

June 10, 2015

Mr. Dana Stalcup, Director  
Division of Assessment and Remediation  
Office of Superfund Remediation  
and Technology Innovation  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Mail Code: 5204P  
Washington, DC 20460

SUBJECT: MEMORANDUM OF UNDERSTANDING CONSULTATION ON THE  
DECOMMISSIONING OF THE MALLINCKRODT SITE, ST. LOUIS,  
MISSOURI

Dear Mr. Stalcup:

This letter is intended to inform you of the decommissioning oversight actions that the U.S. Nuclear Regulatory Commission (NRC) has taken, and intends to take, for the Mallinckrodt LLC site, located in St. Louis, Missouri.

On October 9, 2002, the NRC and the U.S. Environmental Protection Agency (EPA) entered into a Memorandum of Understanding (MOU) on "Consultation and Finality on Decommissioning and Decontamination of Contaminated Sites." Under the MOU, EPA agreed to continue its Comprehensive Environmental Response, Compensation, and Liability Act deferral policy of not listing sites on the National Priorities List that are subject to NRC's licensing authority. The MOU provides that, unless an NRC-licensed site exceeds any of the three trigger criteria contained in the MOU, EPA agrees to a policy of deferral to NRC decision-making on decommissioning without the need for consultation.

For sites that trigger the criteria in the MOU, NRC will consult with EPA at two points in the decommissioning process: (1) prior to NRC approval of the license termination plan or decommissioning plan (DP), which NRC terms Level 1 consultation; and (2) following completion of the final status survey (FSS), which NRC terms Level 2 consultation.

The NRC is sending this letter to notify you that the Mallinckrodt site requires a Level 2 consultation because the average concentrations of Ra-226 reported in Mallinckrodt's FSS (Agencywide Documents Access and Management System [ADAMS] Accession No. ML14177A180) are slightly above the MOU trigger values in a small number of survey units. The NRC previously held a Level 1 consultation with EPA because Mallinckrodt's Phase II DP (ADAMS Accession Nos. ML083150652, ML101620140) included derived concentration guideline levels (DCGLs) that exceeded the soil concentration values in Table 1 of the MOU for U-238, total uranium, Th-232, and Ra-226. NRC sent a Level 1 consultation letter to EPA on June 22, 2009 (ADAMS Accession No. ML091460665), EPA provided comments to the NRC on September 9, 2009 (ADAMS Accession No. ML092800105), and NRC responded to EPA's recommendations on October 21, 2009 (ADAMS Accession No. ML092810106).

As described in more detail in the enclosure, 3 of the 19 survey units have average concentrations that are slightly above the MOU trigger value for Ra-226 (average concentrations of 6.5, 9.1, and 6.9 pCi/g as compared to the MOU trigger value of 5 pCi/g). These average concentrations are based on the systematic samples taken at the surface at the excavation, which in most cases is below the ground surface. Two survey units also had average systematic core sample concentrations that were above the MOU trigger value (average concentrations of 5.3 and 6.0 pCi/g). The average concentrations of Ra-226 from the systematic and systematic core samples are below the DCGL value of 29.4 pCi/g approved for Ra-226 by the NRC in all survey units. The concentrations are also below the cleanup values for Ra-226 documented in the record of decision (ROD) for portions of the Mallinckrodt site being remediated under the Formerly Utilized Sites Remedial Action Program (FUSRAP) by the U.S. Army Corps of Engineers (USACE). The cleanup values being used by USACE for Ra-226 are 15 pCi/g and 50 pCi/g at depths greater than 15 cm and greater than 4 ft (1.21 m), respectively. The average concentrations of U-238, total uranium, and Th-232 were below both the EPA MOU trigger values and the NRC approved DCGL values for all survey units.

Mallinckrodt identified 23 areas of elevated activity in 11 of the Survey Units. These areas are located below the ground surface at depths ranging from 0.167 m to 4 m. Mallinckrodt submitted a license amendment request to the NRC to use the dose assessment approach in addition to the DCGL approach in demonstrating compliance with the NRC's criteria for unrestricted release. Mallinckrodt performed dose assessments to evaluate the projected dose in the survey units containing elevated areas. Mallinckrodt used the same parameters for these dose assessments as were used in the DP and were approved by the NRC during the DP review. The projected doses calculated by Mallinckrodt for these areas are all below the NRC criteria for unrestricted release.

In the September 9, 2009 letter from EPA to the NRC, EPA stated that:

In EPA's view, if the licensee is unable to meet the Table 1 soil values, NRC should consider the use of a more restricted land use and appropriate institutional controls. In addition, NRC should consider determining if the use of site-specific parameters was justified in modeling at this site. The use of site-specific parameters would not alter NRC's obligation to possibly trigger a Level 2 consultation, if Table 1 soil values were found to be exceeded after the Final Status Survey measurements. If a Level 2 consultation is needed, NRC should furnish any site-specific parameters used and their rationale for allowing their use during the dose assessment for the site, in order to facilitate EPA offering its views with a more accurate estimate of the risks posed by residual contamination at the site.

The site-specific parameters used by Mallinckrodt in the development of their DCGL values, as well as the basis for these parameters, are documented in Mallinckrodt's DP (ADAMS Accession Nos. ML083150652, ML101620140). The NRC staff performed an extensive review of these parameters during the DP approval process. The NRC's evaluation is documented in a safety evaluation report (SER) (ADAMS Accession Nos. ML101670444, ML091831289). In this SER, the NRC staff concluded that the proposed DCGL values in the DP do not pose an adverse impact to public health and safety, or the environment. During this review, the NRC

staff also determined that the licensee provided adequate information to justify an industrial scenario as the most likely land use in the foreseeable future. Thus, the NRC staff concluded that an industrial scenario is the appropriate land use for demonstrating compliance with the requirements in Title 10 of the *Code of Federal Regulations* (10 CFR), Part 20, Subpart E.

The NRC staff is in the process of reviewing Mallinckrodt's FSS reports to confirm that the FSS was performed in accordance with the DP, the survey unit concentrations are consistent with the approved DCGL values, and that the dose assessments for the elevated areas were performed appropriately. If the NRC staff confirms that these items are acceptable, the NRC staff will conclude that the site meets NRC's criteria for unrestricted release in 10 CFR 20.1402 and will terminate Mallinckrodt's license. The NRC staff intends to complete its review by September 2015.

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

If EPA believes that unresolved issues remain regarding the Mallinckrodt site, please contact Andrew Persinko, Deputy Director, Division of Decommissioning, Uranium Recovery, and Waste Programs, at (301) 415-7479.

Sincerely,

**/RA/**

Larry W. Camper, Director  
Division of Decommissioning, Uranium Recovery,  
and Waste Programs  
Office of Nuclear Material Safety  
and Safeguards

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

Enclosure:  
Background Information for Mallinckrodt  
Site

cc: Mallinckrodt Distribution List

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## **Background Information for Mallinckrodt Site**

### Background

Mallinckrodt has been operating at the St. Louis Plant since 1867, producing various products, including metallic oxides and salts, ammonia, organic chemicals, and various uranium compounds. The St. Louis Plant, comprised of over 50 buildings on approximately 43 acres, is subdivided into smaller areas, called plants, based on the similarity of operations being performed.

Between 1942 and 1958, uranium processing and waste management activities were conducted by Mallinckrodt in support of early Federal government programs to develop atomic weapons under the Manhattan Engineer District and later the Atomic Energy Commission (MED/AEC). These activities resulted in radiological contamination on Mallinckrodt property and properties adjacent to the site. The contamination at these locations consists of natural uranium and natural thorium and their associated progeny, including thorium-230 and radium. MED/AEC contamination is present in groundwater, soils, and structures. Under the authority of the Formerly Utilized Sites Remedial Action Program (FUSRAP), the U.S. Army Corps of Engineers (USACE) is remediating contamination at the site resulting from past MED/AEC activities. In accordance with the USACE Record of Decision, no remedial action is required for groundwater beneath the site. USACE will conduct perimeter monitoring of the groundwater in the Mississippi River alluvial aquifer, and will evaluate the need for groundwater remediation as part of the periodic reviews performed for the site.

In 1961, Mallinckrodt was issued License No. STB-401 to extract columbium and tantalum (C-T) from natural ores and tin slags. From 1961 to 1985, Mallinckrodt purchased and processed materials for C-T production. These ores and processed byproduct materials contained uranium and thorium isotopes. C-T processing was shut down from 1985 through early 1987, when Mallinckrodt began a two month pilot production run. During the pilot production run, approximately 20,000 pounds of tin slags were processed. In July 1993, NRC amended Mallinckrodt's license to a possession only license for decommissioning and license termination.

Mallinckrodt elected to decommission the C-T project areas of the site in two phases. In Phase I, Mallinckrodt decommissioned the buildings and equipment to the extent necessary to meet the NRC's guidelines for unrestricted release in 10 CFR 20.1402. Phase I of the decommissioning project was completed in February 2007. Mallinckrodt's Phase II decommissioning plan (DP) described Mallinckrodt's plan for decommissioning the remainder of the C-T project areas to meet the criteria for unrestricted release. Phase II included the remediation of radiologically contaminated pavement, soils, and sewers. NRC approved Mallinckrodt's Phase II DP on July 1, 2010 (ADAMS Accession No. ML091960063).

Mallinckrodt performed remediation of the C-T project areas based on their Phase II DP and provided the NRC with a Final Status Survey (FSS) report documenting the residual radioactivity remaining on site (ADAMS Accession No. ML14177A180). In response to an NRC Request for Additional Information (RAI), Mallinckrodt provided additional information regarding

their FSS and associated dose assessments (ADAMS Accession No. ML14339A278). In addition, Mallinckrodt submitted a license amendment application requesting the use of the dose assessment approach as well as the Derived Concentration Guideline Level (DCGL) approach (ADAMS Accession No. ML15063A404). NRC guidance in NUREG-1757 allows for the use of either approach in demonstrating compliance with NRC unrestricted release in 10 CFR 20.1402.

#### Mallinckrodt's Decommissioning Criteria

The NRC criteria for unrestricted release in 10 CFR 20.1402 are that the all-pathways dose to an average member of the critical group criteria is no more than 0.25 mSv per year (25 mrem per year) and is as low as reasonably achievable (ALARA). Mallinckrodt derived site-specific DCGL values, which correspond to a dose of 0.25 mSv per year (25 mrem per year), based on an industrial scenario. As noted in NRC's October 21, 2009 letter to EPA (ADAMS Accession No. ML092810106), the NRC staff determined that the licensee provided adequate information to justify an industrial scenario as the most likely land use in the foreseeable future.

As part of the review of Mallinckrodt's DP, the NRC staff performed an extensive review of the dose modeling performed in the generation of the DCGL values and generated a safety evaluation report (ADAMS Accession No. ML091831289). This review included an evaluation of the scenario selected, the parameter values used, as well as independent calculations to confirm those done by Mallinckrodt.

The DCGL values generated by Mallinckrodt, and approved by the NRC are provided in Table 1. The EPA MOU values for the industrial scenario and the release criteria being used by USACE for the cleanup of the FUSRAP portions of the Mallinckrodt site, as specified in the Record of Decision, are also provided in Table 1 as a comparison.

**Table 1 Comparison of Release Criteria to EPA MOU Values**

	<b>Th-232 (pCi/g)</b>	<b>Ra-226 (pCi/g)</b>	<b>U-238 (pCi/g)</b>	<b>Total Uranium (mg/kg)</b>
Mallinckrodt's DCGL value *	23.9	29.4	721	2480
EPA MOU (Industrial)	5	5	179	1230
USACE Release Criteria (0 to 15 cm)	5	5	50	
USACE Release Criteria (15 cm to 1.21 m [4 ft])	15	15	50	
USACE Release Criteria (>1.21 m [4 ft])	100	50	150	

\* DCGL of thorium series is referenced to Th-232, DCGL of Th-230, Ra-226 and Pb-210 is referenced to Ra-226, and DCGL of natural uranium is referenced to U-238

As part of the FSS report, Mallinckrodt provided dose assessments for areas of elevated activity. Mallinckrodt intends to use the dose assessment approach instead of the DCGL approach in demonstrating compliance with 10 CFR 20.1402 for those areas with elevated concentrations. Mallinckrodt used the same parameters in these dose assessments as were used in the generation of DCGL values for the DP, with the exception of parameter values associated with the physical configuration of the residual contamination (i.e., area, thickness, and cover depth) and concentration of the radionuclides. Two scenarios were considered in the dose assessments of the elevated concentration areas – an *in situ* assessment and an excavation scenario. The *in situ* scenario represents the dose from the elevated concentration area in its current configuration. The excavation scenario was evaluated to bound the dose to an individual who may be exposed to the material through excavating into the elevated concentration area for activities such as pipe installation or constructing new building footers.

#### Residual Radioactivity in Soil at Mallinckrodt Site

Mallinckrodt performed a final status survey on 22 survey units for soil, five survey units for pavement, and one survey unit for the sewers. In the Class 1 soil survey units, systematic soil samples were taken based on MARSSIM guidance. These samples were taken of the soil surface at the point where excavation ended, but before backfilling. In many cases these samples were taken below the ground surface and represent soil located at depth. The average measured activities in each survey unit, as well as the overall average of the systematic samples, are presented in Table 2 below. Mallinckrodt measured the concentrations in the samples using both an on-site lab as well as an off-site lab. The averages in the table below are based on the off-site lab data when available. The concentrations in the table include background. Mean background activity levels of 1.3, 2.5, and 4.4 pCi/g were measured for Th-232, Ra-226, and U-238, respectively.

**Table 2 Summary of Survey Unit Average Concentrations based on Systematic Samples**

Survey Unit	Th-232 (pCi/g)	Ra-226* (pCi/g)	U-238 (pCi/g)	Total Uranium (mg/kg)
1	1.3	2.4	2.7	8
2	1.3	3.4	3.8	11
3	1.4	4.0	4.1	12
4	1.6	3.1	3.7	11
5	4.6	<b>6.5</b>	4.3	13
6	2.6	3.3	3.7	11
7	1.5	2.4	2.6	8
8	1.5	1.7	1.9	6
9	1.4	1.5	1.6	5
10	1.6	3.7	9.6	29
11**	1.1	2.8	9.4	28
12	2.7	<b>9.1</b>	9.0	27
14	1.7	4.4	4.9	15
15	1.8	2.7	3.0	9
16	1.3	1.7	1.8	6
17	1.4	1.9	2.0	6
19	1.8	<b>6.9</b>	7.5	22
20	3.3	1.9	2.1	6
22	1.3	3.5	30	91
Overall Average for Systematic Samples	1.9	3.5	5.7	17

\* Bold numbers represent activities that exceed the EPA MOU values

\*\* Average does not include does not include sample S07 because the elevated area associated with the sample was removed (Section 17.1.3 in FSS)

The overall average concentrations for Th-232, Ra-226, U-238, and total uranium from the systematic samples were less than the EPA MOU values. Additionally, the individual survey unit averages were less than the EPA MOU values for Th-232, U-238, and total uranium. Sixteen of the survey unit average concentrations were below the MOU value for Ra-226, while three were slightly above the MOU value (Survey Units 5, 12, and 19). The measurements in Survey Units 5 and 19 were all taken at a depth of at least 4 ft (1.21 m) below ground surface. In addition, all but two of the samples above the MOU value for Ra-226 in Survey Unit 12 were taken at a depth of at least 6 ft (1.82 m) below ground surface.

In Class 1 survey units where additional subsurface contamination below the excavation was suspected, systematic core samples were also taken (Survey Units 10, 11, 12, and 22). Additionally, systematic core samples were taken in Survey Unit 13, a Class 2 survey unit. The average concentrations in these samples in these survey units are below the MOU values for Th-232, U-238, and total uranium. The average concentration of Ra-226 in the systematic core

samples is below the MOU value for Survey Units 10, 11, and 22, while the average concentration is slightly above the MOU value for Survey Units 12 and 13.

**Table 3 Summary of Survey Unit Average Concentrations from Systematic Core Samples**

Survey Unit	Th-232 (pCi/g)	Ra-226* (pCi/g)	U-238 (pCi/g)	Total Uranium (mg/kg)
10	1.3	3.5	5.3	16
11**	1.8	4.3	5.9	18
12	1.8	<b>6.0</b>	7.4	22
13	1.6	<b>5.3</b>	5.6	17
22	1.3	3.1	27	82

\* Bold numbers represent activities that exceed the EPA MOU values

\*\* Average does not include does not include sample S07 because the elevated area associated with the sample was removed (Section 17.1.3 in FSS)

Systematic samples were not taken at the surface in the Class 2 or 3 survey units. However, systematic core samples were taken in Survey Unit 13, a Class 2 survey unit. As can be seen in Table 3, the Th-232, U-238, and total uranium concentrations are below the MOU value, while the Ra-226 concentration is slightly above for Survey Units 12 and 13. Survey Unit 18, a Class 2 survey unit, had one elevated area identified as noted in Table 4 below. Historic characterization of the remainder of Survey Unit 18 and Survey Unit 21, a Class 3 Survey Unit, shows concentrations that are below the EPA MOU values.

During the FSS, Mallinckrodt identified 23 areas of elevated activity in 11 of the Survey Units. Dose assessments of the activity were performed by Mallinckrodt for the *in situ* scenario for each of these elevated areas. The projected doses were less than the NRC criteria for unrestricted release for all survey units (Table 4). Additionally, Mallinckrodt evaluated the dose to a worker who is exposed to elevated activity that is located at depth. In this evaluation, Mallinckrodt considered the potential dose from Elevated Area 1 in SU-05, Elevated Area 2 within SU-20, and Elevated Area 1b within SU-22. These elevated areas were selected for evaluation based on the potential for these areas to cause the highest doses and based on the likelihood of intrusion into these areas based on their depth. The projected doses were 1.15 mrem/yr, 2.5 mrem/yr, and 0.072 mrem/yr for Elevated Area 1 in SU-05, Elevated Area 2 within SU-20, and Elevated Area 1b within SU-22, respectively.

**Table 4 Summary of Elevated Area Projected *In Situ* Doses**

Survey Unit	Elevated Area	Thickness (m)	Area (m <sup>2</sup> )	Cover (m)	Th-232 (pCi/g)	Ra-226 (pCi/g)	U-238 (pCi/g)	Dose (mrem/yr)
1	Elevated Area 1	0 to 1	6 to 10	0.333	0.0	27.5	112	3.2
	Average Survey Unit							0.5
	<b>Total Dose</b>							<b>3.7</b>
2	Elevated Area 1	0 to 1	10 to 29	1.21	2.4	37.8	39.1	0.9
	Average Survey Unit							1.0
	<b>Total Dose</b>							<b>1.9</b>
5	Elevated Area 1	0 to 1	35 to 55	1.21	37.1	22.1	16.5	3.6
	Elevated Area 2	0 to 1	15 to 22	1.21	14.2	4.0	21.7	1.2
	Average Survey Unit							2.3
	<b>Total Dose</b>							<b>7.1</b>
6	Elevated Area 1	0 to 1	8 to 16	1.21	23.1	27.9	14.5	2.1
	Elevated Area 2*	0 to 0.333	1 to 3	4	707	2125	411	5.3E-11
	Average Survey Unit							2.5
<b>Total Dose</b>							<b>4.6</b>	
10	Elevated Area 1	0 to 1	5	1.21	25.2	3.5	11.2	1.2
	Average Survey Unit							2.0
	<b>Total Dose</b>							<b>3.2</b>
11	Elevated Area 1*	0 to 0.03	4	1.21	104	146	33.8	0.2
	Elevated Area 2	0 to 2	13 to 20	3	27.3	84.9	37.9	8.1E-08
	Elevated Area 3	0 to 4	25 to 50	1.61	64.3	76.4	15.7	0.2
	Average Survey Unit							1.3
	<b>Total Dose</b>							<b>1.6</b>
12	Elevated Area 1	0 to 1.5	18	1.61	23.5	257	11.4	0.1
	Elevated Area 2	0 to 1	320 to 500	3.5	5.9	32.0	25.2	1.4E-10
	Elevated Area 3*	0 to 1	8 to 16	2.35	18.8	131	13.0	2.7E-05
	Elevated Area 4	0 to 0.3048	1 to 3	0.167	3.3	67.2	3.9	1.6
	Average Survey Unit							5.5
<b>Total Dose</b>							<b>7.2</b>	

Survey Unit	Elevated Area	Thickness (m)	Area (m <sup>2</sup> )	Cover (m)	Th-232 (pCi/g)	Ra-226 (pCi/g)	U-238 (pCi/g)	Dose (mrem/yr)
18	Elevated Area 1 surface	1	75	0	1.4	23.4	7.2	17.0
	Elevated Area 1 subsurface	4	75	1	3.7	158	7.0	2.6E-03
	<b>Total Dose</b>							<b>17.0</b>
19	Elevated Area 1	0 to 0.3048	13 to 30	4	5.1	30.6	26.2	7.0E-13
	Average Survey Unit							2.8
	<b>Total Dose</b>							<b>2.8</b>
20	Elevated Area 1	0 to 0.333	30 to 60	4	17.6	22.1	12.6	2.6E-12
	Elevated Area 2	0 to 3	18 to 36	1.61	140.5	287.9	29.5	0.4
	Elevated Area 3	0 to 0.333	1 to 3	4	59.6	218.9	4.2	3.1E-12
	Average Survey Unit							0.8
	<b>Total Dose</b>							<b>1.2</b>
22	Elevated Area 1a	0 to 1	13	0.167	0.1	28.2	7.6	5.2
	Elevated Area 1b	0 to 1	6 to 18	0.333	28.4	5.2	18.2	13.1
	Elevated Area 2	0 to 1	1 to 3	1.21	0.2	58.4	19.4	0.7
	Elevated Area 3	0 to 1	1 to 3	1.21	0.2	122.5	57.2	0.8
	Average Survey Unit							2.0
	<b>Total Dose</b>							<b>21.7</b>

\* inside buried pipe

## Conclusions

The overall average concentrations for Th-232, Ra-226, U-238, and total uranium from the systematic samples were less than the EPA MOU values. Additionally, the individual survey unit averages were less than the EPA MOU values for Th-232, U-238, and total uranium. Most of the survey unit average concentrations were below the MOU value for Ra-226. In the three survey units that had average concentrations above the MOU value for Ra-226, the measurements that were above the MOU value represent samples that are at least 4 ft (1.21 m) below ground surface, with the exception of two samples. Two of the survey units also had average activities of Ra-226 that were slightly above the MOU value in the systematic core samples. The maximum average activity in these survey units was 6 pCi/g.

The maximum average value for Ra-226 in the survey units was 9.1 pCi/g, which is not significantly above the MOU value of 5 pCi/g for Ra-226. This activity is also below the cleanup values of 15 pCi/g and 50 pCi/g being used for Ra-226 by USACE, as documented in the ROD, for other portions of the site at depths greater than 0.5 ft (15 cm) and greater than 4 ft (1.21 m), respectively.

Mallinckrodt performed dose assessments to evaluate the potential dose from elevated areas of contamination. Most of these areas are located at a depth of more than 1 m. The projected doses calculated by Mallinckrodt were less than the NRC unrestricted release criteria for all of the survey units containing elevated concentration areas.