**OFFICE OF NUCLEAR MATERIAL SAFETY
AND SAFEGUARDS
SAFETY EVALUATION REPORT
REVIEW OF FINAL STATUS SURVEY REPORT
FOR THE MALLINCKRODT SITE IN ST. LOUIS, MISSOURI
LICENSE NO. STB-401 DOCKET NO. 40-6563
MALLINCKRODT, LLC.
ST. LOUIS, MISSOURI**

## 1. Background

Mallinckrodt has been operating at the St. Louis Site since 1867. During this period of operation, products included metallic oxides and salts, ammonia, organic chemicals, and various uranium compounds. The St. Louis Site, comprised of over 50 buildings on approximately 43 acres, is subdivided into smaller areas, called plants, based on the similarity of operations being performed (Figure 1-1).

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 occurring uranium and thorium and their associated progeny. 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.

Mallinckrodt received Source Materials License No. STB-401 from the AEC in 1961 to extract columbium and tantalum from natural ores and tin slags. In July 1993, the NRC amended Mallinckrodt's license to a possession only license for the purpose of decommissioning and license termination. Although Columbium-Tantalum (C-T) process operations were performed in an area called Plant 5 at the Mallinckrodt site, support activities were conducted in portions of Plants 1, 3, 6, 7, and 8. The contamination due to licensed activities also consists of natural uranium and natural thorium and their associated progeny.

The portions of the site associated with NRC licensed activities are being remediated under the U.S. Nuclear Regulatory Commission's (NRC) Source Materials License STB-401 in accordance with the NRC's regulations. A description of the areas of the site associated with licensed activities and their status is provided in Table 1-1. Mallinckrodt decommissioned the C-T project areas of the site in two phases. Phase I addressed the buildings. Phase II addressed contaminated soil, pavement and piping including sewers. In Phase I, Mallinckrodt decommissioned the buildings and equipment to the extent necessary to meet the NRC's guidelines for unrestricted release in accordance with 10 CFR 20.1402. During Phase I, most of the decommissioning activities occurred within Plant 5. However, C-T support areas in Plants 3, 6, and 8 were also included in Phase I. Additional C-T support buildings in Plants 1, 6,

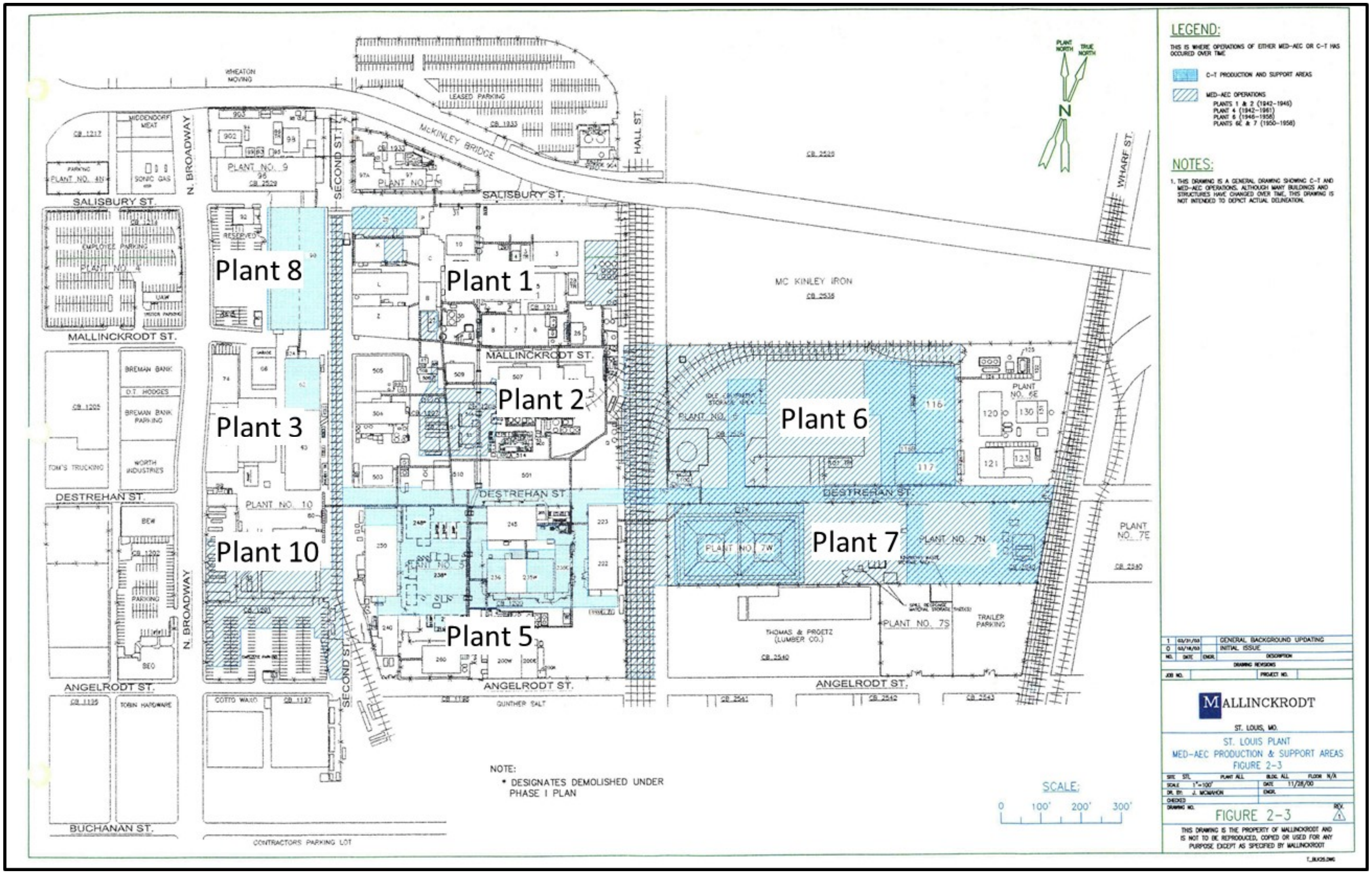

**Figure 1-1 Map of the Mallinckrodt Site (based on Figure 2-3 in the Mallinckrodt Phase II DP)**

**Table 1-1 Status of Areas of the Mallinckrodt Site Associated with Licensed Activities**

| Area | Status |
|---|---|
| Plant 5 Buildings,<br>Building 62 in Plant 3,<br>Buildings 90 and 91 in Plant 8,<br>Incinerator and Building 101 roof in Plant 6 | • Mallinckrodt performed remediation during Phase I decommissioning |
| Building 25 in Plant 1,<br>Buildings 116 and 117 in Plant 6<br>Buildings 700, 704, 705, 706, and 708 in Plant 7 | • Remediated by USACE under FUSRAP |
| Plant 5 soil, pavement, and sewers | • Mallinckrodt performed remediation during Phase II decommissioning |
| Plant 6 | • Mallinckrodt and USACE entered into a delineation agreement to establish remediation responsibilities<br>- Mallinckrodt was responsible for removing buried URO<br>- Remainder of plant is being remediated by USACE under FUSRAP |
| Plant 7 | • Wastewater treatment basin liner was removed by Mallinckrodt and pavement and piping were surveyed as part of FSS for Phase II Decommissioning<br>• Mallinckrodt and USACE entered into a delineation agreement to establish remediation responsibilities<br>- Mallinckrodt was responsible for removing grit chamber<br>- Remainder of plant is being remediated by USACE under FUSRAP |

and 7 were addressed by USACE under FUSRAP. Mallinckrodt submitted the C-T Project Phase I Decommissioning Plan (DP) to the NRC on November 20, 1997. The Phase I Plan was approved by the NRC on May 3, 2002 (ADAMS Accession No. ML021230256). Phase I of the decommissioning project was completed in February 2007 (ML070530675).

Following Phase I decommissioning, the C-T areas remaining for remediation were limited to the soil, pavement, and sewers in Plant 5 as well as portions of Plant 6 and 7. Mallinckrodt's Phase II DP (ML083150652), as revised on June 3, 2010 (ML101620140), described Mallinckrodt's plan for decommissioning the remainder of the C-T project areas to meet the criteria for unrestricted release. The remediation of portions of Plants 6 and 7 was not included in the DP, but was addressed separately as described below. The NRC approved Mallinckrodt's Phase II DP on July 1, 2010 (ML091960063).

Plants 6 and 7 contained residual contamination from both licensed activities and MED/AEC activities. The MED/AEC activities in Plants 6 and 7 resulted in contamination in buildings and soil in these plants. Additionally, in Plant 6, approximately 300 cubic yards of unreacted ore (URO) generated as part of the C-T process was buried in 10 trenches in 1972 and 1973. Plant 7 contained sewers, a grit chamber, and two wastewater neutralization basins that were used to support C-T operations.

Mallinckrodt and USACE entered into two agreements to delineate remediation responsibilities in Plants 6 and 7. Mallinckrodt's responsibilities included the removal of the buried URO in Plant 6 and the removal of the grit chamber in Plant 7. The removal of the URO was authorized by the NRC in a license amendment on May 12, 2008 (ML080940414). Mallinckrodt completed removal of URO in Trenches 1-6 in August 2008, Trenches 7-9 in November 2009, and Trench 10 in April 2013. Mallinckrodt completed removal of the grit chamber in February 2015. On February 9, 2015, USACE provided Mallinckrodt with a letter acknowledging that Mallinckrodt had completed the removal of the URO and grit chambers and stating that the USACE was proceeding with remediation of these areas under FUSRAP (ML15090A705).

Mallinckrodt's Phase II DP requested that the NRC terminate its license in accordance with 10 CFR 20.1402 without accounting for MED/AEC contamination in demonstrating compliance with the dose limits in 20.1402. In its approval of the Phase II DP (ML091960087), the NRC exempted the MED/AEC material from consideration in demonstrating compliance. Without this exemption, the staff could not terminate Mallinckrodt's STB-401 license until USACE completes remediation of MED/AEC required to meet USACE's cleanup criteria. The basis for granting the exemption was: (1) Mallinckrodt will meet 25 mrem/yr unrestricted release criteria for C-T process areas; and (2) unlicensed MED/AEC material is being remediated to NRC unrestricted release standards of 25 mrem/yr by USACE.

The dose from the residual radioactivity at the site is primarily from the direct radiation pathway, therefore the NRC concluded that an individual would not simultaneously receive a dose from both areas (the C-T process areas, and the MED/AEC areas). Therefore, if USACE and Mallinckrodt independently demonstrate that the MED/AEC and C-T process areas, respectively, meet NRC's unrestricted release criteria, then the entire site would meet NRC's unrestricted release criteria at completion of site decommissioning activities. The staff therefore concluded that it is reasonable to terminate License STB-401 after Mallinckrodt completes decommissioning activities in the C-T process areas and demonstrates that the C-T process areas at the site meet NRC's unrestricted release criteria (10 CFR 20.1402). Mallinckrodt's method for demonstrating that the NRC's unrestricted release criteria was met was through the performance of a Final Status Survey (FSS). This finding is based in part on USACE's commitment to remediation of the site under FUSRAP. At the time, Mallinckrodt and USACE had reached an agreement regarding delineation of responsibility for remediating Plant 6, but had not yet agreed on the delineation of responsibility for Plant 7. Therefore the exemption was conditioned on Mallinckrodt and USACE reaching a delineation agreement for Plant 7 before decommissioning was complete. Mallinckrodt and USACE entered into a delineation agreement for Plant 7 on October 31, 2014 (Cover Letter available at ADAMS Accession No. ML15041A076).

## 2. Final Status Survey Approach

Mallinckrodt performed remediation of the C-T project areas based on their Phase II DP and provided the NRC with a Final Status Survey Report (FSSR) documenting the residual radioactivity remaining on-site for which Mallinckrodt was responsible (ML14177A180). Mallinckrodt used two decommissioning contractors, AECOM and EnergySolutions, to perform remediation and the FSS of the C-T project areas.

In response to an NRC Request for Additional Information (RAI), Mallinckrodt provided additional information regarding their FSS and associated dose assessments (ML14339A278). Mallinckrodt provided additional information following a public teleconference with the NRC (ML15177A051). Mallinckrodt also provided a revised Chapter 6 of the FSSR to the NRC (ML15334A417).

In its FSS report and RAI responses, Mallinckrodt proposed to use the dose assessment approach in addition to the Derived Concentration Guideline Level (DCGL) approach to evaluate the dose from elevated areas. On October 20, 2014, Mallinckrodt submitted an evaluation to the NRC in which Mallinckrodt concluded that a license amendment would not be required in order to use this approach (ML14328A618). The NRC reviewed this evaluation, and on January 16, 2015, the NRC sent a letter to Mallinckrodt stating that it found that a license amendment was required (ML14346A422). On February 12, 2015, Mallinckrodt submitted a license amendment application requesting the use of the dose assessment approach as well as the DCGL approach (ML15063A404). The NRC guidance in NUREG-1757 allows for the use of either approach in demonstrating compliance with the NRC unrestricted release criteria in 10 CFR 20.1402. The NRC approved this license amendment request on February 4, 2016 (ML15286A174).

### 2.1 Site Release Criteria

The NRC criteria for unrestricted release in 10 CFR 20.1402 are that the all-pathways dose from residual radioactivity that is distinguishable from background to an average member of the critical group criteria is no more than 25 mrem/yr and is as low as reasonably achievable (ALARA). Mallinckrodt derived site-specific DCGL values for soil and pavement, which each correspond to a dose of 25 mrem/yr, based on an industrial scenario. The basis for the scenario selection is discussed in more detail in Section 4. The soil $DCGL_W$ values are presented in Table 2.1. A sum of fractions (SOF) approach was used to evaluate whether the total dose from all three groups of radionuclides will be less than 25 mrem/yr. A composite $DCGL_W$ of 1.80 x $10^5$ $\beta/(min \cdot 100\ cm^2)$ was established for pavement.

**Table 2-1 Soil $DCGL_W$ values**

| Radionuclide Group | $DCGL_W$ (pCi/g) | Referenced Radionuclide |
|---|---|---|
| Th-232 | 23.9 | Th-232 |
| Natural Uranium | 721 | U-238 |
| 6 Th-230 + Ra-226 + Pb-210 * | 29.4 | Ra-226 |

* Ra-226 and Pb-210 were assumed to be present in equal amounts, while Th-230 was assumed to be present at a level six times as much based on site characterization data.

## 2.2 Final Status Survey Design

In the Phase II DP, Mallinckrodt committed to conducting a FSS consistent with the approach presented in the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM), to the extent possible. Section 14.4 of the DP includes a description of the planned FSS instrumentation, radionuclide concentration background values, survey methodology, and quality assurance/quality control (QA/QC) methods. The NRC staff reviewed the FSS Design information in Section 14.4 of the DP according to NUREG-1757, Volume 2, Section 4.4 (Final Status Survey Design) as part of its review of the DP. Based on the review, the NRC staff determined that Mallinckrodt's FSS design was adequate to demonstrate compliance with radiological criteria for license termination. The licensee's FSS activities generally followed what was initially planned and approved by the NRC; specific deviations are discussed below.

The licensee's Phase II FSS design was based on the application of a formal data quality objectives (DQOs) process to plan and perform the FSS activities. Application of DQOs helps to ensure that the type, quality, and quantity of data collected are adequate for the intended decision applications.

The licensee utilized the graded approach presented in MARSSIM for survey unit classification. This approach ultimately determines the FSS design for survey units. Table 2-2, reproduced from the Phase II FSSR, summarizes key design elements. However, it is important to note the survey unit maximum size listed in the table for Class 1 and Class 2 areas only applies to land areas and not structural surfaces or paved areas. All "structural" survey units in the C-T Plant area were assigned a Class 3 classification.

**Table 2-2 FSS Design (based on Table 4-1 in Mallinckrodt's FSSR)**

| Parameter | Class 1 | Class 2 | Class 3 |
|---|---|---|---|
| Classification | Areas where, prior to remediation, there existed residual radioactivity above the $DCGL_W$. | Areas where, prior to remediation, there may have existed residual radioactivity, but at levels below the $DCGL_W$. | Areas where there is a low likelihood of residual radioactivity. Previous remediation precludes an area from being classified as a Class 3 area. |
| Survey Unit Maximum Size | 2,000 $m^{2\ (1)}$ | 10,000 $m^2$ | No limit |
| Scan Measurements | 100% | 10% to 100% | 0 to 10% |
| No. of Stationary Measurements | 15 | 15 | 15 |
| Measurement Locations | Random-start, systematic spacing | Random-start, systematic spacing | Random |
| Investigation Level | SOF > 0.5 | SOF > 0.5 | SOF > 0.5 (2) |

Notes:
(1) 3,000 $m^2$ for subsurface material (see C-T Phase II DP, Table 14-4).
(2) Value used in lieu of C-T Phase II DP, Table 14-5 value of 0.1 × DCGL + 95% upper confidence limit of mean concentration of background reference population.

The initial classifications for areas of the C-T Plant were presented in the C-T Phase II DP. All figures presented here are reproduced from the Phase II FSSR. The initial Class 3 designations for the sewer lines (Figure 2-1) did not change during FSS activities.

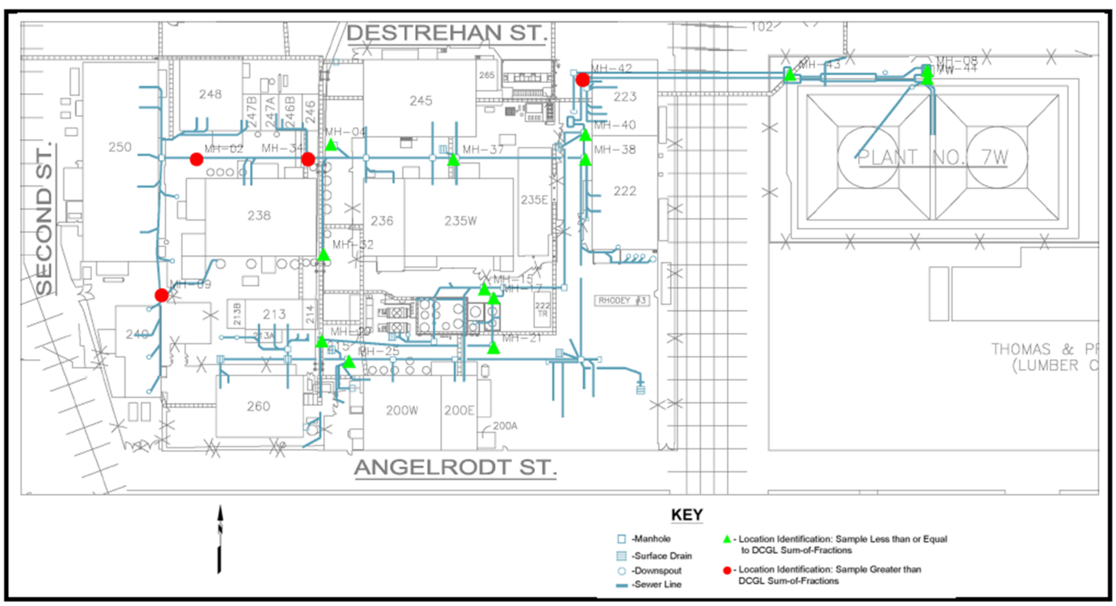


**Figure 2-1 Sewer lines (from C-T Phase II DP Figure 4-1 and FSSR Figure 4-4)**

For the pavement areas, the initial Class 1 and Class 2 designated areas ultimately became Class 1 subsurface survey units for FSS activities, while the remaining pavement areas subject to FSS activities (SUA and SUB) maintained the initial Class 3 designation (Figures 2-2 and 2-3). Additionally, the initial Class 3 designations for the wastewater neutralization basins in Plant 7W were upgraded to Class 2 areas for FSS activities.

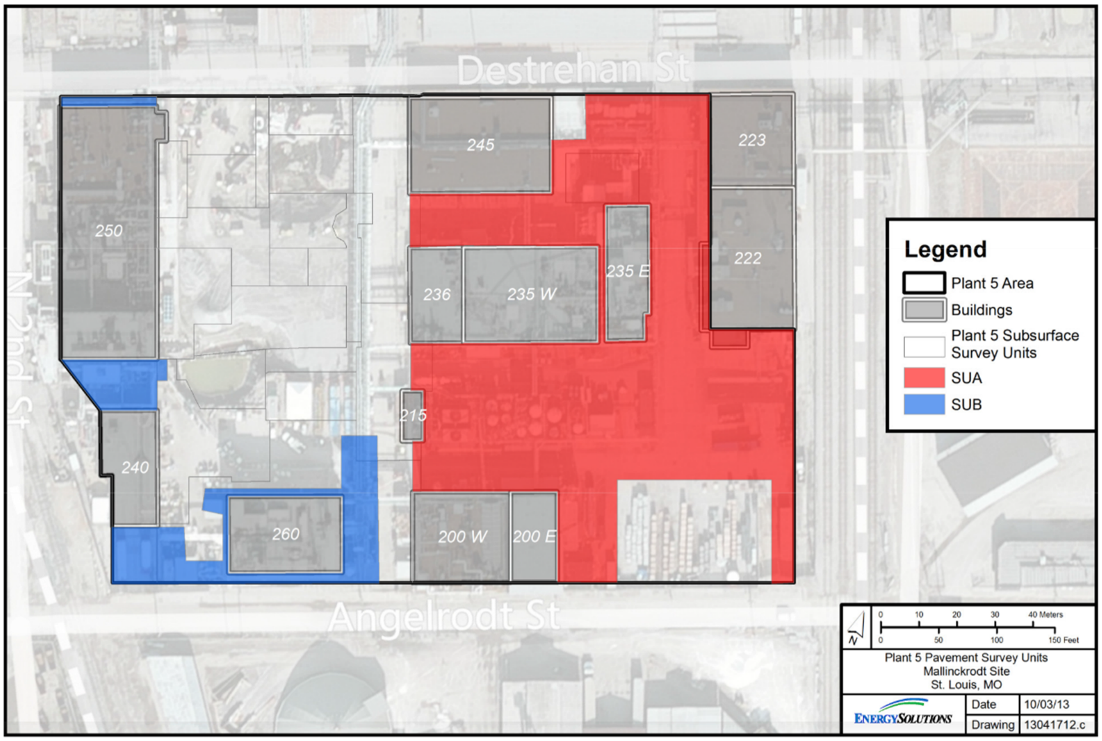


**Figure 2-2 Plant 5 Pavement Survey Units (from FSSR Figure 6-1)**

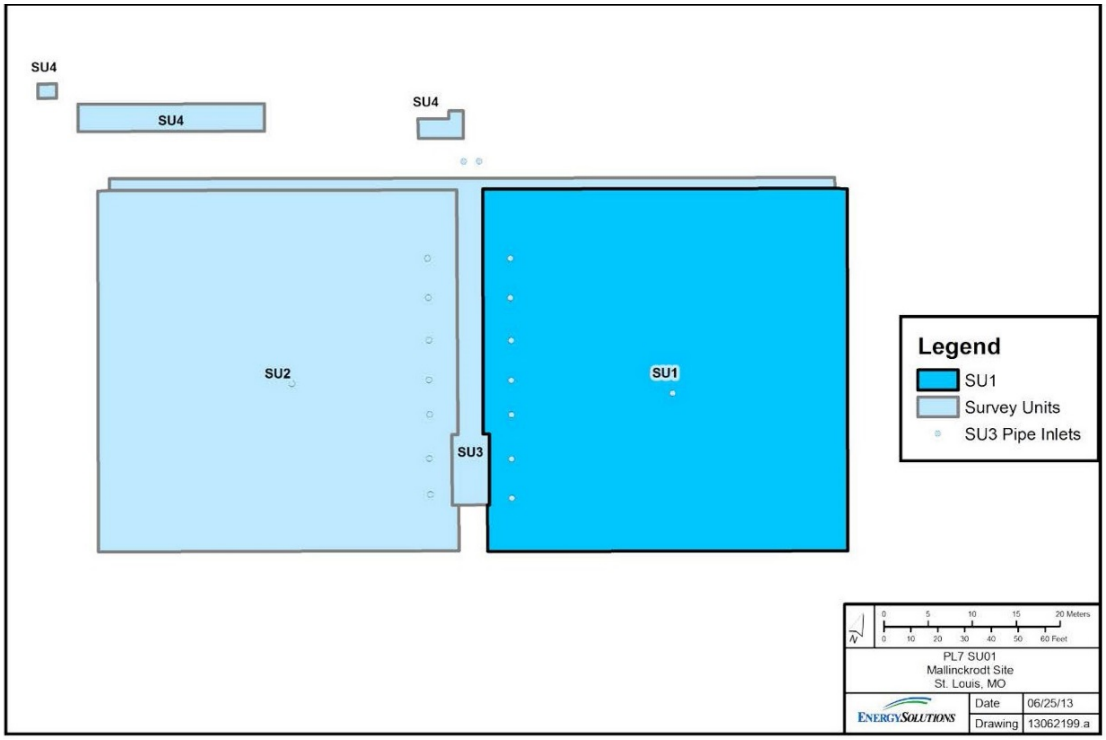


**Figure 2-3 Plant 7 Pavement Survey Units (from FSSR Figure 30-1)**

Mallinckrodt referred to the survey units with the potential for residual soil contamination as subsurface survey units. The initial subsurface classifications presented in the DP changed for some areas based on FSS data. In each instance the classification increased (Figure 2-4). The Class 2 survey unit SU18 was segregated out from the Class 3 survey unit SU21 based on characterization data. The classification of SU22 was also increased from Class 3 to Class 1 based on characterization data. Additionally, a portion of the Class 2 survey unit SU13 was segregated and was included in the Class 1 survey unit SU10.

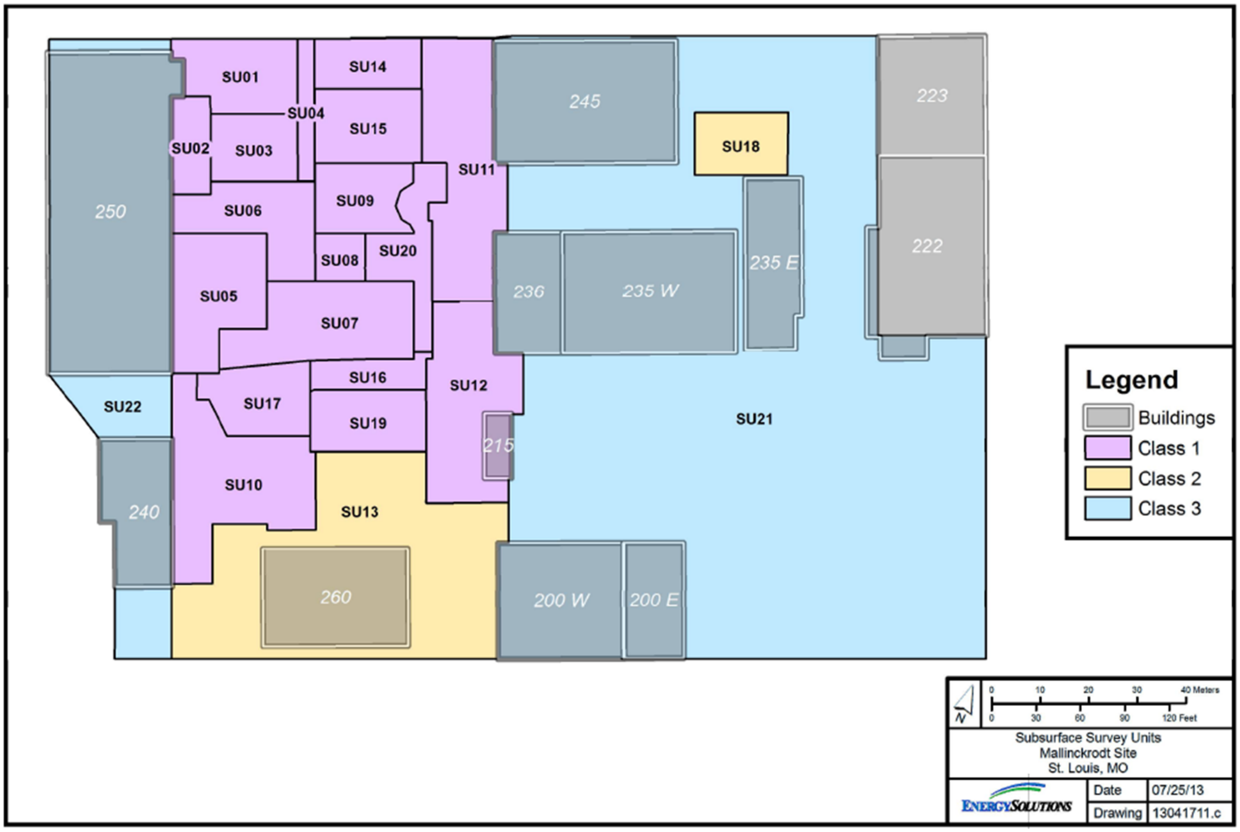


**Figure 2-4 Subsurface Survey Units (based on Figure 4-6 in Mallinckrodt's FSSR)**
Note that the Classification of SU22 was increased to Class 1 based on characterization data.

### 2.2.1 Surface Scans

Scanning surveys were performed by the licensee in all survey units to meet the required coverage percentages presented in Table 2-2. The purpose of the scans was to identify elevated radiation levels that could exceed the release criteria. In Class 2 and 3 survey units where the required scan coverage was less than 100 percent, the licensee selected the areas for scanning within the survey unit with the highest potential for elevated residual radioactivity, based on the licensee's professional judgment.

Additionally, Global Positioning System (GPS) units were used during the collection of scan data when practical and available to obtain position-correlated scan data logged at 1 second intervals. Where GPS was ineffective or unavailable, the results of surveys were recorded manually.

The licensee used the resultant position-correlated survey scan maps to aid with bias sample collection. The scan data were post-processed and the technicians were directed to the general area of concern (based on z-score values) to resurvey and identify the bias sample location.

### 2.2.2 Surface Activity Measurements of Pavement and Structures

The licensee performed direct alpha and/or beta-gamma surface measurements on structural materials (i.e. asphalt and concrete) in Plant 5, the wastewater neutralization basin, and sewer structural survey units to quantify any residual surface contamination remaining. The count time necessary for each measurement varied and was based on the specified detection sensitivity. At a minimum, the required number of direct measurements, as presented in Table 2-2, were collected. Additional direct measurements were often collected at judgmental locations (i.e., locations considered more likely to be contaminated based on licensee professional judgment) identified during scans. Measurement locations were recorded using GPS technology when applicable.

### 2.2.3 Soil Sample Measurements

The licensee collected soil/media samples for laboratory analysis to quantify any residual soil contamination remaining in subsurface (land area) survey units. At a minimum, the required number of samples as presented in Table 2-2 was collected. Additional samples were often collected from judgmental locations identified during scans.

The Wilcoxon Rank Sum (WRS) test was selected by the licensee as the statistical test to evaluate FSS data because the site contaminants are present in background. The licensee followed the process as prescribed in section 5.5.2.2 of MARSSIM for calculating the required number of data points necessary for statistical evaluation. The calculations resulted in 15 measurements for all structural and subsurface survey units and the number of measurements was independent of survey unit classification.

For Class 1 and 2 survey units, a random-start systematic pattern was used. The spacing of the measurement locations was determined using the equations presented in MARSSIM for either a square or triangular grid pattern. Section 4.5.2.2 of the Phase II FSSR presents only the spacing equation used for a square grid; however, a triangular pattern was applied to many survey units. Any inaccessible measurement locations, due to site conditions or health and safety concerns, were replaced with other randomly determined locations. The licensee indicated that for SU08 systematic locations were selected based on the orientation of the AECOM grid system over the entire excavation area and no random-start location specific to the survey unit was identified. The characterization data were used for the Class 2 SU18 and the Class 3 SU21 and no separate FSS was performed.

In survey units where it was reasonably suspected that subsoil contamination existed below the excavated areas, borehole samples were collected at the systematic locations. Biased borehole locations that were considered more likely to be contaminated were also sampled. Horizontal core sampling was judgmentally performed in selected excavation walls when elevated activity was present in areas that could not be excavated.

Soil and bulk material samples were analyzed by the licensee's on-site laboratory to assist in guiding remediation, waste characterization, and FSS activities. Samples were prepared by drying, grinding, mixing, sifting (no. 4 plus sieve), and weighing prior to analysis. Sample analyses were performed using gamma spectroscopy based on U.S. Environmental Protection

Agency Method 901.1, including directly measuring Ra-226 based on its 186 kilo-electron volt (keV) gamma-ray and indirectly measuring Th-232 and U-238 by their gamma-emitting progeny Ac-228 and Th-234, respectively, in accordance with the laboratory's approved procedures. Radiological data were reported as picoCuries per gram (pCi/g) dry weight.

Most systematic and biased samples with an on-site gross SOF result of 0.5 and greater (i.e., the result was half of the $DCGL_w$ value or greater), were also analyzed by an off-site laboratory. The off-site laboratory that performed the gamma spectroscopy analysis of the FSS soil and bulk material samples was TestAmerica Laboratories Inc. of St. Louis, MO. Sample analyses were performed using gamma spectroscopy based on EPA Method 901.1 in accordance with the laboratory's approved procedures. The activity concentration of Ra-226 was inferred from Bi-214 after a sufficient in-growth period to achieve secular equilibrium. The activity concentrations of Th-232 and U-238 were inferred by measuring their gamma-emitting progeny Ac-228 and Th-234, respectively. Samples were packaged in hermetically sealed containers prior to initiating the in-growth period to avoid radon-222 losses. Radiological data were reported as pCi/g dry weight.

The NRC issued an RAI questioning the statement in Section 7.2.2 of the FSSR that indicates the on-site laboratory, by design, reported conservative sample results which was contradictory to Section 5.6.3.1 that states the on-site laboratory consistently under-reported the concentration of Th-232 and as a result added 0.051 to the Th-232 $DCGL_W$ fraction. The licensee's response to the RAI indicated that the primary radionuclide of concern that drove the majority of the SOF calculations was Ra-226. By design, this concentration was over-reported based upon quantification using the 186 keV photopeak. Additionally, AECOM's site lab noted the issue with under-reporting the Th-232 concentrations but the EnergySolutions site lab did not have the same issue with the Th-232 concentrations.

The licensee indicated that sieved (no. 4 plus) material was analyzed separately to verify residual radioactivity was consistent with sample results. Historical records indicate the site was backfilled in the late 1800s with a cinder fill, which included a slag-type material. The material is not part of the C-T process and was separated out by sieve from samples collected from the excavation during the sample preparation process. This material was radiologically screened to ensure that significant levels of radioactivity, if present, were investigated. The licensee indicated that none were present. The licensee indicated that even though it is Mallinckrodt's position that the slag material is not related to the C-T process, it was checked to ensure that it does not contain residual radioactivity that otherwise is not accounted for in the FSS process. In the RAI responses for the FSS, Mallinckrodt also stated that most subsurface structural concrete was removed and surveyed. Structural concrete that was integral to the stability of the excavations and surrounding buildings was not removed and was scanned and left in place. The concrete that exceeded the acceptable surface contamination limits in Table 1 of NRC's Regulatory Guide 1.86 (ML003740243) was disposed of as radioactive waste, while the material that was below this criteria was size reduced and returned to the excavation.

### 2.2.4 Data Quality Assessment

Mallinckrodt committed to perform decommissioning activities in a manner that would ensure the results were accurate and that uncertainties had been adequately considered.

Mallinckrodt's Quality Assurance Program (QAP) applied to all stages of decommissioning through the final survey, validation of the data, and the interpretation of the results. Among other things, the QAP included data/document control requirements and controls for measuring and testing equipment to ensure adequate quality throughout the data life cycle. Additionally, a comparison of the on-site vs. off-site laboratory analytical performance was conducted to ensure on-site laboratory consistency with off-site laboratory results.

### 2.2.5 Data Set Analysis Approach

Section 14.4.3.8 of C-T Phase II DP describes the licensee's process for data analysis. A deviation from this process noted in the FSS was that a database was not developed to process the data sets for each survey unit. The licensee noted that the database was never developed; instead, a combination of Microsoft Excel spreadsheets and hand calculations were utilized.

As multiple radionuclides were present, both the gross and net SOF were calculated for all samples. The individual SOFs and survey unit average SOFs were then assessed via the various DP-requirements. Sample SOFs that were >0.5 to ≤1 and >1 were highlighted in the tables for the potential for further action, such as reclassification of Class 2 or 3 survey units, and/or additional investigations, remediation, and/or dose assessments.

Specific tests were applied to the data from each survey unit as described in the Phase II DP. In survey units where systematic core samples were taken, these tests were applied to both the systematic samples taken at the surface of the excavation and the systematic samples taken at depth. Individual SOF results were first compared by the Min/Max screening test. Failure of this screening test in a Class 2 or 3 survey units would require reclassification. A related test that was only applied in Class 2 and 3 survey units was the low-level test. Failure of this test would necessitate further action and evaluations. Class 1 survey units that failed the Min/Max test were further evaluated using the DCGL test and the WRS test. Areas of elevated contamination were evaluated using dose assessments, as described in more detail in Section 4 below.

## 2.3 NRC Evaluation of Final Status Survey Approach

The NRC staff reviewed Mallinckrodt's FSS approach and has determined that Mallinckrodt's FSS design approach is adequate to characterize the site to demonstrate compliance with radiological criteria for license termination and is consistent with guidance in MARSSIM. During FSS activities, the licensee used the DP as approved by the NRC, with the exception of the dose assessment approach which was subsequently approved by the NRC in license amendment 7. Mallinckrodt also deviated by not developing a database for data assessment, as Mallinckrodt chose to evaluate their data using Microsoft Excel and hand calculations instead. The NRC is in agreement that the use of Microsoft Excel and hand calculations is an acceptable method of performing data assessment and this deviation does not affect the outcome of the data assessments.

Based on its review of the analytical methods and instruments used, the NRC staff has determined that the instruments used to collect the data were capable of detecting the radiation type (e.g., alpha, beta, or gamma) and survey unit-specific minimum detectable concentrations were well below 50 percent of the $DCGL_w$ values. The calibration of the instruments used to collect the data was current and radioactive sources used for calibration were National Institute of Standards and Technology traceable. Instrument response was checked before instrument use each day, at a minimum. Therefore, the NRC staff finds that the survey methods used to collect the data were appropriate for the media and type of radiation being measured.

The Regulatory Guide 1.86 limits were not intended for use as a decommissioning criteria. However, the NRC staff finds that the use of these limits by Mallinckrodt was acceptable because the criteria are less than Mallinckrodt's pavement $DCGL_W$ value and the concrete that was evaluated using these criteria is not expected to have been volumetrically contaminated because the concrete was not contaminated at the time it was poured, there was insufficient radioactivity to activate nuclides on the interior, and there were no processes present by which radioactive material could penetrate the exterior of the concrete.

The NRC staff finds that the survey unit classifications are consistent with guidance in MARSSIM, with the exception that the sewer survey unit should have been a higher class than Class 3 because it had concentrations above the $DCGL_W$ in one manhole, MH42, which is discussed in detail below. The characterization of the sewers is discussed in more detail in Section 3. Additionally, the NRC staff finds that the data analysis approach that Mallinckrodt used for the systematic samples is consistent with guidance in MARSSIM. The NRC staff concluded that the use of the dose assessment approach to evaluate elevated areas is acceptable in its approval of license amendment 7.

## 3. Final Status Survey Results

Mallinckrodt provided the results of its FSS for in Chapters 6 to 33 in its FSSR.

### 3.1 Pavement Survey Units

FSS results for the two Plant 5 Class 3 pavement survey units (SUA and SUB) are presented in Chapter 6 of the FSSR. The data assessments for both of these survey units were performed based on the assumptions, methods, and performance criteria established to satisfy the DQOs in accordance with the C-T Phase II DP Section 14.4.3.8.

For the Class 3 pavement SUA and SUB, 10 percent beta surface scan coverage was planned. Chapter 6 referred the reader to chapter Figures 6-2 and 6-3 for the surface scan data. The surface scan results, based on the z-scores of the count rates, were plotted on an overlay map for SUA (Figure 6-2 in FSSR). The illustrated scanning coverage showed that the 10 percent scanning density coverage was met or exceeded. The z-scores were not plotted for SUB, but the text indicates that the scanning coverage of SUB was approximately 100 percent and the maximum beta reading recorded was 9,210 dpm/100 $cm^2$ (ML15334A417).

Both of the respective figures showed the random and biased beta and alpha surface activity measurement locations. The random and biased measurement results were provided for both survey units in individual tables; the random measurement results also included descriptive statistics. All direct surface measurements in SUA and SUB, for both systematic and bias locations identified during scans, were well below the $DCGL_W$. The licensee used large-area detectors with a physical area of 821 $cm^2$ to quantify surface activity levels, which are in units of disintegrations per minute per 100 $cm^2$. Therefore, the surface activity levels that the licensee provides in the report are representative of the 100 $cm^2$ average activity levels over the detector surface area. As a result of averaging the observed count rates over an area that is more than 8-times the DCGL unit area, areas of contamination greater than the $DCGL_W$ can be masked. This issue is of particular importance for survey unit classification. As the pavement areas were designated as Class 3, assurance was necessary that contamination levels did not exist that would exceed the licensee's action level for reclassification to either Class 2 or Class 1. The licensee accounted for this issue in a table footnote where the range of the maximum possible hot spot activity levels was provided to ensure compliance was demonstrated with both the structural surface $DCGL_W$ and the survey units' Class 3 designation. Mallinckrodt calculated this range based on the assumption that all of the activity detected was concentrated in a 100 $cm^2$ area. The resulting activities were still over an order of magnitude lower than the $DCGL_w$ value for pavement.

The Min/Max screening test results presented for both survey units was simply the maximum systematic value as background was not accounted for in the surface activity measurement calculation. The low level screening test limit could not be calculated per the equation provided in Table 14-5 of the C-T Phase II DP because a background reference area was not used. Elevated Measurement Comparison (EMC) calculations were not necessary because no elevated areas above the $DCGL_W$ were identified. The licensee performed a retrospective analysis of the data using the Sign test (since background was not accounted for) for each survey unit to ensure the sample size was adequate. In both SUA and SUB the actual sample size exceeded the retrospective number.

### 3.2 Plant 5 Soil Survey Unit Results

There were 18 subsurface soil survey units initially designated as Class 1, two as Class 2, and two as Class 3. The Class 1 units were survey units 1 – 12, 14 – 17, 19, and 20. The Class 2 survey units were SU13 and SU18, and the Class 3 survey units were SU21 and SU22. However, based on results, SU22 was reclassified as a Class 1 for the FSS. Table 3-1 provides a brief summary of the FSS results with the licensee's FSS conclusions.

**Table 3-1 Summary of Plant 5 Subsurface Soil Survey Unit Final Status Surveys (adapted from Figure ES-1 in FSSR)**

| Survey Unit | Class | Data Set Analysis | | | | | Elevated Areas | |
|---|---|---|---|---|---|---|---|---|
| | | Min/ Max | Low Level [a] | DCGL [b] | WRS [b] | Retrospective Analysis | Area(s) | Dose Assessment |
| Plant 5 Pavement | 3 | Pass | Pass | N/A | N/A | Pass | -- | N/A |
| SU01 | 1 | Pass | N/A | N/A | N/A | Pass | EA#1 | Pass |
| SU02 | 1 | Pass | N/A | N/A | N/A | Pass | EA#1 | Pass |
| SU03 | 1 | Pass | N/A | N/A | N/A | Pass | -- | N/A |
| SU04 | 1 | Pass | N/A | N/A | N/A | Pass | -- | N/A |
| SU05 | 1 | Fail | N/A | Pass | Pass | Pass | EA#1 | Pass |
| SU06 | 1 | Pass | N/A | N/A | N/A | Pass | EA#1 | Pass |
| | | | | | | | EA#2 | Pass |
| SU07 | 1 | Pass | N/A | N/A | N/A | Pass | -- | N/A |
| SU08 | 1 | Pass | N/A | N/A | N/A | Pass | -- | N/A |
| SU09 | 1 | Pass | N/A | N/A | N/A | Pass | -- | N/A |
| SU10 | 1 | Pass | N/A | N/A | N/A | Pass | EA#1 | Pass |
| SU11 | 1 | Fail | N/A | Pass | Pass | Pass | EA#1 | Pass |
| | | | | | | | EA#2 | Pass |
| | | | | | | | EA#3 | Pass |
| SU12 | 1 | Fail | N/A | Pass | Pass | Pass | EA#1 | Pass |
| | | | | | | | EA#2 | Pass |
| | | | | | | | EA#3 | Pass |
| | | | | | | | EA#4 | Pass |
| SU13 | 2 | Pass | N/A | N/A | N/A | Pass | -- | N/A |
| SU14 | 1 | Pass | N/A | N/A | N/A | Pass | -- | N/A |
| SU15 | 1 | Pass | N/A | N/A | N/A | Pass | -- | N/A |
| SU16 | 1 | Pass | N/A | N/A | N/A | Pass | -- | N/A |
| SU17 | 1 | Pass | N/A | N/A | N/A | Pass | -- | N/A |
| SU18 [c] | 2 | N/A | N/A | N/A | N/A | Pass | EA#1a | Pass |
| | | | | | | | EA#1b | Pass |
| SU19 | 1 | Fail | N/A | Pass | Pass | Pass | EA#1 | Pass |

| Survey Unit | Class | Data Set Analysis | | | | | Elevated Areas | |
|---|---|---|---|---|---|---|---|---|
| | | Min/ Max | Low Level [a] | DCGL [b] | WRS [b] | Retrospective Analysis | Area(s) | Dose Assessment |
| SU20 | 1 | Fail | N/A | Pass | Pass | Pass | EA#1 | Pass |
| | | | | | | | EA#2 | Pass |
| | | | | | | | EA#3 | Pass |
| SU21 | 3 | Pass | Fail [d] | N/A | N/A | Pass | -- | N/A |
| SU22 | 1 | Pass | N/A | N/A | N/A | Pass | EA#1a | Pass |
| | | | | | | | EA#1b | Pass |
| | | | | | | | EA#2 | Pass |
| | | | | | | | EA#3 | Pass |
| Sewerage | 3 | Pass | Pass | N/A | N/A | Pass | -- | N/A |
| Plant 7 Pavement - SU1 | 2 | Pass | N/A | N/A | N/A | Pass | -- | N/A |
| Plant 7 Pavement - SU2 | 2 | Pass | N/A | N/A | N/A | Pass | -- | N/A |
| Plant 7 Pavement - SU3 | 2 | Pass | N/A | N/A | N/A | Pass | -- | N/A |
| Plant 7 Pavement - SU4 | 2 | Pass | N/A | N/A | N/A | Pass | -- | N/A |

(a) The low level screening test is not applicable to Class 1 and 2 survey units
(b) The DCGL and WRS tests are not applicable if the Min/Max test is passed
(c) A specific FSS was not performed for SU18 and a dose assessment was performed to demonstrate compliance
(d) The low level test failed. Areas exceeding the investigation level were investigated further and were found not to exceed the DCGL.

### 3.2.1 Gamma Walkover Survey Results for Subsurface (soil) Survey Units

The licensee's FSS report documented the gamma walkover survey results for each survey unit via several methods. The data presentation methods included the following:

- narrative discussion,
- survey unit maps with:
  - either geo-referenced, z-scored scan data plots or static direct gamma radiation counts when satellite reception was poor;
  - cumulative frequency distribution (CFD), or similar graphs; and
  - embedded table with descriptive statistics summary (mean, standard deviation, min/max, etc.).

The figures demonstrated that high density (up to 100 percent coverage) scans had been performed for Class 1 survey units and medium (25 to 50 percent area coverage) to high density for Class 2 and 3 survey units. The decommissioning plan required 100% coverage for Class 1 survey units and at least 10% coverage for Class 2 survey units. The mapped data plots indicated that, overall, these required coverages were achieved. There were some void spaces apparent on the GWS figures, representing inaccessible areas or where satellite reception was lost.

Additionally, the licensee noted a few instances where 100 percent scan coverage was not performed. In SU08, a GWS was not performed because the berm was showing signs of saturation and groundwater was entering the survey unit, and there was an urgent need for buttress construction to begin. However, Mallinckrodt collected soil samples in this survey unit at a density that was over 35 times higher than was necessary per the DP.

For SU10, the licensee noted that 100 percent GWS was not performed due to standing water. The NRC issued an RAI for this survey unit requesting justification for not removing the water or sampling under the water. The licensee's RAI response indicated the area in question was approximately 2 to 3 square meters in size in the deepest point of the excavation and was dewatered as much as possible. The response also noted that the surrounding GWS showed no indication of elevated activity and that they had demonstrated in other survey units that once the clay layer was reached, as stated to be the case for this survey unit, residual contamination had been removed.

In SU19, a GWS was not performed along the south and west edges due to safety concerns associated with the vertical walls. The walls were surveyed from the top of the excavation by hanging a detector over the edge of the excavation.

Finally, a GWS was not performed inside Buildings 240 and 250 even though they are in a Class 1 survey unit (SU22). The NRC requested that the licensee either perform a 100 percent GWS of SU22 or provide justification for how the FSS is sufficient without the GWS inside these buildings. The licensee's response to this RAI indicated that in lieu of scans, 15 systematic borehole samples were collected throughout the buildings and the sample results did not identify contamination of concern beneath the buildings. The licensee's response also indicated that the results for the additional biased samples collected throughout SU22, where residual contamination or elevated radiation levels were identified, provide further information to support the assumption that contamination that was identified was due to the sewer lines that ran along the two buildings and that contamination did not extend laterally beneath the buildings.

### 3.2.2 Soil Sample Results

The licensee presented quantitative analytical results from soil samples that were collected based on both the statistical design to demonstrate that the $DCGL_W$ for each survey unit had been satisfied and biased samples collected from GWS or other types of anomalies. Other anomalies encountered included but were not limited to buried pipes, concrete footers, excavation walls, and old backfill materials. Biased samples were collected for investigative purposes. All excavated survey units were also assessed as to whether there was potential subsoil contamination within the unexcavated areas. The licensee then provided prior characterization data as to why there was not contamination in those areas, or when data were unavailable, the licensee implemented additional final status subsurface investigations via systematic borehole sampling.

Sample locations were documented on maps and each survey unit chapter contained data tables with radionuclide concentrations and measurement uncertainties as quantified by the on-site laboratories and also from the commercial laboratory when samples were sent for off-site analysis. Class 2 and 3 survey units each had suspect results that called into question whether portions of the survey units should have been upgraded to a Class 1 designation. Areas identified were either segregated to adjacent Class 1 survey units, a dose assessment was performed, or additional investigations performed.

There were a number of Class 1 survey units that failed the min/max test for at least one of the statistical samples and were therefore tested for compliance via the WRS test, the results of which were summarized in Table 3-1. All of these survey units passed the WRS test. Two of the Class 1 survey units failed the min/max test based on their systematic core data. Both of these survey units passed the WRS test.

The only Class 3 survey unit remaining at the time of the FSS, SU21, contained radionuclide concentrations in several borehole samples that exceeded the background reference area concentrations plus a fraction of the $DCGL_W$, and as such, failed the low level screening test. The licensee assessed each location and reasoned that each location was either an expected statistical deviation above the limit or was an isolated area that was below the SOF of 1 and therefore did not warrant reclassification.

In order to assess the potential contamination under Buildings 240 and 250 in SU22, borehole samples (up a depth of 3 meters) were collected at each of the 15 statistically determined surface sample locations distributed throughout SU22. An additional 15 biased borehole locations were sampled (up to depths of 5 meters) based on gamma walkover survey data collected exterior to the buildings, as well as 13 biased locations (up to depths of 2 meters) along the eastern edge of the survey unit. The systematic and biased samples taken under the buildings all had an SOF of less than 1. Some of the sample results from the biased locations along the eastern edge of the survey unit were greater than 1 and were evaluated with dose assessments, as described in more detail in Section 4 below. During site characterization, core samples were also taken under buildings 200W, 204, 235E, 235W, 245, and 260. These sample results all had an SOF of much less than 1.

## 3.3 Plant 7 Pavement Results

FSS results for the four Plant 7 pavement survey units (SU1 – SU4) are presented in Chapters 30 to 33 of the FSSR. These four survey units include the two concrete wastewater neutralization basins and the Weir Chamber, Grit Chamber, and Pump Vault. The data assessments for these Class 2 survey units were performed based on the assumptions, methods, and performance criteria established to satisfy the DQOs in accordance with the C-T Phase II DP Section 14.4.3.8. Data collected included beta surface activity scans and systematic and biased surface activity measurements,

Beta surface scans were performed over the basin pavement areas. The chapters referred the reader to Figures 30-4, 31-4, 32-12, and 33-14 in the FSSR for the surface scan data. Each of the respective figures also showed the random and biased beta and alpha surface activity measurement locations. The random and biased measurement results were provided for each survey unit in individual tables; the random measurement results also included descriptive statistics. All direct surface measurements, for both systematic and bias locations identified during scans, were well below the $DCGL_W$. As was discussed in Section 3.1, the licensee used large-area detectors for direct measurements in units of disintegrations per minute per 100 $cm^2$, but these detectors have a physical area of 821 $cm^2$. The licensee accounted for this issue in a table footnote where the range of the maximum possible hot spot activity levels was provided to ensure compliance was demonstrated with the both the structural surface $DCGL_W$ and the appropriateness of the Class 2 designation for the survey units.

All direct surface measurements in Plant 7, for both systematic and bias locations identified during scans, were below the $DCGL_W$. The Min/Max screening test results was simply the maximum systematic value as background was not accounted for in the surface activity measurement calculation. The Min/Max test was passed in all four Plant 7 survey units. EMC calculations were not necessary because no elevated areas above the $DCGL_W$ were identified. The licensee performed a retrospective analysis of the data using the Sign test (since background was not accounted for) for each survey unit to ensure the sample size was adequate.

## 3.4 Sewer Lines and Manholes

The bulk of the sewer system servicing the C-T manufacturing buildings was removed during remediation and portions of sewer line servicing Buildings 240 and 250 were replaced. A small portion of the sewer line was left in place (historically grouted) which was addressed in a separate dose assessment in Chapter 17 of the FSSR and is discussed in more detail in Section 4 of this document. Another portion of sewer also left in place ran between Buildings 236 and 245, turned 90 degrees north at MH-38, ran north to MH-42, and turned east to MH-43 and MH-44.

The sewer lines and manhole characterization data were presented in Figure 4-1 of the C-T Phase II DP. These data were augmented by additional investigations and additional sediment samples collected from manhole openings in the sewerage remaining in use. The characterization data indicated that there were five manholes of concern: MH-04, MH-09, MH-34, MH-42, and MH-43. MH-04, MH-09, and MH-34 were remediated/removed and therefore are considered addressed. The characterization data for MH-42 and MH-43 and the sewerage remaining in use downstream of MH-04 FSS results for the C-T plant sewerage survey unit are presented in Chapter 29 of the FSSR. All sediment sample results from the manholes, except the sample taken at MH-42 are below the $DCGL_W$ value for soil. The sediment sample from MH-43 had an SOF value of 0.83. The sediment in MH-43 was subsequently remediated and no sediment remains downstream of MH-42 (i.e., between MH-42 and MH-44 and points downstream).

The FSSR Chapter 4, Section 4.1.4 identifies the site's spatial boundaries as including "the internal surfaces of the impacted sewer lines remaining in use downstream of Building 238 extending to the wastewater neutralization basins, and other sewers in the Plant 5 area". However, per Section 29.1 of the FSSR, the survey unit is specified as comprising the sediment in sewers downstream of Building 238 and extending to the Waste Water Treatment Plant Basin. The actual sewer lines and manhole surfaces are not included as a structural survey unit. As such, there are no direct measurement data of surface activity levels provided in the FSSR, for either lines left in place or for any lines associated with subsurface soil survey units and removed during remediation of those units, though sediment samples were taken from the manholes in the sewers during site characterization.

The licensee provided justification for this approach in RAI responses based on a conceptual site model where sewer lines/manholes would eventually be abandoned in-place, degrade, and be then be considered part of the soil column. In its November 19, 2014, responses to a request for additional information (ML14339A278), Mallinckrodt stated that no direct beta measurements or scans were performed inside the sewer lines because the remaining sewer lines are actively servicing the plant and the abandoned sections associated with the Plant C-T buildings were removed. However, the sewer lines were visually inspected and sediments samples were analyzed. The licensee stated that sewer lines are a closed system and the interior surface would only be contaminated as a result of direct contact with contaminated sediment and that any contamination of the sewer would be consistent with the sediment sample results as presented in Table 29-1 of Chapter 29 of the FSSR.

In the additional information provided by Mallinckrodt on June 10, 2015 (ML15177A051), the licensee further stated that the sewer is constructed of vitrified clay pipe approximately 8 feet below grade surface and the manholes are constructed of brick and mortar. Mallinckrodt stated that approximately 155 million gallons of water flow through the Plant 5 sewer system daily as a result of the current pharmaceutical manufacturing process. Based on the current routing of the sewer, Mallinckrodt stated that there are no known sediment traps where contaminated sediment may have collected other than the 90-degree bend at MH-42 and the sediment that accumulated at the Lift Station that has been remediated.

Mallinckrodt evaluated the potential dose from the sediment in MH-42 by considering a vertical average radionuclide concentration in the sewer sediment and in soil between the ground surface and the sewer. Mallinckrodt also stated that there was no soil above the sediment in the manhole and therefore data from borehole INV-2, which was in the vicinity of MH-42, was considered to be the best representation of adjacent soil. The gross soil DCGL SOF for the soil column in and adjacent to MH-42 calculated using the sediment results from MH-42 and the results for INV-2 was 0.32.

### 3.5 NRC Evaluation of FSS Results

The NRC staff reviewed the results of the final status survey to assess whether the licensee's procedures as implemented and that their documentation and interpretation of the results satisfied the commitments of C-T Phase II DP and RAI responses.

#### 3.5.1 NRC Evaluation of Plant 5 Pavement Results

The NRC staff review concluded that Mallinckrodt surveyed the Plant 5 pavement in accordance with their DP. The NRC staff finds that the method that Mallinckrodt used verify that the use of large area detector was not missing elevated areas (i.e., calculating the maximum possible hot spot activity levels by assuming all activity measured by the detector was present within a 100 $cm^2$ area) is acceptable because this approach is conservative. Since all direct systematic and biased surface measurements in SUA and SUB were well below the $DCGL_W$ value approved in the Phase II C-T DP, the NRC staff concludes that Mallinckrodt demonstrated that the Plant 5 Pavement meets the $DCGL_W$ value.

#### 3.5.2 NRC Evaluation of Plant 5 Soil Results

The NRC staff reviewed the GWS data for the soil survey units. The figures were representative of high density (up to 100 percent coverage) scans having been performed for Class 1 survey units and medium (25 to 50 percent area coverage) to high density for Class 2 survey units. The decommissioning plan required 100 percent and at least 10 percent coverage for Class 1 and Class 2, respectively. The mapped data plots indicated that, overall, these required coverages were achieved. There were some void spaces apparent on Class 1 GWS figures, representing inaccessible areas or where satellite reception was lost. Individual scanning paths were not discernable on the figures to verify the actual coverage and that the perpendicular, overlapping scan paths specified in report Sections 4.4.1.1 and 4.4.2.1 were made. EnergySolutions Group represented each data point on the figures with a to-scale circle of 1-meter diameter. This method ensures an accurate representation of the actual coverage. The initial remediation contractor, AECOM, presented maps after applying a data kriging method—i.e. interpolation between co-located points—otherwise described in Section 4.4.1.4 of the report as the contouring process. Per the report, "The contouring process involved creating a regularly spaced grid and assigning values to every spot on the grid." This method essentially fills in data between actual measured locations based on a weighted average of co-located measurements using the gamma exposure rate inverse square law of a point source to approximate the count rates. The contouring process could inadvertently result in the appearance of data over small areas that were not directly scanned. The z-score method for presenting scan did not make it possible for the NRC review to evaluate the relative count rate magnitude of the various anomalies. As all anomalies were not subjected to individual biased sampling, the NRC's review cannot confirm that biased samples were collected from locations with the maximum observed count rates. However, based on Mallinckrodt's GWS figures, it appears that biased samples were taken from all significant anomalies, so the NRC staff concluded that the biased sampling performed by Mallinckrodt was appropriate for assessing potential elevated areas.

In addition to apparent void spaces in the GWS due to lost satellite reception, there were some inaccessible areas that were not subject to GWS. These include areas of SU10 that had standing water, a portion of SU19 that was near a vertical wall in the excavation that represented a safety issue, and areas of SU22 under buildings 240 and 250. The NRC staff finds that Mallinckrodt's justification for the lack of GWS data in the inaccessible area in SU10 is acceptable because the surrounding GWS showed no indication of elevated activity and in other survey units Mallinckrodt found that the residual contamination had been removed once the clay layer was reached. The NRC staff finds that it was acceptable to evaluate the residual radioactivity in SU19 by hanging a detector over the edge of the vertical walls because this approach would assess the residual radioactivity in the walls. The NRC staff finds that the use of bore holes to evaluate potential residual radioactivity under Buildings 240 and 250 is an acceptable approach because the GWS would not readily detect the residual contamination under the building.

The NRC staff reviewed the systematic soil and biased soil samples and subsequent data evaluation and concluded that the sampling and data evaluation is acceptable because it was done in accordance with guidance in MARSSIM. Table 3-1 provides a summary of the results relative to demonstrating compliance with the release criteria. The NRC staff also reviewed the systematic and biased core sample data. The NRC staff concludes that Mallinckrodt appropriately took core samples in locations where there was the potential for contamination at depth, and the core samples were therefore adequate to identify residual radioactivity at depth. The NRC staff also reviewed the core samples taken under buildings 240 and 250 as part of the FSS and the core data from under site buildings taken during site characterization. The NRC staff finds that Mallinckrodt took adequate samples to identify contamination under these buildings. The NRC staff also concludes that the characterization of the elevated areas the sides of Buildings 240 and 250 was sufficient to identify the extent and concentration of the residual radioactivity in this area.

### 3.5.3 NRC Evaluation of Plant 7 Results

The NRC staff reviewed the Plant 7 results. The NRC review confirmed that the surface scan results, based on the z-scores of the count rates, were plotted on an overlay map for each survey unit, and the illustrated scanning coverage appeared to represent that greater than 10 percent scanning density coverage was met, and the data plots were indicative of medium to high density scan coverage. Neither the figures nor the narrative text provided specific scan range summaries. There were numerous apparent locations of elevated beta radiation, the > +3 z-scores represented in red on the maps. As noted for Plant 5 subsurface gamma walkover survey data presentation, the z-score method for presenting scan data did not make it possible for the NRC review to evaluate the relative count rate magnitude of the various anomalies. As all anomalies were not subjected to individual biased measurements, the NRC's review cannot confirm that biased measurements were collected from locations with the maximum observed count rates. However, Figures 30-4, 31-4, 32-12, and 33-14 in the FSSR, indicate that biased samples were taken from all significant anomalies. For this reason, the NRC staff concludes that Plant 7 was surveyed appropriately. The measured results in Plant 7 were all less than the $DCGL_W$ value for pavement. As was discussed in Section 5.5.1, the NRC staff finds that the method that Mallinckrodt used verify that the use of large area detector was not missing elevated areas is acceptable. The NRC staff therefore concludes that Mallinckrodt demonstrated that Plant 7 meets the $DCGL_W$ value.

### 3.5.4 NRC Evaluation of Sewer Results

The NRC staff believe that while it may have been more appropriate to classify the sewers as a Class 1 survey unit because the sample from MH-42 was above the $DCGL_W$ value, the justification provided by Mallinckrodt for only sampling the sewers at the manholes was sufficient. The basis for this is that the radionuclides in the sewers were associated with the sediment, there is no reason to believe that the sediment would build up in locations other than the manholes, and the sewer has been in use with large amounts of non-radiologically contaminated water flowing through it since licensed operations ceased. Large amounts of non-radiologically contaminated water have also flowed through the system since the characterization samples were taken, and as a result the concentrations remaining in the system may be less than what was measured in the samples.

The NRC staff finds that it is acceptable to evaluate the residual contamination in MH-42 by considering the average vertical concentration because the sediment sample in MH-42 was taken at the bottom of the manhole and the sediment would be mixed with soil above and around it if it was brought to the surface through future construction activities. Because the vertical average concentration was below the $DCGL_W$ value, the NRC finds that the residual contamination in MH-42 is consistent with the unrestricted release criteria in 10 CFR 20.1402. The remaining sewer sediment samples are below the $DCGL_W$ value, so the NRC also concludes that the residual contamination in the remainder of the sewer is also consistent with the unrestricted release criteria in 10 CFR 20.1402.

## 4. Dose Assessment

Mallinckrodt calculated a total dose for each soil survey unit. As described in the SER for Amendment 7 (ML15286A174), the projected dose from residual radioactivity at the Mallinckrodt site is through direct radiation, soil ingestion, and inhalation of dust pathways, and water dependent pathways (i.e., groundwater or surface water pathways) are not present at the site. Because the projected dose is through the direct radiation, soil ingestion, and inhalation of dust pathways, an individual is not expected to receive a dose from multiple survey units at the same time. Unlike sites with water dependent doses an individual would not receive a dose from multiple survey units because water transportation residual radioactivity from one survey unit to another is not possible, and therefore the residual concentration/dose in a survey unit will not increase over time due to natural processes.[1]

### 4.1 Dose Assessment Methodology

[1] For sites at which an individual could receive a dose from more than one survey unit at a time, the total dose would need to be evaluated on a site-wide basis when using the dose assessment approach.

The industrial worker scenario was assumed in the dose assessment performed for both the development of the DCGLs and the dose assessments performed as part of the FSS because Mallinckrodt intends to continue industrial use of the site, and the foreseeable future use of the site is continued industrial or commercial use. The total dose for each soil survey unit was calculated by adding the average survey unit dose to the dose for each elevated area in the survey unit. The average survey unit dose was determined for each survey unit by multiplying the SOF calculated based on the individual radionuclide $DCGL_W$ values by 25 mrem/yr since the $DCGL_W$ values correspond to a dose of 25 mrem/yr for residual radioactivity located at the surface.

The dose assessments for areas of elevated activity were provided as part of the FSSR. In these dose assessments, Mallinckrodt used the same parameters 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.

### 4.2 Dose Assessment Results

During the FSS, Mallinckrodt identified 23 areas of elevated activity in 11 of the survey units. Dose assessments of the elevated activity were performed by Mallinckrodt for the *in situ* scenario for each elevated area (Table 4-1). Three of these elevated areas are located inside a buried pipe. In these cases the pipe was removed to the extent possible and the remaining pipe was grouted.

**Table 4-1 Summary of Elevated Area Projected *In Situ* Doses for Soil Survey Units**

| Survey Unit | Elevated Area | Thickness (m) | Area ($m^2$) | 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 |
| 2 | Elevated Area 1 | 0 to 1 | 10 to 29 | 1.21 | 2.4 | 37.8 | 39.1 | 0.9 |
| 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 |
| 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 |
| 10 | Elevated Area 1 | 0 to 1 | 5 | 1.21 | 25.2 | 3.5 | 11.2 | 1.2 |
| 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 |
| 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 |
| 18 | Elevated Area 1 surface | 0 to 1 | 75 | 0.161 | 0.04 | 27.0 | 2.40 | 4.6 |
| | Elevated Area 1 subsurface | 0 to 4 | 75 | 1.161 | 2.42 | 155.84 | 2.6 | 1.6 |
| 19 | Elevated Area 1 | 0 to 0.3048 | 13 to 30 | 4 | 5.1 | 30.6 | 26.2 | 7.0E-13 |
| 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 |
| 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 |

* inside buried pipe

Mallinckrodt also evaluated an excavation scenario in which a worker is exposed to elevated activity that is located at depth. In this evaluation, Mallinckrodt considered the potential dose from Elevated Area 1 in SU05, Elevated Area 1 in SU18, Elevated Area 2 in SU20, and Elevated Area 1b in SU22. 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, 1.01 mrem/yr, 2.5 mrem/yr, and 0.072 mrem/yr for Elevated Area 1 in SU05, Elevated Area 1 in SU18 Elevated Area 2 in SU20, and Elevated Area 1b in SU22, respectively.

Mallinckrodt calculated the average survey unit doses based on the SOF calculated from the systematic samples for each survey unit. The total survey unit dose was then calculated by adding the elevated area doses for the survey unit to the average survey unit dose. The projected doses were less than the NRC criteria for unrestricted release for all soil survey units (Table 4-2).

**Table 4-2 Summary of Projected *In Situ* Doses for Soil Survey Units**

| Survey Unit | Systematic Samples $SOF_{Net}$ | Average Survey Unit Dose Dose (mrem/yr) | Total Elevated Area Dose (mrem/yr) | Total Dose (mrem/yr) |
|---|---|---|---|---|
| **SU01** | 0.02 | 0.50 | 3.23 | 3.73 |
| **SU02** | 0.04 | 1.00 | 0.87 | 1.87 |
| **SU03** | 0.06 | 1.50 | N/A | 1.50 |
| **SU04** | 0.05 | 1.25 | N/A | 1.25 |
| **SU05** | 0.09 | 2.25 | 4.84 | 7.09 |
| **SU06** | 0.10 | 2.50 | 2.12 | 4.62 |
| **SU07** | 0.04 | 1.00 | N/A | 1.00 |
| **SU08** | 0.02 | 0.50 | N/A | 0.50 |
| **SU09** | 0.01 | 0.25 | N/A | 0.25 |
| **SU10** | 0.08 | 2.00 | 1.23 | 3.23 |
| **SU11** | 0.05 | 1.25 | 0.38 | 1.63 |
| **SU12** | 0.22 | 5.50 | 1.70 | 7.20 |
| **SU13** | 0.14 | 3.50 | N/A | 3.50 |
| **SU14** | 0.10 | 2.50 | N/A | 2.50 |
| **SU15** | 0.05 | 1.25 | N/A | 1.25 |
| **SU16** | 0.01 | 0.25 | N/A | 0.25 |
| **SU17** | 0.03 | 0.75 | N/A | 0.75 |
| **SU18** | N/A | N/A | 6.23 | 6.23 |
| **SU19** | 0.11 | 2.75 | 0 | 2.75 |
| **SU20** | 0.03 | 0.75 | 0.40 | 1.15 |
| **SU21** | 0.04 | 1.00 | N/A | 1.00 |
| **SU22** | 0.08 | 2.00 | 19.79 | 21.79 |

**4.3 NRC Evaluation of Dose Assessment**

In the NRC's approval of license amendment 7, the NRC staff found that it is acceptable for Mallinckrodt to use the dose assessment approach to demonstrate compliance with the license termination criteria in 10 CFR 20.1402. In its review of the DP the NRC staff also previously concluded that the industrial worker scenario was appropriate for the Mallinckrodt site (ML091831289) and that the parameter values selected by Mallinckrodt for the dose assessments were acceptable.

The NRC staff finds that the method used by Mallinckrodt to calculate the average dose for each survey unit (i.e., multiplying the SOF by 25 mrem/yr) is acceptable and is conservative because this approach assumes that residual radioactivity is located at the surface. The site is paved and many areas of the site have also been backfilled, so the residual radioactivity is not located directly at the surface. Summing of *in situ* dose from elevated areas within the survey unit is also acceptable and is conservative because this approach assumes that the elevated areas are co-located, while in reality the elevated areas are in different portions of the survey units.

In the *in situ* dose assessments performed for the elevated areas, Mallinckrodt assumed the same parameter values as were assumed in the previously approved DP calculations except for those related the radionuclide concentration and physical configuration of the elevated area (*i.e.*, area, thickness, and cover depth). The NRC staff finds that the use of the same parameters from the DP, except for those related the radionuclide concentration and physical configuration of the elevated area (*i.e.*, area, thickness, and cover depth), is appropriate because those are the only differences between the conceptual model for the dose from the whole survey unit and the dose from the elevated area. The NRC staff review compared the parameters assumed for the concentrations to the concentrations measured in the FSS samples and found that the activities used in the elevated area dose assessment are representative of the concentrations of residual radioactivity in the elevated areas. The NRC staff also reviewed the assumed areas and cover thicknesses for the elevated areas and found that they reasonably represent the elevated areas. Mallinckrodt used probabilistic distributions for the thickness of the elevated areas that in some cases have a wide range. The thickness of the elevated areas could have been more accurately represented by a narrower distribution based on the observed thickness. However, independent NRC calculations for the elevated areas at Mallinckrodt found that the projected dose is not sensitive to the range of thicknesses assumed by Mallinckrodt, and therefore the probabilistic distributions assumed by Mallinckrodt are acceptable. NRC staff also performed independent dose assessment calculations for the *in situ* dose assessments and found that Mallinckrodt's calculations were performed accurately.

The NRC staff also finds that Mallinckrodt's evaluation of the potential dose due to an intrusion event ensures that the dose will remain less than 25 mrem/yr even if the material is uncovered. The NRC staff evaluated the parameters assumed for the intruder assessment and the calculations performed and found that the parameters are appropriate for evaluating an intrusion event and that the calculations were performed correctly.

For the above reasons, the NRC staff concludes that the dose assessments were performed appropriately for each survey unit. Because each of the survey unit doses is less than

25 mrem/yr, the NRC staff concludes that the dose assessments performed by Mallinckrodt demonstrate that the final residual radioactivity at the Mallinckrodt site is less than the 25 mrem/yr annual dose criterion for unrestricted release in 10 CFR 20.1402 and that there is reasonable assurance that the dose to the average member of the critical group is not likely to exceed this dose criterion.

## 5. NRC Inspections and Confirmatory Assessments

The NRC Region III inspectors performed a number of inspections and confirmatory assessments during the time Mallinckrodt was performing remediation activities. Additionally, NRC's contractor, Oak Ridge Associated Universities (ORAU) also performed confirmatory surveys.

### 5.1 NRC Inspections

Summaries of the NRC inspections performed over the course of the Mallinckrodt remediation project are provided below.

The NRC Region III inspectors conducted an on-site inspection on January 31, 2011, and an in-office review on February 23, 2011 (ML110680213). During the inspection, the inspectors reviewed the contractor's on-site laboratory and radiological survey instrumentation QA program. The inspectors also reviewed the licensee's Master Project Plan (MPP), Work Plan (WP), Health and Safety Plan (HASP), Field Sampling Plan (FSP), the Quality Assurance Project Plan (QAPP), and select procedures. The inspectors interviewed select licensee and contractor management and staff regarding their roles, responsibilities, and knowledge related to the decommissioning project and safety. NRC inspectors found that the licensee's MPP, WP, HASP, FSP, QAPP and procedures were consistent with the DP. The inspectors observed that the management and staff were knowledgeable and cognizant of their roles and responsibilities regarding the project and safety. No violations or findings of significance were identified.

During an inspection on April 28, 2011 (ML111430673), the NRC inspector observed that the waste water discharges were in compliance with 10 CFR, Part 20, Appendix B release limits. The inspector also observed that the on-site laboratory was adequately calibrated to perform the isotopic analyses and the established nuclide library was adequate for the identification of radionuclides of concern. During the FSS, the inspector observed the workers conducting sampling by collecting a sample near the surface of the excavation, removing the rocks, and only using the soil for the isotopic analyses, based on the assumption that rocks were clean. The inspector selected one biased sample collected by ORAU containing a mixture of rock and soil, and had the licensee's contractor analyze it at the on-site laboratory. Significant activities were found both in rock and soil. The inspector also noted that based on the approved dose model used to derive the $DCGL_W$ values, the licensee should collect one-meter composite samples instead of near surface samples. The inspector determined that due to under-estimation of sample activities by excluding the rock, the site may not be ready for the FSS unless additional excavation was performed. No violations were identified.

During another inspection on June 1, 2011 and June 2, 2011 (ML111721708), the inspectors observed NRC's contractor ORAU performing confirmatory surveys of SU01, SU02, and SU03.

Inspectors also observed licensee's contractor conducting final status surveys, excavation, and remediation. Inspectors reviewed the licensee's FSS sampling results for SU02 and verified material greater than ¼-inch was included in the sample analysis. Inspectors observed FSS sample collection from SU01 and SU03, sample processing for laboratory analyses, and excavation remediation activity guided by action levels based on gamma scans. They evaluated the overall performance on-site of licensee's contractor in addition to laboratory and radiological survey instrumentation quality assurance programs. Additionally, inspectors conducted independent confirmatory gamma scans of SU01, SU02, and SU03. No violations or findings of significance were identified.

Two on-site inspections were conducted on December 16, 2011 and April 26, 2012 by NRC Region III inspectors (ML12181A332). The inspections included an independent confirmatory survey of SU09 and SU17, and in-process inspector reviews of the licensee's decommissioning activities and FSS packages of completed survey units. The inspector determined that decommissioning activities were being conducted in accordance with the DP, work plans, procedures, and the NRC regulations. The inspection report shows that licensee's contractor completed an audit of their radiation safety program for the C-T Phase II Decommissioning Project and identified two findings and six observations of low safety significance, which were corrected and preventative actions were taken. The inspectors determined that the licensee's effluent releases were not exceeding the 10 CFR, Part 20, Appendix B release limits. The inspectors also determined that the licensee was temporarily storing excavated material in accordance with the DP, work plans, procedures, and the NRC regulations. No violations or findings of significance were identified.

The NRC Region III inspectors completed two on-site inspections on August 28, 2012, and December 11, 2012; and on January 23, 2013, conducted an in-office review of laboratory analytical results of samples collected from the December 11, 2012 inspection (ML13039A359). During the December 11, 2012, on-site inspection, the NRC inspectors reviewed the FSS packages of SU10, SU11, and SU19 to ensure the licensee conducted the survey as described in the DP. The inspectors also reviewed the comparative analysis of on-site gamma spectroscopy with ORAU confirmatory sampling results to ensure the accuracy of the on-site laboratory. The inspectors conducted confirmatory radiological surveys of SU11 and collected three soil samples for analysis by the NRC's contract laboratory, ORAU, for the isotopes of concern. The inspectors observed that the licensee's contractor, EnergySolutions, conducted FSS activities in accordance with guidance in MARSSIM, the DP, FSP, and the QAPP; and determined that the quality assurance program for the on-site laboratory and the DQOs for sample collection and analysis were achieving their purposes. Based on inspection reviews of completed survey units and independent confirmatory surveys the inspectors concluded that the licensee was conducting the FSS activities in accordance with the DP and license requirements. No violations or findings of significance were identified.

On March 15, 2013, the NRC Region III inspector completed an inspection at the C-T Plant 5 area (ML13101A108). During this on-site inspection, the inspector examined decommissioning activities conducted under Mallinckrodt site-specific work plans and the NRC approved DP, and included an examination of decommissioning documentation and representative records, observations of activities, and interviews with personnel. The inspector performed confirmatory radiological surveys of the backfilled and affected areas within and around the Plant 5 area, and discussed the status of radioactively contaminated material identified in the ground next to Building 240. Based on independent confirmatory surveys, the NRC inspector concluded that the licensee was conducting the decommissioning of the Plant 5 area in accordance with the DP and license requirements. No violations or findings of significance were identified.

### 5.2 ORAU Confirmatory Surveys

At the request of the NRC, ORAU conducted confirmatory survey activities within the Plant 5 area during two site visits. The survey activities included visual inspections/assessments, measurement, and sampling activities. The first site visit occurred on April 28, 2011, and included survey activities within SU01. Due to the licensee's schedule for backfilling the excavation, preliminary data had been collected and the results indicated that SU01 was ready for FSS activities. Therefore, when ORAU arrived, the licensee's FSS activities were in progress. ORAU began gamma walk-over scans and identified several locations having elevated radiation levels within SU01. ORAU also observed the licensee's procedure for collecting soil samples. The soil samples were sieved resulting in the removal of potentially contaminated slag material (greater than the sieve size) and the excess material/slag was left behind in the surveyed area.

As a result of the findings from the first site visit, and at the request of the NRC, ORAU performed a follow-up site visit to resurvey this area, during the period of June 1 through June 2, 2011. However, during the time between the two site visits, the licensee indicated that emergency sewer repairs were performed on an adjacent building which compromised the original SU01 boundaries. The original SU01 boundaries had been redefined and additional soil removal had been performed. The licensee also indicated that SU03 was ready for confirmatory activities at the time of the second visit. SU02, just west of SU01 and SU03, had been backfilled prior to the second visit. Additionally, soil to be used as backfill was also subject to confirmatory surveys and sampling; however, it was not available during either site visit. Similarly during the second confirmatory site visit, the licensee was still performing FSS scans within all survey units.

#### 5.2.1 Gamma Walk-Over Scans

ORAU performed high density surface scans within SU01 and SU03. Scans were performed using 2-inch × 2-inch sodium iodide, thallium-activated [NaI(Tl)] detectors coupled to ratemeter-scalers with audible indicators. ORAU field personnel relied on the audio output to identify any locations of elevated direct gamma radiation that might suggest the presence of residual contamination. Gamma detectors were also coupled to GPS systems that enabled real-time gamma count rate and position data capture. Numerous locations exhibiting elevated direct gamma radiation were identified by ORAU during the scanning phase and marked with flags for further investigation during the sampling phase. A mean count rate of 12,600 cpm was observed for the gamma walk-over scans performed during the first site visit on April 28, 2011. Detector response was the highest at the corners and western edge of SU01 where count rates were in excess of 60,000 cpm. Scans performed during the second site visit, June 1—2, 2011, revealed a slightly higher mean count rate; however, there were fewer areas with elevated count rates that could have been indicative of residual contamination. The additional remediation following the emergency sewer repair removed most of the contamination observed during the first site visit.

### 5.2.2 Soil Sampling

ORAU observed slag material scattered throughout SU01 and SU03. If this material was present at a specific sample location it was collected as part of ORAU's sample. Surface samples, at 15 cm depths, were collected from judgmental locations that exhibited an elevated detector response. A static one-minute count was taken prior to sample collection and an approximate count rate was recorded after the sample was collected. If the detector response significantly increased after taking the initial sample, additional samples were collected from the same location at a greater depth or immediately adjacent to the initial sample. The sample material was also screened during sample collection to ensure the material exhibiting elevated radiation levels was obtained.

During the first confirmatory site visit, ORAU collected 12 soil samples from eight locations. FSS samples were also being collected by the licensee during the ORAU confirmatory activities. ORAU observed that the licensee sieved out the greater than one-quarter inch (+¼ inch) sample material in the field and only the less than one-quarter inch (-¼ inch) material was retained as the sample. ORAU also observed that the larger +¼ inch portion of the sample contained slag material.

During the second confirmatory visit, ORAU collected 13 samples from SU01 and SU03. SU02 had already been backfilled at the time of the second site visit and was not originally planned for confirmatory activities; however, three samples were collected at the request of NRC. Similarly, the licensee was still performing FSS scans within the survey units.

### 5.2.3 Summary of Confirmatory Survey Findings and Results

ORAU's confirmatory report indicated that based on the independent measurement and sample results obtained during the first site visit, that the original SU01 was not ready for FSS activities or confirmatory activities. Due to the larger slag material observed in the field during sample collection, the ORAU Project Manager requested that the ORAU laboratory staff first count the entire sample and then sieve each sample and then count both the -¼ inch and +¼ inch sample material separately via gamma spectroscopy. Concentrations for one or more of the radionuclides of concern were in excess of the $DCGL_W$s in four of the twelve confirmatory samples. The ORAU laboratory analyses also indicated elevated radionuclide concentrations in the slag (+¼ inch sample material) in three of the 12 soil samples with U-238 contributing the highest activity concentrations within the slag. During this site visit, ORAU observed larger slag material that exhibited elevated radiation levels (and noted this observation to the NRC), yet the licensee's procedure was to sieve the +¼ inch sample material out of each sample in the field and leave it behind in the excavation. The NRC took custody of one ORAU sample and requested that the site laboratory perform a preliminary analysis of the sample. The on-site laboratory's purpose was to screen samples prior to sending them to an off-site laboratory for analysis. Typically when the site lab received a sample, only the -¼ inch material remained. The NRC requested a quick gamma spectroscopy count of the entire ORAU sample. The result slightly exceeded the $DCGL_W$ for Ra-226. Then the NRC requested the +¼ inch material be sieved and counted separately. This result greatly exceeded the Ra-226 $DCGL_W$.

ORAU also observed that the FSS technicians were not relying on the audible response of the instrument to pinpoint judgmental locations real time. Their method was to post-process the data in the office then return to the survey unit to investigate suspect locations. However, listening to the audible output would enable the FSS technician to stop and pause at elevated locations allowing the radiological instrumentation response to reach full deflection than would be observed when simply passing over an anomalous area. Furthermore, ORAU noted that if the technicians had utilized the audible feature in combination with an in-field screening method during the sample sieving process, they may have also identified the +¼ inch slag material as a radiological contamination issue.

Due to an ORAU laboratory error, the samples from the second site visit were not analyzed by the same methodology as the samples from the first site visit. Laboratory personnel sieved the samples and inadvertently discarded the +¼ inch sample material in a radioactive waste container (in accordance with the standard ORAU laboratory procedure for soil samples). Therefore, only the -¼ inch material from the second set of samples was analyzed. The independent measurement and sample results obtained during the second site visit identified two sample locations within SU01 that, based on the discarding of the +¼ inch sample material, likely exceeded the $DCGL_W$s. Radiological analyses of one sample identified the presence of elevated concentrations of Pb-210, Th-230 and Ra-226. A particle was isolated from another sample that contained excessive uranium concentrations. One sample also had elevated Th-230 concentration but Ra-226 and Pb-210 concentrations were not elevated. Two soil samples, from one sample location within SU02, exceeded the $DCGL_W$ for Ra-226.

ORAU's confirmatory report indicated that although ORAU identified a number of locations within SU01 and SU03 which were in excess of the $DCGL_W$s, the licensee may use EMC calculations to determine $DCGL_{EMC}$s for small areas of elevated activity and the calculated $DCGL_{EMC}$s should demonstrate that these small areas of localized contamination will meet the approved unrestricted release criteria.

### 5.3 NRC Conclusions Based on Inspections and Confirmatory Survey Findings

As is summarized above, the NRC Region III inspectors performed a number of inspections and confirmatory assessments during the time Mallinckrodt was performing remediation activities. The inspectors observed that the decommissioning and FSS activities were being conducted in accordance with the DP.

ORAU identified a number of issues during its confirmatory surveys including that locations in SU01 and SU03 that were above the $DCGL_w$ values and that potentially contaminated material was being sieved and discarded without being surveyed appropriately. Mallinckrodt performed additional remediation of SU01 and SU03 after the ORAU confirmatory surveys. Additionally, Mallinckrodt evaluated elevated areas in their survey units using dose assessments as described above. Also, in response to the issue identified by ORAU, Mallinckrodt changed their process to no longer discard the material that did not pass the sieve and to perform a screening count of this material. Mallinckrodt performed an investigation if the material was above half of the $DCGL_W$. The NRC staff therefore considers Mallinckrodt to have appropriately addressed these issues.

## 6. Conclusions

Mallinckrodt completed the decommissioning of its site in St. Louis, Missouri. Based on observations during NRC inspections and the findings in this SER, decommissioning activities have been carried out in accordance with the DP. The NRC staff has reviewed the FSS data and results for the Mallinckrodt Columbium-Tantalum Plant, license number STB-401 according the Consolidated Decommissioning Guidance (NUREG-1757) and guidance in MARSSIM (NUREG-1575). For the reasons described above, the NRC staff has concluded that the FSS design and data collected were adequate to characterize the residual radioactivity. The NRC staff also concluded that the data analysis and dose assessments performed are appropriate and that the projected dose from residual radioactivity in these areas is less than 25 mrem/yr. As is documented in the NRC's SER for the Phase II DP, the NRC staff concluded that the DCGL values are ALARA. Additionally, the NRC staff concluded in its approval of Mallinckrodt Amendment 7 that the ALARA requirement in 10 CFR 20.1402 is met for the dose assessment approach because of the difficulty in performing any additional remediation of residual radioactivity located in inaccessible areas. For these reasons, the NRC staff has determined that Mallinckrodt has demonstrated that the licensee's site will meet the radiological criteria for license termination described in 10 CFR Part 20, Subpart E and the exemption granted by the NRC in its approval of the Phase II DP, and that there is reasonable assurance that the dose to the average member of the critical group is not likely to exceed the 25 mrem/yr dose criterion.

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