the transport body, will be put with material of its origin or with material of like kind. Then the larger quantity, whether a stockpile or excavation cavity, will be subject to characterization together with the other material of like kind before its disposition. If loose material were returned to its excavation cavity, it would be either excavated again or would be surveyed as part of the excavation cavity to assess compliance with soil criteria, *i.e.*, DCGL.

91. 4. Define non-impacted material. How does it differ from soils and materials less than the DCGLw 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.

Response:

*Non-impacted material* is indistinguishable from background radioactivity and does not contain radioactive material of C-T or MED-AEC origin. That is a lower radioactivity concentration than the decommissioning criterion of DCGL above background. In the event Mallinckrodt were to plan to release such unaffected, or non-contaminated material, it would develop a quality statistical survey for that application to demonstrate radioactivity is indistinguishable from background. This provision in DP §12.1.6 concerns removal and disposition of solid waste demonstrated to present no discernable radioactivity above background. It does not affect decommissioning criteria, *i.e.*, does not affect applicability of DCGL proposed in CT §5 for soil or pavement, nor of applicability of final status survey provisions in DP §14 to soil or pavement on-site concluding decommissioning. CT 2 DP §12.1.6 is being revised to clarify the intent.

92. 5. Identify whether Mallinckrodt intends to use 10 CFR 40.13 as a decommissioning criteria. [See page 12-4 of the DP.]

Response:

Specification of 10 CFR Part 40.13 in CT 2 DP, p. 2-4, §12.1.6 is not intended to be a decommissioning criterion, *i.e.*, to decide what radioactivity concentration may remain on-site. Rather, reference in §12.1.6 to 10 CFR Part 40.13 is intended to apply specifically to regulate transfer of solid waste contaminated by an *unimportant quantity* of source material or more than an *unimportant quantity* of source material to an acceptable disposal facility.

## 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), 40.42(g)(4)(ii), 70.38(g)(4)(ii) and 10 CFR 30.33(3), 40.32(b), 70.22(a)96).

93. 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. [see page 9-4 of the DP.]

Response

An SSRO, mentioned in DP §9.2.2 on page 9-4, is intended to refer to Mallinckrodt's Radiation Safety Officer, or RSO. DP §9.2.2 is being revised to refer to Mallinckrodt's RSO as one who also reviews and approves procedures addressing radiation safety issues.

94. 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.]

Response

The Administrative Controls Plan (ACP) was submitted as Attachment 2 to the C-T Phase I Decommissioning Plan. It was implemented successfully and has been refined. The ACP presents guidelines for creation, use, and control of administrative controls for C-T decommissioning activities involving radioactive material. Its purpose is to provide more specific guidance to C-T project managers and supervisors about how to administer procedures, field instructions, safety work permits, final status surveys, and adjustments to the decommissioning process than would be appropriate in a DP.

95. 3. Explain what equivalent means with respect to qualifications. Equivalent qualifications are not defined by NRC. [See page 9-5.]

Response

The statements,

Minimum qualifications for C-T decommissioning management positions are specified hereafter. In the event a person having equivalent although not exact qualifications were to occupy one of the positions, Mallinckrodt would inform the NRC.

are intended to be in place in §9.3, before §9.3.1 in order to apply to all decommissioning management positions specified in §9.3. Page 9-5 is being revised to locate the statements as intended.

Anticipating all exceptions to the proposed qualifications that should not disqualify a candidate does not seem reasonably achievable. As a result, the term, *equivalent*, seems needed and functional even if not reasonably definable. For instance, a statistician or a mathematician with suitable experience might be a capable candidate for Quality Assurance Manager without having the exact qualifications specified in §9.3.6. To provide the NRC reasonable assurance and opportunity to react to Mallinckrodt's judgment about *equivalence*, Mallinckrodt has proposed to inform the NRC if a deviation from qualifications specified in §9.3 were to arise.

96. 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 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.

Response

Mallinckrodt's Radiation Safety Officer, Tim Woodford, has been a health physicist with Mallinckrodt for eight years where he has been involved in day to day operations with NRC license STB-401, including C-T Phase I decommissioning. He has been the RSO during the past 3 years.<sup>18</sup> Mr. Woodford has been involved with radiation protection for 22+ years, and has 100 hours of formal health physics training. He served as Alternate Radiation Safety Officer, and Radiation Safety Officer for a period of three years with American Radiolabeled Chemicals in Maryland Heights, MO. He came to Mallinckrodt with experience in the source material management aspect of health physics from his years of providing oversight at FUSRAP and UMTRA sites. As such, Mallinckrodt's intended RSO for Phase II decommissioning should be considered qualified for the uranium series and thorium series and their quantities that will be encountered during C-T Phase II decommissioning.

The NRC guidance also states that if the RSO does not have the decommissioning experience in its acceptance criteria<sup>19</sup> for an RSO, the RSO could be supported by a contractor or someone on his or her staff who does have the experience. Complementary to the RSO, the CT 2 DP proposes that the remediation contractor will also have a manager responsible for implementing radiation protection, environmental protection, and occupational health and safety [ref. DP §9.1.6]. The CT 2 DP further proposes requisite qualifications for this contractor RPHS Manager [ref. CT 2 DP §9.3.5, p. 9-6] that it interprets should be sufficient to satisfy NRC criteria.

CT 2 DP, §9.1.3 and §9.3.2 are being revised to provide information requested in this item and to align with the revised organization chart, Figure 9-1.

97. 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.

Response

Mallinckrodt's methodology to review, approve, issue, and modify plans, procedures, and safety work permits is specified in its Administrative Controls Plan (ACP). The ACP also specifies that each user of a procedure, a field instruction, a safety work permit, or final status survey design receive instruction.

To guide implementation of training described in CT 2 DP §9.4, Mallinckrodt's Radiation Safety Plan, §12 "Radiation Safety Training," applies to C-T decommissioning. It specifies that the RSO or Designated Alternate, who during Phase I decommissioning was

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<sup>18</sup> M. Puett, Mallinckrodt, letter to John Buckley; NRC, March 18, 2002

<sup>19</sup> USNRC, *NMSS Standard Review Plan*. NUREG-1727. §9.3.1, Sept. 15, 2000.

the contractor RPHS, determines the potential radiological health hazard associated with a work directive and the commensurate training of participants.

Implementation of administration of directives and training is prescribed in procedures:

- Instructions and Procedures, CT-QA-4.1
- Safety Work Permits, CT-RP-22
- Radiation Protection Training, CT-RP-26

98. 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.

Response

Formal organizational relationships among Mallinckrodt and contractor managers and supervisors are identified in CP §9.1 and Figure 9-1. That decommissioning occurs on the same plant site where Mallinckrodt managers and supervisors are sited is an advantage for interface with contractor supervision. There will be routine meetings between the Mallinckrodt CT project manager and other Mallinckrodt managers, as appropriate, with contractor supervision. These meetings would typically be held on a weekly basis. There will be routine monthly reports on project status and activities.

99. 7. Provide a description of the oversight responsibilities and authority Mallinckrodt will exercise over contractor personnel.

Response

Mallinckrodt's C-T Project Manager is responsible for ensuring that the overall C-T project decommissioning, including work performed by contractors and subcontractors, is accomplished in conformance with the Phase II DP and with applicable health, safety, quality, technical, and contractual requirements. [ref. CT 2 DP §9.1.2]

Mallinckrodt's Radiation Safety Officer is responsible for auditing contractor's compliance with the radiation safety program. The RSO has authority to stop work on any operation he or she believes has potential to threaten the health and safety of personnel, the public, or the environment. [ref. CT 2 DP §9.1.3]

Mallinckrodt's Safety Manager is responsible for ensuring that the C-T Phase II occupational safety program is in conformance with applicable and relevant laws, regulations, and NRC requirements. He or she will audit contractor performance to ensure compliance with the CT Phase II DP. [ref. CT 2 DP §9.1.4]

To assure implementation of representations made in DP §9 "Project Management and Organization," Mallinckrodt's quality assurance policy<sup>20</sup> provides for establishment of project organization. It charges Mallinckrodt's Quality Assurance Manager with monitoring the organization and verifying whether activities affecting license termination data quality are being performed correctly.

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<sup>20</sup> Mallinckrodt. *Quality Assurance Project Plan*. CT-QAP Plan. rev. 1. §1. Management Commitment and Organization, §1.1 Policy.

The Administrative Controls Plan specifies positions responsible for reviewing and approving administrative directives.

100. 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.

Response

CT 2 DP §9.4, "Training," provides that Mallinckrodt will train decommissioning personnel with respect to site-wide industrial safety. The remediation contractor will provide other training, including radiation safety training.

Radiation safety training will address topics listed in CT 2 DP §9.4.2. *Radiation workers* will be trained in these topics and the topics described in 10 CFR Part 19.12.<sup>21</sup>

Mallinckrodt's RSO or Designated Alternate, who during Phase I decommissioning was the contractor RPHS, or may be a training subcontractor will provide radiation safety training [ref. CT 2 DP §9.4]. The contractor Operations Manager is responsible to ensure that field personnel are properly trained to perform their assigned decommissioning tasks. [ref. CT 2 DP §9.1.7].

101. 9. Provide a commitment that the contractor will comply with all radiation safety requirements at the facility.

Response

In its proposed CT Phase II Decommissioning Plan, Mallinckrodt states that the contractor Project Manager will be responsible for assuring field work is conducted in accordance with applicable health and safety requirements. [ref. DP §9.1.5] The DP also provides that the contractor RPHS is responsible to implement safety and environmental protection during decommissioning.

Mallinckrodt's Radiation Safety Plan, §1.1 "Introduction," states:

The purpose of this Radiation Safety Plan is to define the regulations, standards, policies, engineering controls, and/or general radiological work practices which will be utilized at the St. Louis site to ensure the safety of both on-site personnel and members of the general public and of the environment. Applicability extends to all Mallinckrodt employees, contractors, subcontractors, and visitors.

Thereby, the plan intends that administrative directives will expect contractors and subcontractors to comply with radiation safety specifications.

An objective of the Administrative Controls Plan is to ensure that C-T decommissioning is performed safely and in compliance with governing regulations, the NRC license, and the NRC-approved decommissioning plan. Project directives, including procedures, field instructions, safety work permits, and final status survey designs, are instruments by which

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<sup>21</sup> Mallinckrodt. *Radiation Safety Plan*. CT-RS Plan. rev. 2. §12.

by appropriate Mallinckrodt and contractor managers specify actions and prohibitions to direct contract employees to comply with radiation safety requirements.

Table 76. Status of Provision in CT Phase II Decommissioning for NRC Regulation of a Respiratory Protection Program

10 CFR Part 20 Regulation		Provision in CT Phase II DP and or Radiation Safety Plan
10 CFR Part 20 Paragraph Number	Subject of 10 CFR Part 20 Paragraph	
20.1101(b)	Use procedures & engineering controls	DP §10.1.6.1 & RS Plan §4.1.1 specifies practicable use of engineering and administrative control of radioactive material
20.1701	Use process or engineering controls	DP §10.1.6.1 & RS Plan §4.1.1 specifies practicable use of engineering and administrative control of radioactive material DP §8.3.4 & §8.5.3 describe water misting to control dust.
20.1702	Increase monitoring and limit intakes by ..(c) respiratory protection	DP §10.1.6.1 & RS Plan §4.2.1 provide for personal protective equipment, including respiratory protection, when engineering or process control is impractical.
20.1703(a)(1)	Equipment certified by NIOSH/MSHA	DP §10.1.2.3 specifies use of NIOSH-approved respirators. RS Plan §4.2.1 specifies use of NIOSH/MSHA-approved respirators.
20.1703(a)(2)	Equipment not certified by NIOSH/MSHA	Exception for respiratory protection equipment not certified by NIOSH/MSHA is not requested nor mentioned.
20.1703(a)(3)(i)	air sampling	DP §10.1.1 for specifies occupational air monitoring, DP §11.2.5.2 specifies environmental air monitoring, and RS Plan §3.1.2 in part .
20.1703(a)(3)(ii)	Bioassays & surveys	DP §10.1.3 specifies monitoring personnel intake from airborne radioactive material and or bioassay. RS Plan §3.3 specifies conditions for bioassay sampling.
20.1703(a)(3)(iii)	Test respirator for operability	DP §10.1.2.5 & RS Plan §4.5.1
20.1703(a)(3)(iv)	Written procedures	CT-RP-18, CT-RP-38, CT-RP-39, CT-RP-43 for air sampling. Radiation Safety Plan §4.2.1(i) specifies that procedures be written for respirator use. Procedures for respiratory protection against radioactive particulate will be written and approved for use before implementation.

10 CFR Part 20 Regulation		Provision in CT Phase II DP and or Radiation Safety Plan
10 CFR Part 20 Paragraph Number	Subject of 10 CFR Part 20 Paragraph	
20.1703(a)(3)(v)	Fit Testing	DP §10.1.2.1 specifies medical exam and DP §10.1.2.2 specifies respirator fit testing. RS Plan §4.3 specifies medical qualification and fit testing for respirator use.
20.1703(a)(4)	Policy statement	RS Plan 4.2 represents a policy statement about respiratory protection
20.1703(a)(5)	Notification: relief from respirator use	RS Plan 4.2.1(e) & (f) provide for relief from respirator use.
20.1703(a)(6)	Use of equipment within limitation; communication	DP §10.1.2.3 specifies selection of appropriate respirator type.
20.1703(b)	Allowance for respiratory protection when estimating airborne exposure	Employment of respiratory protection factor to account for respirator limiting inhalation is acceptable in 10 CFR Part 20.1703(b). Before use, accepted factors would be adopted in a written procedure.
20.1703(b)(1)	Conditions for applying a protection factor	Before use, acceptable conditions for application of accepted factors would be adopted in a written procedure.
20.1703(b)(2)	Exception if assigning higher protection factor.	Exemption to assign respirator protection factor > than specified in 10 CFR Parts 20.1001 and 20.2401, Appendix A is not requested in the DP.
20.1703(c)	Equipment to be used in emergency must be certified by NIOSH/MSHA.	RS Plan §4.2.1(d) allows respirator use in an emergency condition. The RS Plan will be revised to specify that respiratory protection equipment be certified by NIOSH/MSHA for emergency use.
20.1703(d)	Notify NRC ≥ 30 days before first using respiratory protection equipment	The Radiation Safety Plan will be revised to specify that, in accordance with 10 CFR Part 20.1703(d), Mallinckrodt's RSO shall notify the NRC at least 30 days before respiratory protection equipment is first used.
20.1704	Allows the NRC to impose further restrictions on use of respiratory protection equipment.	No response is necessary in the DP or the RS Plan since the NRC has not imposed any further restriction.

APPENDIX 77

ANALYSIS OF POTENTIAL FOR AIRBORNE RADIOACTIVE PARTICULATE

The source of regulated radioactive material in air or water in the environment of Plant 5 during C-T decommissioning is mostly in soil that is to be removed by excavation. In this circumstance, uranium series and thorium series radionuclides have been measured in the cinder fill soil during characterization surveys. Complete survey data are reported in CT Phase II Decommissioning Plan, §4 Radiological Status of the Facility.

For the purpose of estimating potential airborne source material, soil core characterization data were filtered to eliminate all samples in which concentration was  $\leq$  Ra<sup>226</sup> mean concentration + 1.28 std dev (= 5.44 pCi/g soil) and remaining data were filtered to eliminate all samples in which concentration was  $\leq$  Th series average concentration + 1.28 std dev (= 2.16 pCi/g soil). That would admit about 10% of data likely to include background radioactivity, which would be a reasonable overlap with background for the purpose of analyzing air samples.

The geometric mean ratios of key U series radionuclides to Th series, as a basis, observed in these data are:

Relationship	Geometric Mean of Ratios
U series -to- Th series	3.0
U <sup>238</sup> -to- Th series	1.4
Th <sup>230</sup> -to- Th series	1.7
Ra <sup>226</sup> -to- Th series	4.0

The DAC for this mixture of U series and Th series radionuclides =  $9.4 \times 10^{-12}$   $\mu\text{Ci}/\text{cm}^3$  air. The portions of this DAC attributable to the parents, U<sup>238</sup> and Th<sup>232</sup>, also the lowest specific radioactivity and presenting the dominant mass among U series and Th series radionuclides potentially becoming airborne are:

$$\begin{aligned} \text{U}^{238} \text{ DAC} &= 8.8 \times 10^{-13} \mu\text{Ci}/\text{cm}^3 \text{ air} \\ \text{Th}^{232} \text{ DAC} &= 6.3 \times 10^{-13} \mu\text{Ci}/\text{cm}^3 \text{ air} \\ \text{U}^{238} + \text{Th}^{232} \text{ DAC} &= 1.5 \times 10^{-12} \mu\text{Ci}/\text{cm}^3 \text{ air} \end{aligned}$$

Oztunali<sup>22</sup> estimated the mass loading of dust in air during construction activity to be about 600  $\mu\text{g}/\text{m}^3$  air. For the purpose of estimating potential airborne concentration of U<sup>238</sup> + Th<sup>232</sup> and their progeny in air during Phase II decommissioning, soil would be assumed to be the source of airborne dust. What U<sup>238</sup> + Th<sup>232</sup> concentration in soil, if suspended in air at 600  $\mu\text{g}/\text{m}^3$ , would produce  $1.5 \times 10^{-12}$   $\mu\text{Ci}/\text{cm}^3$  air, the portion of

<sup>22</sup> Ostunali, O.I., *et.al.*, Data Base for Radioactive Waste Management, Impacts Analyses Methodology Report., NUREG/CR-1759, 3, also reported in Yu, C. *et.al.*, Data Collection Handbook to Support Modeling the Impacts of Radioactive Material in Soil, ANL/EAIS-8, p. 110.

DAC attributable to  $U^{238} + Th^{232}$ , thereby corresponding to  $9.4 \times 10^{-12} \mu\text{Ci}/\text{cm}^3$  air, the DAC for the composite of U series and Th series radionuclides?

$$C_{U^{238}+Th^{232}} \frac{\text{pCi}}{\text{g soil}} \times \frac{1 \text{ g}}{10^6 \mu\text{g}} \times 600 \frac{\mu\text{g soil}}{\text{m}^3 \text{ air}} \times \frac{1 \mu\text{Ci}}{10^6 \text{ pCi}} \times \frac{1 \text{ m}^3}{10^6 \text{ cm}^3} = 1.5 \times 10^{-12} = \text{DAC}_{U^{238}+Th^{232}}$$

$$C_{U^{238}+Th^{232}} = 2.5 \times 10^3 \frac{\text{pCi } U^{238} + Th^{232}}{\text{g soil}}$$

This would be greater than any measurement of  $U^{238} + Th^{232}$  observed in a soil sample during CT characterization surveys. Therefore, it would be unlikely that source material concentration in occupational air would be as much as one DAC, and unlikely that respiratory protection equipment will be needed.

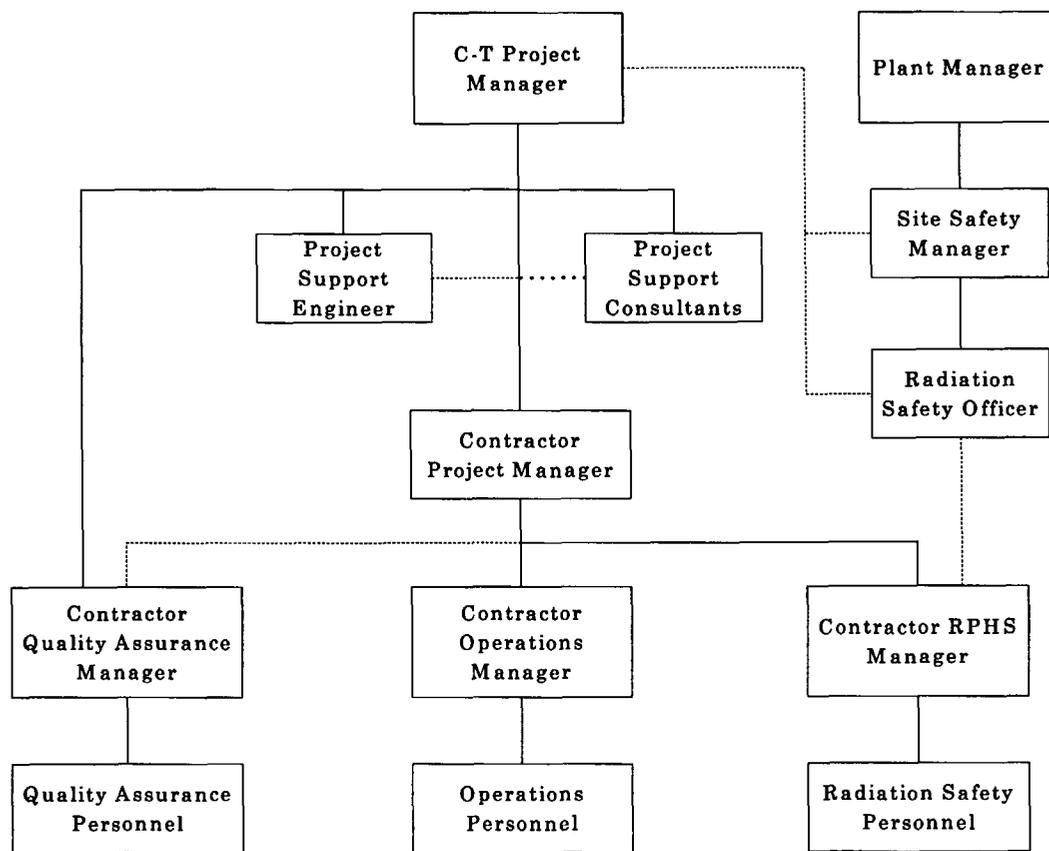


Figure 9-1. C-T Phase II Decommissioning Organization