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Mallinckrodt Inc.
675 McDonnell Boulevard
Hazelwood, MO 63042
314-654-2000

Contact:
Karen Burke
Director, Environmental Remediation
Direct Dial: (314) 654-5838
Fax: (314) 654-6486
e-mail: karen.burke@covidien.com

January 28, 2008

Attn: Document Control Desk
US Nuclear Regulatory Commission
Washington DC 20555 - 0001

RE: NRC Docket 40-06563, NRC License STB - 401

Dear Mr. Buckley:

Mallinckrodt's responses to NRC staff request, dated January 28, 2008, for additional information concerning URO removal are enclosed. Some pages in the initial request for authorization to remove and dispose of the URO have been revised to be compatible with the responses. A copy of the initial text, with revisions indicated by vertical lines in the left margin, is also enclosed. Figures 3-1 and 3-2 and Appendices 1 and 2 in the initial submittal remain unchanged and are not enclosed herewith.

If you have any further questions concerning the URO removal application or concerning these responses, please contact me.

Sincerely yours,

Karen Burke

Karen Burke
Director, Environmental Remediation

Enc.: responses to RAI
revised URO removal text

cc: John Buckley
Thomas Youngblood

NMSS01

PLANT 6W URO REMOVAL LICENSE AMENDMENT APPLICATION SUPPLEMENTAL INFORMATION

NRC RAI Concerning Intentional Mixing to Meet Waste Acceptance Criteria

Please provide the information described in NUREG-1757, Vol. 1, Rev. 2, Section 15.13, on the use of intentional mixing to meet a disposal facilities WAC. Mallinckrodt should provide a description of radiation surveys or the process to show that radioactive materials meet the WAC; identify the source of soils/materials to be mixed with source materials to meet the WAC; and describe how Mallinckrodt will address inhomogeneities in the URO in order to meet the WAC.

Response:

Mallinckrodt intends to have its contractor remove the approximately 4 feet of cover atop the buried URO and set it aside. This will create a depression in which excavation of URO may occur.

The contractor will excavate the URO and material around its margins as described in figures included in the application. That will include peripheral soil enabling sloping sides and marginal material beneath the buried URO.

Aggregating URO and Adjacent Soil. In order to meet the *unimportant concentration* criterion of 0.05 wt% source material[1] and to satisfy waste acceptance criteria (WAC) specified by the receiving disposal facility, excavated bulk URO and adjacent cinder-soil would be aggregated and mixed within the bounds of the excavation. Excavation by conventional earthmoving equipment, *e.g.,* by track-propelled backhoe and loading into railcars by rubber-tire-propelled bucket excavator, is planned. Mixing will be done by operation of the excavation equipment also used to excavate the soil and URO and used to load it into rail cars.

Soil to be mixed with the URO material will originate in Plant 6W as soil surrounding the URO. Mallinckrodt will not import soil from without Plant 6W to achieve conformance with the WAC for disposal.

Although the URO was buried in 30-gallon steel drums, now, some 30 years later, those containers are expected to have disintegrated by rusting and are not expected to interfere with mixing and disposal. The URO was a finer particulate than the coal ash-soil in which it was buried; thus, it would be expected to be blendable with the coal ash-soil. In the event enough remnants of the drums remain to inhibit mixing and disposal, Mallinckrodt would empty their contents and arrange for disposal of the contaminated drums at the same disposal facility as the URO-soil mixture.

Mallinckrodt intends that mixing of URO and soil will be adequate to satisfy WAC in each rail car and thereby avoid substantial, localized concentration in excess of the WAC. The URO-soil-coal ash blend will be characterized by radioactivity measurement prior to release to a carrier for transport

[1] 10 CFR Part 40.13(a)

in order to assess compliance with 10 CFR Part 40.13(a) and with disposal site acceptance criteria. Surveillance would be done by sampling and analysis or by *in-situ* radiation measurements to assess whether stockpiled URO-soil mixture meets the WAC, including localized and average radioactivity concentration. Provision that radioactivity in a pocket of material may not exceed 3 times the average concentration specified as a WAC would also be evaluated. In the event the destined disposal facility were to take possession in rail cars on-site, their personnel would provide additional assurance that shipments leaving the site meet all WAC.

Radioactively contaminated bulk solid waste, *i.e.*, URO-soil, will only be disposed by transfer to a disposal facility authorized by the State in which it is located to receive an unimportant concentration of source material. Disposal is also subject to approval from the cognizant state regulatory agency(ies) in which the disposal facility is located.

Selective Excavation of URO. An unreasonable volume of cinder-soil adjacent a trench containing one or more URO burials might be required to be mixed to achieve an *unimportant concentration* less than 0.05 wt% and or meet the WAC at a RCRA disposal facility. In such unexpected event, URO in that burial or trench would be excavated selectively and separated from the adjacent soil to the extent practical. Mallinckrodt would arrange to transfer it to a facility licensed to receive and dispose of it. That URO, exceeding the WAC at a RCRA disposal facility, would be disposed by licensee-to-licensee transfer to an NRC-licensed or Agreement State-licensed disposal facility authorized to receive it.

Adjacent soil excavated around the margins of the selectively excavated URO and to achieve sloping sidewalls would be verified to satisfy the WAC at a RCRA disposal facility and would be released for shipment to and disposal at such.

Measurements, Radioactivity concentration in URO-soil to be released for transport to disposal off-site will be measured and compared with *unimportant concentration*[2] criterion and with disposal facility WAC to assure compliance in each rail car. Intended measurement will analyze URO-soil samples by gamma spectrometry for long-lived, uranium series and thorium series radionuclides measurable by gamma ray emission. As needed, URO-soil samples will also be analyzed for Th^{230} and Ra^{226} by alpha spectrometry. Because Th^{230} and Ra^{226} in adjacent soil characterization samples tend not to be in radioactive equilibrium with parent U^{238}, but in deficit, a prominent number of samples of the URO-soil mix will be analyzed for Th^{230} and Ra^{226} to test compliance with the WAC.

NRC RAI Concerning the Technical Basis for Surface Contamination DCGL

Please provide the bases for the surface contamination Derived Concentration Guideline Level (DCGL) for equipment release surveys in Table 6-4. The license amendment request proposes 2400 dpm/100 cm^2. Mallinckrodt should explain the basis for 2400 dpm/100 cm^2 or to demonstrate (by RESRAD-BUILD, etc.) that 2400 dpm/100 cm^2 will not exceed the applicable dose criteria.

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[2] 10 CFR Part 40.13(a)

Response:

Explanation of Proposed Limit: Materials License STB-401, condition 16 specifies that equipment considered for release from a restricted area without restriction on use will be subject to NRC "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material," [3, 4]

The initially proposed limit of surface contamination on equipment subject to removal from Plant 6W was derived by apportioning the sum-of-fractions of the limits for uranium series and thorium series compliant with license condition 16 and with NRC Policy and Guidance Directive FC 83-23. The basis of apportionment was the U-to-Th ratio represented by measurements in Plant 5.

More recent measurements of U series and Th series in URO and in adjacent soil in Plant 6W are now proposed as bases of a derivation of maximum acceptable areal contamination on equipment associated with the URO project and subject to removal from Plant 6W. The uranium-to-thorium ratio observed in each sample and the arithmetic average is tabulated in Table 1.

Fourteen samples taken from URO burial zones exhibited average uranium –to- thorium radioactivity ratio about 6 or more. Forty soil samples taken by the USACE in soil adjacent the URO burials exhibited average uranium –to- thorium ratio about 7 or more. Overall, these measurements support an estimate radioactively contaminated equipment subject to survey and release from Plant 6W during the URO removal project could be conservatively represented by a uranium–to- thorium ratio = 5.

A sum-of-fractions of the limits of $U_{natural}$, U^{238}, U^{235}, and $Th_{natural}$ was derived for a conservative U -to-Th radioactivity ratio of 5-to-1. Adjusted for alpha emissions in each of U and Th series in equilibrium per parent disintegration, the sum-of-fractions derivation becomes:

$$Limit_{\alpha} = \frac{5 \times {}^{8}/_{6} + 1 \times {}^{6}/_{6}}{\frac{5 \times {}^{8}/_{6}}{5000} + \frac{1 \times {}^{6}/_{6}}{1000}} = 3300 \frac{\alpha}{min \cdot 100\ cm^2}$$

Where

$Limit_{\alpha}$ = maximum acceptable average alpha radiation emission rate on a surface for unrestricted release ($\alpha/(min \cdot 100\ cm^2)$)

5 = disintegrations of parent U^{238} in uranium series per 1 disintegration of parent Th^{232} in thorium series

8 = 8 alpha emitted in U series per parent U^{238} disintegration

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3 NRC Materials License STB-401, Docket 40-06563.

4 NRC. "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material." July 1982. Enclosure 2 in Policy and Guidance Directive FC 83-23. Termination of Byproduct, Source, and Special Nuclear Material Licenses. Nov 1983.

6 = 6 alpha emitted in Th series per parent Th^{232} disintegration

5000 = maximum acceptable average alpha emission rate per minute per 100 cm^2 surface area from U_{nat}, U^{235}, U^{238}, and associated decay products

1000 = maximum acceptable average alpha emission rate per minute per 100 cm^2 surface area from Th_{nat}, Th^{232} and associated decay products

Since the U to Th ratio was measured and is expressed as radioactivity referenced to parents of series in radioactive equilibrium while the limits are expressed as alpha emission rate, derivation of the $Limit_{\alpha}$ requires the ratio of alpha emitted from each decay series, U/Th = 8/6, to relate parent radioactivity ratio and the alpha emitted by each series. Thereby, a maximum acceptable average areal contamination limit on equipment associated with the URO project and that may be released from Plant 6W during the URO removal project without restriction on use or disposition, $Limit_{\alpha}$, = $3300 \frac{\propto}{min \cdot 100\ cm^2}$. Consistent with NRC FC 83-23, maximum acceptable surface contamination proposed is 3 times the average $Limit_{\alpha}$ and maximum acceptable contamination removable from a surface is 0.2 of the average $Limit_{\alpha}$.

Derivation by RESRAD-BUILD: The RESRAD-BUILD computer model was used to derive maximum acceptable areal radioactivity density (MAAD) of the uranium series and, separately, the thorium series on an interior surface of a building or installed equipment that would cause no more than 25 mrem/yr to a potential occupant. Bases of the modeling are described in C-T Phase I Decommissioning Plan, Appendix C. The results for the uranium series in radioactive equilibrium and, separately, for the thorium series, in Appendix C, Table C1, therein are:

Areal Density of Parent in Series Corresponding to 25 mrem/yr Dose

Source	(dis/min 100 cm^2)
uranium series	1.59×10^4
thorium series	9.54×10^3

Key radionuclides were measured in URO and adjacent soil samples. Uranium to thorium radioactivity ratios averaged about 6-to-1 or greater. A sum-of-fractions of the MAAD, assuming a 5-to-1 ratio, derived 14000 dis/(min·100 cm^2) as the composite MAAD, or $DCGL_W$, in and on buildings and installed apparatus surveyed for release without restriction during C-T Decommissioning.

$$MAAD = \frac{5+1}{\frac{5}{1.59 \times 10^4} + \frac{1}{9.54 \times 10^3}} = 14300 \frac{dis}{min \cdot 100\ cm^2}$$

Thus, the $Limit_{\alpha}$ proposed for unrestricted release of removable items would pose potential dose rate well below 25 mrem/yr to a person.

Table 1. Uranium -to- Thorium Radioactivity Ratio Related to URO Removal

The Basis for Maximum Acceptable Areal Contamination on Equipment Subject to Release

URO Samples

Trench	U -to- Th Ratio	U238 -to- Th232 Ratio
1	0.7	0.6
1	0.6	0.5
1	0.8	0.8
1	5.8	7.9
1	5.3	4
1	19.6	24.1
1	2.1	2.6
1	4.8	6.7
2	7.2	8.2
2	10.3	14.4
2	4.3	3.8
2	12.2	12.7
3	2.1	0.9
3	3.8	3.5
average	5.7	6.5

Adjacent Soil Samples

Trench	U -to- Th Ratio	U238 -to- Th232 Ratio
1	10.2	15.9
1	2.6	1.4
1	2.6	5.6
1	5.0	6.6
1	7.0	10.6
1	2.6	3.6
1	5.7	4.3
1	4.1	8.8
1	6.0	9.9
1	9.7	14.0
1	4.9	2.6
1	18.8	34.1
1	4.6	5.0
1	3.1	4.5
1	5.3	5.7
1	9.2	15.2
1	14.0	30.2
1	4.8	8.4
1	7.8	14.2
1	10	19.0
1	8.4	17.0
1	4.2	8.3
1	18.6	29.8
1	24.9	23.5
2	3.7	3.8
2	15.8	22.7
2	4.7	4.6
2	13.0	31.3
2	4.7	6.7
2	1.0	12.0
2	6.9	8.3
2	3.3	5.3
2	6.0	10.9
3	2.8	2.8
3	2.3	2.6
3	2.2	2.3
3	4.6	3.2
3	3.2	4.1
3	2.4	3.7
3	1.6	1.9
average	6.8	10.6

U -to- Th ratio in URO samples is average of U238, Th230, & Ra226 -to- average of Th232, Th228, & Ra228

U238 -to- Th232 ratio in URO samples is U238 -to- Th232

U -to- Th ratio in adjacent soil samples is average of U238, Th230, & Ra226 -to- Th232 by the USACE.

U238 -to- Th232 ratio in adjacent soil samples is U238 -to- Th232 by the USACE

Radionuclide Concentration Measured in URO Samples

Trench	Sample ID	Radionuclide Concentration (pCi/g)						
		Th-230	U-234	U-235	U-238	Ac-228	Th-228	Th-232
1	1	1122.00	1189.00	59.00	1278.00	1020.00	2187.00	2136.00
1	2	308.00	258.00	12.60	255.00	217.00	588.00	536.00
1	3	1,156.00	1,014.00	37.80	1,220.00	1,110.00	1,793.00	1578
1	4	435.00	2478.00	73.70	2467.00	298.00	324.00	311.00
1	5	671.00	583.00	26.10	573.00	58.00	143.00	142.00
1	6	67.20	85.30	3.43	85.40	4.75	3.83	3.55
1	7	79.30	64.90	2.57	63.90	49.10	25.20	24.50
1	8	5.12	9.11	0.31	8.88	2.13	1.37	1.32
2	11	42.20	61.20	2.76	65.10	7.43	7.96	7.93
2	12	28.40	51.40	2.11	53.70	5.14	4.12	3.74
2	13	2.51	5.73	0.25	5.54	0.61	1.16	1.45
2	14	11.20	36.50	1.59	37.70	0.97	3.09	2.96
3	9	3517.00	747.00	19.80	842.00	491.00	964.00	927.00
3	10	104.00	89.80	3.35	95.00	21.00	28.10	27.20

Radionuclide Concentration in Samples of Soil Adjacent Buried URO by USAEC

Trench	Sample	Measured Radionuclide Concentration (pCi/g)						
		Ra-226	Th-230	U-238	U-235	Ac-227	Pa-231	Th-232
1	SLD04315	2.29	7.4	10.47	0.62	0.36	1.26	0.66
1	SLD04316	0.85	4.86	1.26	0.07	0.09	0.44	0.88
1	SLD04319	5.66	12.49	48.62	2.35	1.05	0.29	8.72
1	SLD04324	3.82	7.35	8.94	0.46	0.21	1.05	1.35
1	SLD05410	7.08	11.56	18.95	1.1	0.19	0.37	1.79
1	SLD04701	2.92	6.78	8.23	0.53	0.56	0.18	2.26
1	SLD04702	8.16	16.71	8.46	0.85	2.53	1.32	1.96
1	SLD04703	2.05	2.77	11.75	0.55	0.14	0.01	1.34
1	SLD04704	6.82	7.57	17.67	1.13	0.63	1.94	1.78
1	SLD04705	12.25	41.49	50.54	3.29	1.62	2.02	3.6
1	SLD04708	2.48	7.45	2.12	0.23	0.38	1.1	0.82
1	SLD04709	10.11	24.1	52.51	2.96	0.88	1.94	1.54
1	SLD04710	6.19	6.48	7.36	0.64	0.45	2.17	1.46
1	SLD04640	5.24	13.79	17.84	0.96	0.48	0.52	3.94
1	SLD04699	5.25	7.25	7.08	0.26	0.46	1.33	1.24
1	SLD04720	15	121.5	166.4	8.81	2.44	1.89	10.94
1	SLD04722	8.18	33.45	250.83	13.29	1.29	4.14	1.09
1	SLD04723	2.78	10.34	33.81	2.04	0.5	1.65	1.12
1	SLD04724	3.59	7.2	14.75	0.77	0.41	1.27	1.76
1	SLD04725	2.92	8.5	17.46	0.98	0.56	1.79	1.23
1	SLD04726	4.94	13.24	31.18	1.85	0.51	1.21	1.64
1	SLD04727	4.88	16.42	44.58	2.52	0.55	1.47	2.62
1	SLD04728	4.26	7.4	22.7	1.17	0.33	0.98	2.73
1	SLD04729	13.85	46.59	69.41	4.14	1.02	2.73	2.33
1	SLD04730	24.64	56.23	37.15	2.38	1.74	1.98	1.58
2	SLD82810	8.27	12.12	10.67	0.72	0.59	0.63	2.8
2	SLD04711	27.53	15.1	39.22	2.16	2.48	1.73	1.73
2	SLD04712	2.89	6.65	4.64	0.31	0.27	0.81	1.01
2	SLD04713	14.71	18.45	134.62	6.32	0.95	2.18	4.3
2	SLD04714	26.81	31.16	53.7	3.1	2.49	2.85	7.96
2	SLD04715	1.14	10.15	92.03	4.57	0.27	0.88	0.63
2	SLD04732	14.22	32.61	30.27	1.95	1.38	3.12	2.53
2	SLD04733	22.84	23.29	30.63	1.9	1.7	1.85	3.71
2	SLD04734	11.65	13.44	29.55	1.6	0.85	1.42	5.59
2	SLD04735	9.94	13.78	36.22	2.11	0.96	1.19	3.33
3	SLD04333	4.81	7.4	6.21	0.45	0.44	1.09	2.19
3	SLD04716	9.95	11.23	12.82	0.79	0.69	2.19	4.97
3	SLD04717	6.16	8.74	8.27	0.65	0.73	2.13	3.55
3	SLD04718	20.17	19.49	12.09	1.01	1.64	1.96	3.79
3	SLD04719	4.18	5.65	7.24	0.34	0.57	1.76	1.78
3	SLD04736	14.55	6.03	21.85	1.09	0.99	0.8	5.98
3	SLD04737	5.73	4.27	6.77	0.48	0.55	1.63	3.57

REQUEST FOR NRC LICENSE AMENDMENT TO REMOVE URO FROM PLANT 6W

NRC Docket 40-06563
NRC License STB-401

Mallinckrodt, Inc.
3600 North Second Street
St. Louis MO 63147

January 28, 2008

Table of Contents

1. SUMMARY OF PROPOSED ACTION

During 1972 and 1973, in conformance with 10 CFR 20.304, Mallinckrodt buried approximately 300 cubic yards of unreacted ore (URO) from its columbium and tantalum extraction operation (*i.e.*, C-T Operations) in steel drums in a series of trenches located in Plant 6 within its St. Louis plant, where Manhattan Engineering District - Atomic Energy Commission (MED-AEC) activities had previously occurred. Mallinckrodt proposes to remove unreacted ore from burial sites 1 through 9 and dispose of it at an acceptable off-site disposal facility in accordance with Federal and State regulations. This action will remove this source of radioactive material from the applicable site.

Successful management and implementation activities similar to URO removal and disposal and an acceptable facility off-site was demonstrated during C-T Phase I decommissioning. Mallinckrodt proposes to utilize approved controls to administer URO removal and disposition in a manner that protects remediation workers, members of the public, and the environment. Provisions specific to the URO remediation project are described herein.

2. GENERAL INFORMATION

2.1. LICENSE STB-401

The name of the licensee holding STB-401 is Mallinckrodt Inc., which has its principal offices at 675 McDonnell Blvd, St. Louis, MO 63042. The licensed facility is located at the St. Louis Plant, which is located at 3600 North Second Street, St. Louis, MO 63147.

2.2. HISTORY

2.2.1. C-T Operations and URO

Mallinckrodt processed columbite mineral ore and tin slag to extract columbium and tantalum (C-T). Mallinckrodt's C-T process generated an unreacted ore (URO) residue containing materials that were not dissolved during the C-T processing steps. Specific URO composition varied with raw material composition and process conditions. It contained some natural uranium, natural thorium, and their progeny in addition to non-radioactive constituents. In 1972 and 1973, approximately 300 cubic yards of URO was buried in conformance with 10 CFR 20.304 as approved by the Nuclear Regulatory Commission (NRC) in a series of trenches located in Plant 6, where MED-AEC activities had occurred. URO burial trenches were generally excavated to a depth of six feet. An approximate two-foot thick layer of URO in drums was placed in the trench and compacted. The trench was then backfilled with excavated soil and compacted. URO burial trench locations are identified in Figure 3-1. A finished goods warehouse, Building 101, was subsequently constructed above one of the trenches.

2.2.2. MED/AEC Operations

MED-AEC facilities in the area previously known as the Destrehan Street Plant were partially decommissioned in 1950 and 1951. Further decommissioning was performed in the early 1960's. This includes areas now known as Plants 6 and 7. Decommissioning activity included decontamination or demolition of buildings and removal of some soils and subsurface materials.

The Formerly Utilized Sites Remedial Action Program (FUSRAP) was created by the U.S. Congress to identify and control or remediate sites where residual radioactivity remains from activities conducted under contract to the MED and AEC during the early years of the nation's atomic energy program. Some facilities that produced radioactive materials for commercial sale are also included under FUSRAP at the direction of Congress.

The DOE, under the FUSRAP, had the initial responsibility for remediating radioactive and chemical contamination in the areas of the St. Louis Plant that formerly housed MED-AEC operations. However, in October 1997, Congress transferred the FUSRAP from DOE to the U.S. Army Corps of Engineers (USACE). Under FUSRAP, USACE is responsible for the cleanup of both radioactive and hazardous chemical contamination resulting from MED-AEC activities at the St. Louis Plant (SLDS) with oversight by the U. S. Environmental Protection Agency (EPA). These responsibilities are outlined in a Federal Facilities Agreement (FFA) negotiated by EPA Region VII and DOE[1]. The FFA has been amended to transfer these responsibilities to USACE. The FFA further defines the conditions dictated by the EPA to manage remediation at St. Louis. The document creates broad obligations for clean up of all residual waste from uranium processing, including such waste that might have mixed or commingled with other radioactive or hazardous material substance at the SLDS site.

The USACE is currently remediating soils containing subsurface residues of MED/AEC operations as part of the FUSRAP. Some buildings and adjacent open areas in Plants 6 and 7 were used to support C-T manufacturing following their decontamination and release to Mallinckrodt by the AEC in the early 1960s. Some buildings and areas in Plants 6 and 7 were used solely for MED-AEC operations. Soils in these areas contain residues from uranium refining and are therefore subject to remediation by USACE under FUSRAP. The USACE will remediate Plant 6 and 7 soils.

3. LOCATION

3.1. PHYSICAL BOUNDARIES

URO was buried in Plant 6W in ten excavated trenches whose locations are identified in Figure 3-1. Dimensions and volume of each burial zone are identified in Table 1. As physical confirmation occurs, actual volume may vary somewhat.

[1] Federal Facilities Agreement between US Department of Energy and US Environmental Protection Agency, June of 1990, Docket No. VII-90-F-0005.

Table 1. URO Burial Data

Burial Site ID Number	Burial Zone Dimensions Length (ft)	Width (ft)	Depth (ft)	URO Burial Zone Volume (ft^3)
1	29	10	2	580.
2	29	10	1.5	435.
3	29	10	1.5	435.
4	35	10	2	700.
5	35	26	1	910.
6	29	10	2	580.
7	30	10	2	600.
8	30	12	2	720.
9	32	14	2	896.
10[b]	100	10	2	2000.
			total =	7856. ft^3
			total =	291. yd^3

[a] ref. Figures 3-1 and 3-2.

[b] Burial 10 is not subject to this request for removal.

Each burial trench has about 3 to 4 feet of compacted soil cover. In addition, trenches 1 thru 9 are covered by 3 to 5 inches of asphalt while trench 10 is covered by 5 to 10 inches of concrete floor slab. The building with its floor slab atop it make URO buried in trench 10 inaccessible for excavation at this time. Consequently, URO trench10 is excluded from this source removal project.

3.2. DELINEATION WITH FUSRAP

URO buried in Plant 6W is in the middle of the former Destrehan Street Plant used for MED-AEC activities and therefore is subject to the FUSRAP. Mallinckrodt has worked cooperatively with the USACE to agree on delineation of a geographical boundary between buried URO and surrounding land within which Mallinckrodt would remove all material, including the URO. Mallinckrodt proposes the boundary to be that depicted in Figures 3-1 and 3-2, which includes the encompassing trenches 1 through 9 as well as additional soils around these trenches. By removing all material within a designated boundary, a maximum acceptable residual radioactivity concentration specification will not be needed. Removal to a geographical boundary may be verified by measurement of the excavation width and depth; thus a final radiation status survey will not necessary.

The USACE has accepted responsibility under the FUSRAP for management of impacted soils or remediation of impacted soils in Plant 6W outside the boundary within which Mallinckrodt will remove URO. Once Mallinckrodt has completed removal of all soils as depicted on Figures 3-1 and 3-2, the USACE will follow and remediate deeper soils which are beneath the footprint of C-T trenches 1 through 9 and will backfill the area upon completion of the remediation.

4. DESCRIPTION OF URO

URO buried in sites 1 through 9 originated from C-T processing during the first half of 1973 or earlier, excluding 1970 processing, while that buried in site 10 originated from C-T processing during 1970. Available records indicate the composition of ore processed during this time was as summarized in Table 2.

Table 2. Composition of C-T Ore

Year	tin slag to columbite input weight ratio	Weight Fraction in Each Ore		Weight Percent in Ore Composite		U to Th weight ratio
		U in columbite	Th in tin slag	U	Th	
1969	2.7	4.2E-04	5.8E-03	0.011	0.43	0.03
1970	2.7	8.2E-04	5.9E-03	0.022	0.43	0.05
1971	3.4	9.1E-04	5.1E-03	0.021	0.40	0.05
1972	3.7	6.3E-04	5.2E-03	0.013	0.41	0.03
Jan - May 1973					0.52	

Minor amounts of refractory minerals containing U and Th occur in these mineral ores. In tin slag, refractory material also results as molten tin slag cools.

The C-T URO buried in Plant 6W resulted from C-T feed material that was primarily tin slag with a lesser fraction of columbite ore. The tin slag and columbite ore were pulverized and leached with acid to dissolve the columbium and tantalum. After filtration, undissolved ore was neutralized, washed, and dewatered. Thus, URO is comprised of tin slag ore and columbite that did not dissolve by acid leaching. Uranium or thorium that might have dissolved in the C-T process would have reacted with hydrofluoric acid during ore digestion to form insoluble compounds UF_4 and ThF_4.[2]

Moisture content of URO was reported to be 39% at the time of burial. The URO was packaged in thirty-gallon steel drums before burial. Bulk density of the URO was reported to average 65 lb/ft^3.

The radioactivity concentration in URO is described in separate sources. Summary records of burial report the average thorium content in buried URO to have been 1.8 wt% Th.[3] Measurements by Mallinckrodt report columbite processed during December 1968 through April 1969 contained 0.15 wt% U. Tin slag processed during February and March 1969 contained

[2] USNRC. *Environmental Impact Appraisal* for renewal of Source Material License No. SMB-920. Docket 40-6940. NUREG-1027. Nov. 1983.

[3] Brown George and Clifford Whithaus, "Record of Burial or Radioactive Materials," Mallinckrodt Chemical Works, for date of burial July 2 thru 16, 1973.

1.96 wt% Th.[4] Sources have identified concentrations as noted in Table 3. The best estimate is that URO contains about 1.8 wt% thorium and about 0.1 as much uranium, or about 0.15 wt% U.

Table 3. Radionuclide Concentration in Unreacted Ore

Data Source	U^{238} (pCi/g)	Th^{230} (pCi/g)	Ra^{226} (pCi/g)	Th^{232} (pCi/g)
ORNL composite CH 21[A]	620	na	590	1100
Tin Slag URO, 1969	na	na	na	2000
Columbite URO, 1969	500	na	na	< 18
NUS, 1980	2000	na	1500	460

na = not analyzed

[A] 1977 composite sample

5. ORGANIZATION AND ADMINISTRATION

5.1. Introduction

The URO remediation project will be administered in accordance with the provisions in this section. As the project progresses, changes to the project organization may be justified in response to the varying level of site activities. Effective with NRC approval of this license amendment, the licensee may make changes to the organizational structure provided that the safety and quality functions maintain an independent reporting relationship from that of operations, and that the persons responsible for safety functions satisfy educational and experience qualifications.

5.2. Management Organization[5]

5.2.1. Organization

Implementation of the URO removal project will be managed by a team comprised of management, radiation safety, and occupational safety personnel from the Mallinckrodt and contractor organizations. The URO project organization is illustrated in Figure 1.

While Mallinckrodt is responsible for ensuring overall successful implementation of the URO removal, it will contract the services of a remediation contractor to perform the tasks required by the license amendment.

The contractor will develop and/or implement the radiological safety, occupational safety, and environmental protection programs and the procedures required by this URO license amendment. The contractor will provide the equipment, materials, and a trained and experienced labor force to perform the URO removal activities. The contractor will also provide an independent quality assurance program as required by the URO project license amendment.

[4] Kuebler, J.R., Mallinckrodt. "Summary" memo. April 8, 1969

[5] C-T Phase II DP, §9.1, Feb. 26, 2003.

Mallinckrodt will use consultants to assist in the management of the activity. These persons and/or organizations take their direction from the Mallinckrodt Project Manager and may interact directly with the contractor Project Manager and personnel at the request of the Mallinckrodt Project Manager.

Mallinckrodt managers responsible for site contract administration, quality assurance, project engineering, corporate environmental affairs, and legal will support the Mallinckrodt Project Manager. These support functions will be utilized as appropriate and are not identified on Figure 1.

The responsibilities of the primary managers with safety-related responsibilities are provided below.

5.2.2. Mallinckrodt URO Project Manager

The Mallinckrodt URO Project Manager/RSO will provide overall leadership and management of the URO removal project. He or she reports to a Vice President of the Company. The Site Safety Manager and project management and consultants will support the Project Manager.

The URO Project Manager/RSO is responsible for ensuring that the overall URO removal project, including the work performed by contractors and subcontractors, is accomplished in conformance with this license amendment and with applicable health, safety, quality, technical, and contractual requirements. The Mallinckrodt Project Support Engineer is responsible for assuring that NRC requirements are met. He or she also is responsible for coordinating activities between plant operations and the URO removal contractor. He or she will use other Mallinckrodt staff or consultants as appropriate to perform this coordination. The Project Manager/RSO has full authority to halt any operation that he or she believes has the potential to threaten the health and safety of site or contractor personnel, the public, or the environment, is not in conformance with License STB-401, or is otherwise not meeting NRC requirements. He or she is also responsible for ensuring that established environmental programs and contractor environmental programs are in compliance with applicable and relevant laws and regulations. The URO Project Manager is the designated contact with the NRC.

The Mallinckrodt URO Project Manager and Radiation Safety Officer (RSO), is also responsible for ensuring that radiation safety programs are in compliance with applicable and relevant laws and regulations and for auditing the contractor's compliance with these programs. The RSO reports to a Company Vice President.

5.2.3. Mallinckrodt HSE Manager

The Health, Safety, and Environment Manager (HSE Manager) is responsible for ensuring that the URO removal project occupational safety program is in conformance with applicable and relevant laws, regulations, and NRC requirements. He or she may also audit contractor performance to ensure compliance with this URO removal license amendment and other generally applicable requirements. The HSE Manager reports to the Plant Manager. The HSE Manager advises the Mallinckrodt URO Project Manager/RSO on matters pertaining to occupational safety. The HSE Manager has the authority to halt any operation that they believe has the potential to threaten the health and safety of personnel, the public, or the environment.

5.2.4. Contractor Project Manager

The contractor's Project Manager is responsible for the execution of all of the URO removal activities. He is the primary interface with the Mallinckrodt URO Project Manager/RSO. The contractor's Project Manager is directly responsible for all field work being performed by the contractor. As such, he is responsible for field work being conducted in accordance with applicable health, safety, quality, and technical requirements, including Mallinckrodt procedures. The contractor's Project Manager has full authority to halt any operation when he believes these requirements are not being met.

5.2.5. Contractor Radiation Safety Officer

The contractor Radiation Safety Officer (RSO) is responsible for implementation of safety and environmental protection, including radiation protection, environmental protection, and occupational health and safety in the URO removal project. The contractor RSO reports directly to the contractor Project Manager and is functionally independent of Operations, thus assuring independence of action in matters pertaining to radiation and environmental protection, health, and safety. The contractor RSO has the authority to halt any operation that they believe has the potential to threaten the health and safety of personnel, the public, or the environment.

5.2.6. Contractor Operations Manager

The contractor's Operations Manager reports directly to the contractor's Project Manager and receives program and task directives directly from the contractor's Project Manager. The contractor's Operations Manager is responsible for nuclear materials accounting, field engineering, waste management, daily work assignments for all field personnel and the physical execution of the field operational activities for the implementation of the URO removal project. The Operations Manager will ensure that all personnel are properly trained to perform assigned tasks and that the training is appropriately documented. The contractor Operations Manager has the direct responsibility to ensure that all field activity is protective of the health and safety of personnel, the public, and the environment and has the responsibility and authority to halt work in the event they are put at risk.

5.2.7. Contractor Quality Assurance Manager

The contractor's Quality Assurance representative is responsible for establishing and assuring implementation of the contractor quality assurance program, including periodic audits. This function is independent of Operations and will report directly to the Mallinckrodt URO Project Manager/RSO with copies of audits provided to the contractor's Project Manager.

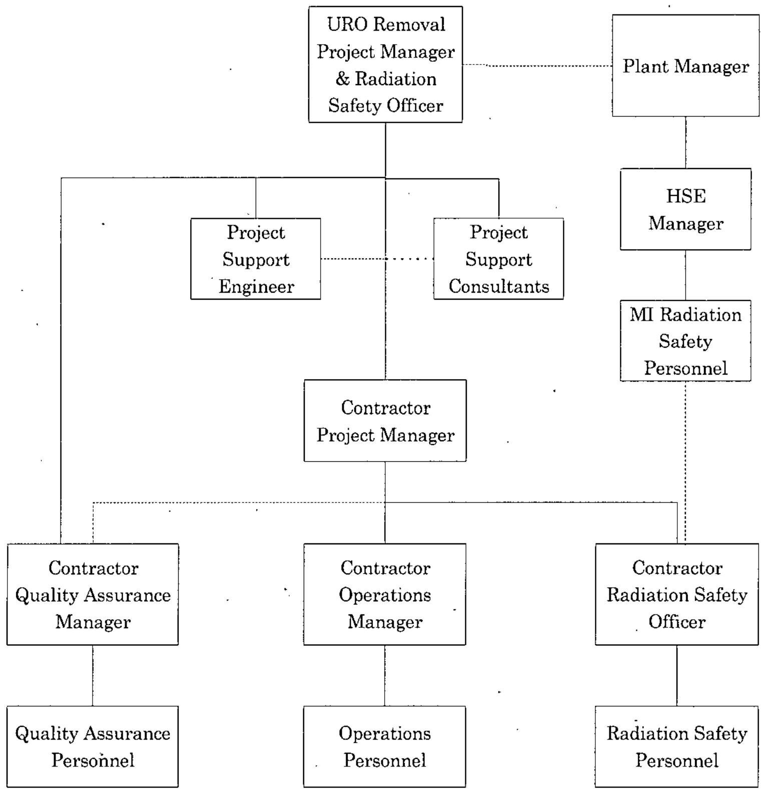

Figure 1. URO Removal Project Organization

Work Controls[6]

Remediation activities for the URO removal project will be performed in accordance with written instructions. There will be four general types of written instructions in use for the URO Project: Plans, Procedures, Field Instructions, Safety Permits (Safety Work Permits, Radiation Work Permits, Hot Work Permits, *etc*.). These written instructions will be reviewed and approved by the contractor operations representative and the RSO, as well as being reviewed and approved by the Mallinckrodt Project Manager/ROS or his or her designated representative where applicable, *e.g*., when health, safety, and quality of the URO removal issues are addressed.

> **Plans** are broad-based documents that provide management guidance for operations in the field. Plans include URO removal contractor developed plans such as a Health and Safety Plan, Waste Management Plan, Quality Assurance Plan, and the Industrial Safety Plan. All plans affecting the health, safety, and quality of the URO removal will be reviewed by Mallinckrodt. Specific procedures, field instructions, and radiation work permits, as discussed below implement these programs and plans.

6 C-T Phase I DP, §2.4.4, July 30, 2002.

Procedures are essential, written instructions and specifications to provide the controls needed to ensure safety and other objectives of the procedure are achieved. A procedure is ordinarily appropriate for repetitive activities such as defining how to operate equipment, calibration methods, or other routine work activities.

Field Instructions are the primary written instructions for remediation work for the URO removal project. They may be as short as a simple job order (e.g. run temporary electricity into Building XX), or as detailed as necessary to safely accomplish the work. The detailed field instructions provide specific instructions in a logical and sequenced manner for one-time or short duration activities requiring a disciplined approach to ensure that health and safety requirements are met.

Safety Work Permits (SWP), or Radiation Work Permits (RWP), specify necessary industrial and radiation safety controls, including personnel monitoring, monitoring devices, protective clothing, respiratory protection equipment, special air sampling, and additional precautionary measures. SWP or RWP are issued for non-routine activities where there is a need to prescribe the conditions under which the work may be done in order to assure adequate protection of workers and the public from the potential hazards that may be encountered. SWP required for remediation activities are usually identified during the preparation and review of procedures and field instructions. SWP or RQP will be prepared in accordance with the contractors written procedure that will be reviewed by Mallinckrodt.

Daily Safety Permits check for hazardous conditions, allow use of spark-generating tools and equipment, ensure adequate ventilation, *etc.*

Mallinckrodt will implement administrative controls that establish guidelines for creation, use, and control of these administrative documents to ensure that URO removal is performed safely, and in conformance with governing regulations, and the NRC license. It will also implement a procedure to manage URO removal records.

5.3. ADJUSTMENTS TO THE ADMINISTRATIVE PROCESS[7]

URO source removal is intended to remove radioactive sources, thereby diminishing the extent of controls needed to assure protection of health, safety, and the environment as it progresses. Mallinckrodt may make justified changes related to the URO removal process without filing an application for an amendment to the license to change the URO removal project when the following conditions are satisfied:

a. the change does not conflict with requirements specifically stated in license STB-401 or impair Mallinckrodt's ability to meet all applicable NRC regulations;
b. there is no degradation in safety or environmental commitments addressed in the NRC-approved license amendment for the activity being performed;

[7] C-T Phase I DP §2.6, Jan. 9, 2002

c. the quality of the work, the remediation objectives, or health and safety will not be adversely affected significantly;
d. the change is consistent with the conclusions of actions analyzed in the Environmental Report;
e. does not result in there no longer being reasonable assurance that adequate funds will be available for URO removal; and
f. does not reduce the coverage requirements for scan measurements and/or sample density.

Persons having managerial responsibilities as identified in Section 5.2, including proponents of controlled documents, will be asked to report any change to the URO removal process that would seem to violate either of conditions a through f. Determination of whether the conditions are met will be made by and each change shall require approval by Mallinckrodt's URO Project Manager/RSO, the contractor's Project Manager, and the contractor's RSO. The contractor's and Mallinckrodt's URO Project Managers are responsible for ensuring that the project is in accordance with applicable health, safety, quality, and technical requirements. Mallinckrodt's URO Project Manager/RSO shall be responsible for approval of operational and engineering changes. The contractor's RSO and Mallinckrodt's Radiation Safety Officer are responsible for assuring that each change conforms to health and safety program requirements.

Mallinckrodt shall retain records including written safety and environmental evaluations of each authorized change that provide the basis for determining that conditions in this 5.3 have been met. The records of each evaluation shall be retained until license termination.

5.4. CONTRACTOR

Mallinckrodt will select an experienced and qualified contractor to perform the URO removal. By letter to the NRC, Mallinckrodt will identify persons occupying positions in the organization named herein, their experience, and qualifications.

5.5. PROPOSED SCHEDULE

Mallinckrodt intends to have its contractor begin the URO removal project as soon as reasonable after NRC approval of this application for license amendment. Due to the coordination with the US Corps of Engineers under the delineation agreement concerning Plant 6W, the URO removal will have to be performed in phases. In general, this means that URO removal activities will be conducted alternately with FUSRAP activities. Mallinckrodt expects it will complete the overall URO removal within 12 months after NRC approval to do the project.

6. HEALTH AND SAFETY

A Health and Safety Program for the URO removal Project will be developed to ensure the safety of all contractors and Mallinckrodt employees, visitors, and members of the public during URO removal. This section describes the measures to protect workers, the public, and the environment during remediation. In recognition that both the amount of radioactivity and the general safety hazards will be reduced as the project progresses, the Health and Safety Program may be modified to be commensurate with the activities being performed. Mallinckrodt will review and approve the Health and Safety Program, and any revisions that are made during the project. Any such adjustment to the requirements of this health and safety program shall be made in accordance with §5.4 herein.

The Health and Safety Program will consist of the following three parts:

- Industrial Safety Program
- Radiation Protection Program
- Environmental Protection Program

6.1. Industrial Safety Program

Industrial safety provisions have been adopted for the URO removal project that augment Mallinckrodt Health, Safety and Environmental Guidelines by adding procedures specific to URO removal when needed. The procedures and administration form the Industrial Safety Program for URO removal. Provisions of the industrial safety program that apply to the URO remediation project are described herein. The total package of procedures and administration will then form the Industrial Safety Program for the URO Project. Table 6-1 lists typical industrial safety procedures that will be used for the planned remediation activities.

Table 6-1
Industrial Safety Procedures

Accident Investigation, Reporting, and Recordkeeping
Safety Color Code for Marking Physical Hazards
Working with Hazardous Chemicals
Welding and Thermal Cutting
Posting Requirements
Safety Training
Selection and Use of Personal Protective Equipment
Aerial Work Platforms
Scaffolds
Housekeeping
Equipment Lockout/Tagout
Operation of Lifting and Handling Equipment
Hand and Portable Power Tools
Electrical
Fall Protection
Guarding Floor Holes and Openings, Wall Holes and Openings
Fire Protection Program
Permit-Required Confined Space Entry Program
Excavation, Trenching, and Shoring
Drum Handling Procedure
Operation of Motorized Vehicles and Mechanized Equipment
Handling, Use, and Storage of Compressed Gas Cylinders
Hot Work
Heat Stress Program

6.1.1. Industrial Safety Training

The St. Louis Plant site-wide industrial safety program or contractor equivalent will be used for training all unescorted individuals involved in activities at the URO project. The purpose of the program is to promote an awareness of the potential risks, and to provide knowledge and proficiency in industrial safety consistent with the assigned tasks. Training takes place on a continuing basis.

Personnel involved in the URO Project will be trained to perform their assigned responsibilities safely. On-the-job training and equipment-specific training will supplement the Mallinckrodt site-wide training program. Training in the proper use of specialized equipment is given before the individual uses that equipment. Credit may be given for applicable training received off-site.

The primary objectives of the industrial safety training program for the URO Project:

- provide information on the industrial safety and hygiene hazards associated with working at the URO Project, and the steps to be taken to provide a safe work environment including those hazards unique to building demolition;
- enable each person to comply with plant rules and respond properly to warnings and alarms under normal and accidental conditions; and,
- enable individuals to recognize potential site specific hazards and to take appropriate measures to prevent personal injury or damage to facilities and equipment

The industrial safety training program will be reviewed and revised as needed to meet changing conditions and ensure that instructions are sufficiently well understood to permit practical application. The status and extent of the training of each individual will be documented to verify that workers are adequately trained for each assigned job.

The industrial safety training program includes:

- weekly shop-talks on pertinent industrial safety information, injury statistics, and specific safety issues;
- specific training on specialized equipment including the use of cranes, forklift trucks, front-end loaders, and scissors lifts;
- general industrial safety training including proper lifting, hearing conservation, eye protection, slips and falls, hazardous material handling, and use of power tools; and,
- specialized training including first aid, CPR, fire fighting, use of respirators, and HAZWOPER.
- safety work permits addressing confined space entry, asbestos removal, lock-out/tag-out, *etc.*

6.2. Radiation Protection Program

Provisions to ensure radiation safety that are proposed to apply to the URO remediation project are described herein. The provisions of the program were previously approved by NRC staff,[8] have been exercised, and are implemented by Mallinckrodt procedures.

[8] CT Phase I DP, §3.3, Jan. 9, 2002

6.2.1. Radiation Protection

The Radiation Protection Program will consist of procedures to protect workers, the public, and the environment from ionizing radiation.

A radiation protection program will be adopted for the URO Project that addresses the following topics. The contractor will be required to implement the program with oversight by the Site RSO.

- health and safety protection measures and policies
- instrumentation, calibration, and equipment
- use of air samplers, monitoring policy methods, frequency, and procedures
- contamination control and personnel decontamination
- external exposure control
- airborne releases and monitoring
- Safety Work Permits, including ALARA
- engineering controls
- transportation
- accident response
- posting and labeling
- records and reports
- potential sources of contamination exposure

An analysis of potential radiological dose during occupational work is presented in Appendix 1.

6.2.2. Radiation Safety Training

All unescorted individuals involved in activities on-site for the URO Project will be required to complete the Mallinckrodt radiation safety training course or the contractor equivalent course. The purpose of the training is to increase awareness of the potential radiation risks during URO removal, and to provide a level of proficiency in personal radiation protective measures consistent with assigned tasks. On-the-job training, as deemed necessary by the contractor RSO, will be used to complement the formal radiation safety training.

All individuals will be trained before entering a controlled area to perform work and workers will be retrained every year. Credit may be given for applicable training received off-site, but plant-specific training is required for all URO removal personnel. Training and examination results will be formally documented.

A primary objective of the radiation safety training program is to comply with the instruction requirements of 10 CFR 19.

The radiation safety training will be reviewed and revised as appropriate to meet changing conditions and ensure that instructions are sufficiently well understood to permit practical application.

The radiation safety training program includes the following topics:

- radiation fundamentals - basic characteristics of radiation and contamination
- radiation exposure limits, administrative control levels, and controls - external radiation exposure control methods, procedures, and equipment

- radiation contamination limits and controls - contamination and internal radiation exposure control methods, procedures, and equipment
- contaminated materials associated with URO removal work - potential radiological problems
- radiological work planning - integrating radiation safety and operational requirements to ensure safe conduct of work
- emergency procedures and systems - work related information and actions
- biological effects of radiation - basic understanding of biological effects and methods of assessment
- the Radiation Protection Program
- workers rights and responsibilities
- radiation exposure reports which workers may request pursuant to 10 CFR 19.13
- ALARA

6.2.3. Radiation Protection Instrumentation

Instrumentation utilized for personnel monitoring will be calibrated and maintained in accordance with radiation safety procedures. These procedures utilize the manufacturers calibration guidance. Portable instruments are calibrated on a semi-annual basis or as required due to maintenance. Specific requirements for instrumentation include traceability to NIST or other recognized standards, field checks for operability, background radioactivity checks, operation of instruments within established environmental bounds (*i.e.*, temperature and pressure), training of individuals, scheduled performance checks, calibration with isotopes with energies similar to those to be measured, quality assurance tests, data review, and record keeping. Where applicable, activities of sources utilized for calibration are also corrected for decay. All calibration and source check records are completed, reviewed, signed off and retained in accordance with Quality Assurance Program requirements. A list of typical radiation instrumentation and minimum detectable activities (MDA) is given in Table 6-2. Typical personnel monitoring equipment is shown in Table 6-3. In the event an instrument of the type listed in Table 6-2 is employed on URO removal, its background count rate or exposure rate and its lower limit of detection will be estimated for its application.

In the event alternative radiation survey instrumentation is employed, it will be selected to meet the functional objectives tabulated in this §6.2.3. Alternative instrumentation must also be able to measure adequately to assess compliance with radiological protection requirements.

Table 6-2
Typical Instruments for Performing Radiation Protection Surveys

Instrument Type	Radiation Detected	Scale Range	BKG	Typical MDA 95% confidence Level
Scintillation (Ludlum 2224) Scaler/Ratemeter with 43-89 probe	Alpha Beta Beta	0-500,000 cpm	<10 cpm <300 cpm	100 dpm/100 cm^2 500 dpm/100 cm^2 4500 dpm/100 cm^2 (scan)
Micro-R Meter (Ludlum) 1" x 1" NaI Detector	Gamma	0-3,000 μR/h or 0-5,000 μR/h	7 μR/h	1-2 μR/h
Ion Chamber (Victoreen)	Gamma	0.1-300 mR/h	<0.1 mR/h	<0.2 mR/h
3" x ½" NaI Scintillation Detector Digital Scaler	Gamma	0-500,000 cpm	3,000 cpm avg shielded 9,000 cpm avg unshielded	250 cpm 500 cpm

435 cm^2 gas flow (43-27) Digital Scaler	Alpha	0-500,000 cpm	<10 cpm	20 dpm/100 cm^2
100 cm^2 gas flow (43-68) Digital Scaler	Alpha Beta Beta	0-500,000 cpm	<10 cpm <300 cpm	100 dpm/100 cm^2 500 dpm/100 cm^2 4500 dpm/100 cm^2 (scan)
60 cm^2 gas flow (43-4) Digital Scaler	Alpha	0-500,000 cpm	<10 cpm	200 dpm/100 cm^2
60 cm^2 Count Rate Meter (PRM-6)	Alpha	0-500,000 cpm	<100 cpm	350 dpm/100 cm^2
50 cm^2 Personnel Room Monitor (Ludlum 177)	Alpha	0-500,000 cpm	<100 cpm	500 dpm/100 cm^2
Ludlum 2" GM Tube (Pancake)	Beta Gamma	0-500,000 cpm 720 cpm = 0.2 mR/h	<200 cpm	70 cpm
Bicron AB-100 Scintillation Probe	Beta	0-500,000 cpm	<200 cpm	200 dpm/100 cm^2

Notes:

1) Instrument MDAs are based upon static measurements, one minute count times unless otherwise noted.
2) Instrument MDAs depend upon background.

Table 6-3

Typical Equipment for Performing Personnel Monitoring

Equipment Description	Purpose
Personal Air Samplers (BZ) Gillian or equivalent	Breathing zone air monitoring
Area Air Samplers SAIC or equiv.	High volume air monitoring
Area Air Samplers SAIC or equiv.	Work area low volume air monitoring
Personnel Dosimetry TLD, OSL, or equiv.	Deep dose, eye dose, skin dose
Alpha Frisker Ludlum 43-68 or equiv.	Contamination monitoring
Alpha Frisker Ludlum 177	Contamination monitoring
Beta Frisker Bicron AB100	Contamination monitoring
Micro-R meter Ludlum or equiv.	Exposure rate
Ion Chamber	Dose rate

6.2.4. ALARA

An objective of radiation protection during URO removal is to achieve as low as reasonable exposure to regulated radioactive material and radiation from it. The most effective emphasis will be to consider during preparation of each radiation safety work permit whether any particular action and or engineered control beyond good health physics practice would be reasonable to specify to try to reduce exposure.

6.2.5. Survey And Release Criteria For Equipment [10]

Although Mallinckrodt prefers to dispose of contaminated equipment when it is cost-effective, equipment that is to be released without restriction on use will be subject to NRC "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material," as specified in Materials License STB-401, condition 16. Table 6-4 lists equipment surface release limits for the uranium series and thorium series distributions representative of C-T URO. The composite maximum acceptable average areal density ($MAAAD_{\alpha}$) for equipment, 3300 dpmα/100 cm^2 is derived by the sum-of-fractions method. A composite MAAADα = 3300 αdpm/100 cm^2 applies to surfaces of all URO affected equipment surveyed for unrestricted release.

Table 6-4
Equipment Surface Release Limits

Equipment Location	Average[a] (dpmα/100 cm^2)	Maximum (dpmα/100 cm^2)	Removable (dpmα/100 cm^2)
Any	3300	9900	660

a Basis is average of U to Th ratio in 14 URO samples. U -to- Th series ratio averaged 5.7 -to- 1. Equipment surface release limits are based on U –to- Th ratio = 5 –to-1.

6.3. ENVIRONMENTAL PROTECTION PROGRAM

An environmental protection program has been developed as needed to monitor air and water effluents discharged from the URO removal project.[12] Those provisions, described herein, shall apply to the URO removal project.

In recognition that both the amount of radioactivity and the general environmental hazards may be reduced as URO remediation progresses, the Environmental Protection Program may be modified to be commensurate with the activities being performed.

6.3.1. The Program

An Environmental Safety Program will be developed and implemented as required to monitor air and water effluents discharged from the C-T URO removal project. During URO-soil

[10] Examples of *equipment* are described in CT Phase I DP, section 4.4.1.1.

[12] C-T Phase I DP, §3.4, Jan 9, 2002.

handling, samples will be routinely collected or measurements routinely made at on-site and site boundary or off-site locations to determine the extent of environmental discharges during remediation. Monitoring locations will be chosen commensurate with remediation activities.

In recognition that both the amount of radioactivity and the general environmental hazards will be reduced as URO removal progresses, the Environmental Safety Program may be modified to be commensurate with the activities being performed by following the criteria described in Section 5.3.

6.3.2. Environmental Air Monitoring

Environmental sampling stations will be provided during remediation or decontamination activities as required by 10 CFR Part 20 (Appendix B limits) to verify there are no adverse impacts to on-site workers and the public. Each environmental sampling station will be equipped with an air sampler.

Collection and analysis of the continuous air samples will be performed during remediation or decontamination activities as required by 10 CFR Part 20. The samples will be analyzed for gross alpha and gross beta activity to interpret the uranium and thorium series. The analytical instruments will be calibrated using standards traceable to the National Institute of Science & Technology (NIST) or other recognized standards.

6.3.3. Liquid Effluent Monitoring

It will be the policy of Mallinckrodt during the URO Project to minimize the production of contaminated aqueous liquids. There are four possible sources of contaminated aqueous liquids: water collection in an excavation pit, sink and shower water, decontamination fluids, and water used for dust suppression. Mallinckrodt expects sink and shower water to contain insignificant amount of regulated radioactive material in readily dispersible biological material, and thereby may be discharged to sanitary sewerage in accordance with 10 CFR Part 20.2003 without monitoring. Should rain water or surface water be collected, it will ordinarily be used for dust suppression of solid waste destined for NRC-approved disposal. In the event other aqueous waste potentially containing significant concentration of regulated radioactive material were considered for discharge to sewerage, Mallinckrodt would, beforehand, filter it to remove non-dispersible solids, sample and analyze it, estimate the concentration in sewage, compare it with the 10 CFR Part 20, Appendix B, Table 3, monthly average concentration limit, and estimate the total radioactivity inventory discharged.

6.3.4. Direct Radiation Monitoring

The environmental safety program is designed to assure that direct radiation in unrestricted areas does not exceed limits in 10 CFR 20.1301. The objective of direct radiation monitoring is to verify the effectiveness of the environmental safety program in meeting the limits.

The monitoring of penetrating radiation will be performed using standard environmental thermoluminescent dosimeters that are placed at various locations around the perimeter of the restricted remediation area. These dosimeters will be collected by Health and Safety personnel and analyzed quarterly by a qualified contract vendor to measure the integrated gamma dose for each location.

6.3.5. Action Levels

The following action levels will be established in procedures to aid in compliance with environmental safety regulations in 10 CFR 20.

Medium	Action Level (fraction of limit)	Regulation 10 CFR 20
Environmental air	≤ 0.75	App. B, Table 2, col 1
Effluent water	≤ 0.6	App. B, Table 2, col 2
Sewage	≤ 0.6	App. B, Table 3
Gamma radiation	≤ 0.5	Part 20.1301(a)(1)
Gamma radiation	≤ 0.5	Part 20.1301(a)(2)

If an action level is exceeded, the Mallinckrodt RSO and the contractor RSO will be notified and corrective action will be implemented as appropriate. Investigation may include additional measurements or analysis to assess compliance with the regulation and to ensure that the total radiological dose from inhalation and irradiation by external gamma-rays does not exceed 100 mrem/yr with emphasis to attain levels as low as reasonably achievable.

7. REMOVAL ACTION

7.1. REMEDIATION CRITERIA

URO buried in Plant 6W is surrounded by land that is subject to the FUSRAP. Mallinckrodt has cooperated with the USACE to agree on delineation of a geographical boundary between buried URO, within which Mallinckrodt would remove all material, including the URO, and surrounding land. Mallinckrodt proposes the boundary to be that depicted in Figures 3-1 and 3-2 enclosing URO. By removing all material within a designated boundary, a maximum acceptable residual radioactivity concentration specification will not be needed. The USACE has accepted responsibility for remediation under the FUSRAP outside the boundary within which Mallinckrodt will remove URO.

The estimated volume of URO to be removed is 5856 ft^3 = 217 yd^3 (ref. Table 1 without URO site 10). Within the geographical boundaries described in Figures 3-1 and 3-2, an additional 2340 cubic yards of soil (ref. Table 4) is estimated to be subject to removal by Mallinckrodt in accordance with the delineation agreement between Mallinckrodt and the USACE. This additional excavation will includes soil buried the buried URO and will include soil excavated to accommodate sloping excavation side walls.

7.2. SOURCE REMOVAL TASKS

Utility lines, including water, electricity, gas, *etc.*, within the excavation boundary will be located and marked prior to initiation of remediation activities and will be relocated as necessary to perform this work.

Macadam pavement atop URO burials 1 through 9 will be removed. Next the soil covering the buried URO will be removed by excavation. Mallinckrodt intends to have its contractor remove the approximately 4 feet of cover atop the buried URO and set it aside. This will create a depression in which excavation of URO may occur.

URO contents will be removed and transported to the rail loading facility in Plant 6W.

A finished goods warehouse, Building 101, including a concrete floor slab, was constructed above burial number 10. URO in Burial 10 is unavailable until such time as absence of use of Building 101 allows access to the URO beneath it.

Extent of the removal of URO is to be verified by visual inspection. Trench cover will be distinguished from buried URO by visual inspection and engineering measurements compared with original CT URO plot plan drawings. The contractor will excavate the URO and material around its margins as described in figures included in the application. That will include peripheral soil enabling sloping sides and marginal material beneath the buried URO. Excavated material may be segregated or mixed as a function of radioactivity concentration by radioactivity measurement in order to manage disposal options. URO contents will be transported to the rail loading facility on site for loading into a shipping container for transport.

Sloping, benching, and or shoring techniques may be utilized as the excavation depth is increased. It is prudent to plan for the prospect of excavating some soil beyond the boundaries of buried URO itself. The extent of removal will be in accordance with agreed dimensions and will be verified by visual inspection. Allowing for excavation of one foot beyond the boundaries of the buried URO and for a side wall slope factor results in a contingent estimated volume of URO, intermingled fill, and adjacent soil that is tabulated in Table 4. Some additional excavation may be necessary to enable USACE access.

As soon as reasonable after URO is removed, Mallinckrodt will notify the USACE and the USACE will be admitted to areas affected in order to remediate residual MED-AEC material. In the event of unanticipated delay by USACE in assuming access, excavation(s) would be lined with sheeting and backfill would be specified to ensure no subsidence.

7.3. Radiation Protection Specific to URO Removal

Personnel accessing the site to work on this project shall receive Mallinckrodt Site Orientation and Safety Training.

Radioactivity concentration in URO is expected to be greater than encountered during C-T Phase I decommissioning. While URO is being excavated and handled, monitoring and control of potential worker exposure via inhalation and direct irradiation will be emphasized. Workplace air will be sampled for airborne particulate to evaluate potential inhalation exposure to remediation workers. Gamma radiation emitted by URO will be measured by a dosimeter on each worker and by area radiation survey.

7.4. Procedures

Applicable procedures already developed may be used to implement the URO removal project. Procedures will be revised and or supplemented as needed to apply to URO removal and disposition. Mallinckrodt will ensure that all procedures are protective of human health and the environment and are in accordance with applicable regulatory requirements.

8. WASTE MANAGEMENT

8.1. Overview

Radioactive waste from the URO removal project will be managed in accordance with the requirements of this URO Waste Management Plan. This plan ensures that radioactive waste from the URO removal project will be handled, stored and disposed of in a manner protective of human health and the environment and in accordance with applicable regulatory requirements.

8.1.1. Overview

Preliminary planning envisions excavation of the URO burials in a phased approach to coordinate requirements of the USACE for the FUSRAP area encompassing URO burials 1 through 6 and shipping the URO-soil will be performed first. Afterward, areas encompassing 7 and 8 and area 9 would be excavated and the URO-soil shipped. Mallinckrodt proposes to:

1. delinate excavation boundaries in accordance with the URO engineering plot plan and the Mallinckrodt-USACE delineation agreement;
2. excavate open-pit by conventional bucket excavator or track-propelled backhoe;
3. manage disposal options by recombining or mixing excavated URO-soil if needed for the purpose of managing the radioactivity concentration in shipment to meet waste acceptance criteria of a disposal facility off-site;
4. transport excavated URO and soil to the rail loading facility on-site (also used by the USACE for MED-AEC waste);
5. load URO and or soil into gondola-type rail cars, intermodal containers for rail shipment, or highway trailers to be delivered to a carrier for transport to an appropriate disposal facility off-site acceptable to the NRC and State in which it is located; and
6. comply with specifications for delivery to a carrier and to the recipient waste disposal facility.

8.1.2. Regulatory Requirements

Processing and disposal of radioactive waste will be performed in accordance with the relevant requirements of 10 CFR 20, 10 CFR 40, 10 CFR 71, DOT regulations, and 49 CFR 172-178 and the applicable disposal site waste acceptance criteria.

Non-impacted wastes that are indistinguishable from background radioactivity will be managed in accordance with applicable State and Federal solid and/or hazardous material requirements as appropriate. *Mixed waste*, if any, will also be managed in conformance with State and Federal hazardous waste regulations.

Subject to coordination with the USACE, Mallinckrodt may either 1) leave excavations without filling or restoration and agree to immediate access by the USACE in order to facilitate USACE remediation of land beyond the boundary, or else 2) backfill with earth to prevent subsidence.

8.2. WASTE DESCRIPTION

Solid Waste. URO removal activity will generate two general categories of solid waste: debris of pavement and subsurface material. Pavement includes macadam and concrete pavement removed to access subsurface materials. Subsurface materials will include URO and adjacent cinder-fill soil. In this discussion, subsurface material will generally be referred to as "soil" or solid waste.

Radioactive Waste. URO radioactive waste contains natural uranium series and thorium series radionuclides. It will not contain any of the radionuclides listed in Tables 1 or 2 of 10 CFR 61.55, except those present in background due to atmospheric fallout. All URO radioactive waste will therefore be Class A.

Radioactive waste to be managed during URO remediation includes URO, intermingled soil, and adjacent soil or cinder fill excavated during URO removal. Solid waste would also include bulk material used during remediation and discarded. Allowing for excavation of a foot or so beyond the boundaries of the buried URO and for a side wall slope factor results in an estimated volume of URO, intermingled fill, and adjacent soil that is tabulated in Table 4.

Table 4. Estimate of Volume of URO and Surrounding Soil to be Excavated

Burial Site No.	Excavation			
	Area (ft^2)	Depth[A] (ft)	Volume[B] (ft^3)	Volume[B] (yd^3)
1 thru 6	6719	8	42343	1568
7 and 8	2320	7	11072	410
9	2236	10.5	16940	627
			total =	2605

[A] average excavation depth

[B] accounts for URO and side wall slope

Mixed Waste. Mallinckrodt does not anticipate that buried URO contains mixed waste; although core sampling and analysis is planned to detect whether mixed waste may exist. If mixed waste were discovered, Mallinckrodt has a permit to manage hazardous waste on-site in accordance with a RCRA Part B permit with the State of Missouri. In the event mixed waste is identified during remediation activities, Mallinckrodt will characterize the wastes, identify a disposal method, assess the effect on the schedule, assess related disposal costs, modify handling procedures, as needed, and will notify the NRC and the Missouri DNR.

8.2.1. Solid Radioactive Waste Handling

Pavement and soil will be loaded into roll-off containers or dump trucks at the excavation site or will be loaded directly into rail cars for rail transport. Water misting or similar technique will be used as appropriate to control dust emissions during excavation and loading. Loose material generated during excavation will remain in the excavation. Loose material generated during loading will be removed from pavement and the exterior of containers and trucks before they are moved from the excavation area. Surveys will be performed as appropriate to ensure that loose contaminated material is not carried from Plant 6W on containers or vehicles.

Aggregating URO and Adjacent Soil. In order to meet the *unimportant concentration* criterion of 0.05 wt% source material[13] and to satisfy waste acceptance criteria (WAC) specified by the receiving disposal facility, excavated bulk URO and adjacent cinder-soil would be aggregated and mixed within the bounds of the excavation. Excavation by conventional earthmoving equipment, *e.g.*, by track-propelled backhoe and loading into railcars by rubber-tire-propelled bucket excavator, is planned. Mixing will be done by operation of the excavation equipment also used to excavate the soil and URO and used to load it into rail cars.

Soil to be mixed with the URO material will originate in Plant 6W as soil surrounding the URO. Mallinckrodt will not import soil from without Plant 6W to achieve conformance with the WAC for disposal.

Although the URO was buried in 30-gallon steel drums, now, some 30 years later, those containers are expected to have disintegrated by rusting and are not expected to interfere with mixing and disposal. The URO was a finer particulate than the coal ash-soil in which it was buried; thus, it would be expected to be blendable with the coal ash-soil. In the event enough remnants of the drums remain to inhibit mixing and disposal, Mallinckrodt would empty their contents and arrange for disposal of the contaminated drums at the same disposal facility as the URO-soil mixture.

Mallinckrodt intends that mixing of URO and soil will be adequate to satisfy WAC in each rail car and thereby avoid substantial, localized concentration in excess of the WAC. Radioactivity concentration in URO-soil to be released for transport to disposal off-site will be measured and compared with *unimportant concentration*[14] criterion and with disposal facility WAC to assure compliance in each rail car. Intended measurement will analyze URO-soil samples by gamma spectrometry for long-lived, uranium series and thorium series radionuclides measurable by gamma ray emission. As needed, URO-soil samples will also be analyzed for Th^{230} and Ra^{226} by alpha spectrometry. Because Th^{230} and Ra^{226} in adjacent soil characterization samples tend not to be in radioactive equilibrium with parent U^{238}, but in deficit, a prominent number of samples of the URO-soil mix will be analyzed for Th^{230} and Ra^{226} to test compliance with the WAC. In the event the destined disposal facility were to take possession in rail cars on-site, their personnel would provide additional assurance that shipments leaving the site meet all WAC.

Radioactively contaminated bulk solid waste, *i.e.*, URO-soil, will only be disposed by transfer to a disposal facility authorized by the State in which it is located to receive an unimportant concentration of source material. Disposal is also subject to approval from the cognizant state regulatory agency(ies) in which the disposal facility is located.

Selective Excavation of URO. An unreasonable volume of cinder-soil adjacent a trench containing one or more URO burials might be required to be mixed to achieve an

[13] 10 CFR Part 40.13(a)
[14] 10 CFR Part 40.13(a)

unimportant concentration less than 0.05 wt% and or meet the WAC at a RCRA disposal facility. In such event, URO in that burial or trench would be excavated selectively and separated from the adjacent soil to the extent practical. Mallinckrodt would arrange to transfer it to a facility licensed to receive and dispose of it. That URO, exceeding the WAC at a RCRA disposal facility, would be disposed by licensee-to-licensee transfer to an NRC-licensed or Agreement State-licensed disposal facility authorized to receive it.

Adjacent soil excavated around the margins of the selectively excavated URO and to achieve sloping sidewalls would be verified to satisfy the WAC at a RCRA disposal facility and would be released for shipment to and disposal at such.

8.2.2. Temporary On-Site Storage of Waste Prior to Shipping

To the extent practical, radioactive material will be loaded directly into intermodal containers or rail cars. Else, radioactively contaminated material may be staged on-site temporarily in a materials management area (MMA) in Plant 6W to (a) hold it for sampling and analysis; (b) accumulate sufficient quantities for economical shipment; (c) await intermodal containers and or rail cars, (d) to mix to meet waste acceptance criteria,[15] and or (e) coordinate shipments between the carrier and the disposal site. Contaminated material and equipment would be stored in designated staging areas in Plant 6W.

Mallinckrodt anticipates that no more than about 1,000 cubic yards of waste materials will be in temporary storage at any given time and for no longer than three months. Positive control is to be maintained. Soils and materials will be stored in covered containers or in covered piles if needed to control dust or erosion by wind or rain. Covers, surface coatings, or functionally similar techniques would be used. Stormwater run-on and run-off controls and monitoring will be used as appropriate. In the event that additional storage is needed, covered roll-off containers of URO solid waste may be temporarily stored in a MMA within Plant 6W.

Mallinckrodt does not anticipate treating radioactive solid wastes to any significant degree. Soils may be air dried or augmented with water to meet the disposal site moisture specifications. Size reduction of pavement and subsurface materials may be performed to the extent practical during excavation and removal. Additional size reduction may be performed in the MMA. In limited cases, small quantities of wastes exhibiting a hazardous toxicity characteristic may be treated (fixed and/or solidified) in containers to eliminate the characteristic.

Positive control is to be maintained in two ways: 1) An active 24-hour security system is in place for the entire Mallinckrodt facility and 2) each temporary radioactive material storage area will be enclosed by roping-off and appropriate posting.

It is expected that radiation levels at access points to temporary storage areas will be up to several times background, with the average being less that 50 μR/hr and the maximum less than 100 μR/hr. Thus, the low radiation level beside waste in storage will ensure compliance with 10

[15] NRC: W.D. Travers. "Results of the License Termination Rule Analysis of the Use of Intentional Mixing of Contaminated Soil." SECY-40-0035. Mar. 1, 2004.

CFR 20.1301. In addition, appropriate training will be provided to workers regarding the waste materials temporarily stored on-site.

8.3. WASTE DISPOSAL

8.3.1. Waste Packaging and Transportation

Wastes will be packaged, placarded and/or labeled, and transported in accordance with the requirements of the disposal site and applicable state and federal waste transportation regulations. Covers or similar devices to confine the waste and protect it from the environment will be employed as appropriate. Container liners may be used to minimize container decontamination requirements and costs at the disposal facility.

Wastes will be transported to the disposal facility by rail or truck, depending upon disposal site receiving facilities, equipment availability, cost, and other factors as appropriate.

C-T URO radioactive wastes that will be shipped by rail in gondola cars or intermodal containers will be loaded in Plant 6W. Soils may be loaded directly into a rail car or may be loaded into containers or trucks at the excavation site or at the MMA and be taken to the rail car loading area. Contractor personnel, working under agreement with Mallinckrodt, will load the wastes into rail gondola cars or intermodal containers. Contractor personnel will perform the work using health and safety procedures and protocols.

8.3.2. Waste Disposition

Material or equipment removed from a restricted area in Plant 6W into an unrestricted area shall be subject to appropriate radiation survey.

Non-impacted material, confirmed by radiation survey to be indistinguishable from natural background radioactivity, may be released without restriction.

Equipment or items subject to surficial contamination only shall be subjected to a radiation survey to determine whether it satisfies criteria in §6.2.5 herein before release. In the event material, equipment, or other item is surveyed and found compliant with Materials License STB-401, condition 16, as implemented in §6.2.5 herein, it may be released for unrestricted use and removal or under the provisions of 10 CFR 20.2002.[16] The criteria were derived to satisfy the NRC criteria for unrestricted release specified in NRC Regulatory Guide 1.86 or in NRC Policy and Guidance Directive FC 83-23.

Bulk solid waste may be blended to satisfy waste acceptance criteria specified by the receiving disposal facility. Solid waste material that is potentially contaminated will be characterized prior to release to a carrier for transport and to assess compliance with disposal site acceptance criteria. Radioactively contaminated solid wastes will be disposed of by transfer to a licensed disposal facility or by transfer to a disposal facility authorized to receive an unimportant quantity of source material.

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[16] C-T Phase I DP, §3.6.4.

If waste material, including URO, contains less than the *unimportant quantity* of source material as defined in 10 CFR 40.13(a), it shall be disposed by transfer to a RCRA hazardous waste disposal facility, subject to approval from the cognizant state regulatory agency(ies) in which the disposal facility is located. Reports of analyses demonstrating potential radiological dose consequent to disposal at either site have been performed.[17, 18] Else, it shall be disposed at an NRC-regulated disposal facility authorized by radioactive materials license to receive it.

If waste material, including URO, contains greater than an *unimportant quantity* of source material, *i.e.*, concentration, of source material as defined in 10 CFR 40.13(a) it shall be disposed at an NRC-regulated disposal facility or Agreement State-regulated disposal facility authorized by radioactive materials license to receive it.

In the event mixed waste is identified during remediation activities, Mallinckrodt will characterize such wastes, identify a disposal method, assess the effect on the schedule, assess related disposal costs, and modify handling procedures, as needed, and will notify the NRC.[19]

8.4. LIQUID RADWASTE

URO removal operations will not involve use of significant quantities of liquid chemicals requiring treatment and/or disposal.

Soil management and housekeeping activities will be designed to minimize the exposure of contaminated soils to stormwater. However, stormwater in active remediation areas, decontamination areas, and the Material Management Area may contain contaminated soil particles. Management of potentially contaminated soil that is collected will be the same as for URO and other subsoil excavated during the project.

Should rain water or surface water collect in an excavation pit, it will ordinarily be used for dust suppression of solid waste destined for NRC-approved release for disposal. Minimum use of water is anticipated for dust control during soil remediation and demolition of paved surfaces. No free water will be generated by dust control activity.

Otherwise, water removed from an excavation cavity will be filtered or otherwise treated to remove suspended solids prior to discharge to the plant sewer system in accordance with the FUSRAP MSD wastewater permit. As in the case of radioactive solid waste discussed above, any aqueous radioactive waste generated during URO removal will be Class A.

Used filters and treatment sludge, if any, will be solidified and or dewatered and managed as a solid radioactive waste.

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17 "Disposal of Mallinckrodt 10 CFR Part 40 Section 40.13(a) Material at the USEcology Idaho Site." June 24, 2002. Submitted by Mallinckrodt to NRC on June 24, 2002.

18 "Analysis of Disposal of Unimportant Quantity of Source Material at WCS Andrews Facility." April 17, 2000. Submitted by Mallinckrodt to NRC on April 17, 2000.

19 C-T Phase 1 DP §2.2.4.

8.4.1. Aqueous Effluent

In the event water containing significant concentration of regulated radioactive material were considered for discharge to sewerage, Mallinckrodt would transfer it into the FUSRAP water treatment system where it would be treated, sampled, analyzed, the concentration in effluent water determined, compared with the 10 CFR Part 20, Appendix B, Table 3, monthly average concentration limit, and the total radioactivity inventory discharged would be estimated. Thereby, Mallinckrodt would assure discharge to sewerage in accordance with 10 CFR Part 20.2003.

The treated water may be disposed to the Metropolitan St. Louis Sewer District (MSD) subject to the FUSRAP MSD permit.

8.5. MIXED WASTE

Characterization efforts performed to date have not identified any mixed wastes in the soil or other materials to be remediated during URO removal. Mallinckrodt does not anticipate that mixed waste will be generated by URO removal efforts. In the event mixed waste were to be identified during remediation activities, Mallinckrodt would characterize the wastes, identify a disposal method, assess the effect on the schedule, assess related disposal costs, modify handling procedures, as needed, and would notify the NRC. Mallinckrodt has a RCRA Part B permit authorizing on-site storage of hazardous and mixed waste. Other than the presence of hazardous chemicals, storage in Mallinckrodt's hazardous waste storage facility, and the labeling and transportation requirements of RCRA and State hazardous waste agencies, mixed wastes will have the same radioactive character and will be managed as solid radioactive wastes described above.

A small quantity of radioactive waste that exhibits a hazardous toxicity characteristic may be treated in a container to eliminate the characteristic. Neutralization, stabilization, fixation, and of solidification techniques may be used. Such treatment would typically be performed in the MMA.

8.5.1. Records

Mallinckrodt will maintain records of waste material released from the URO area in Plant 6W or controlled areas. The Document Control procedure presents the record retention requirement.

9. QUALITY ASSURANCE[20]

9.1. OVERVIEW

Provisions to ensure quality of performance that are proposed to apply to the URO remediation project are described in this section.[21] The provisions of the quality assurance program are implemented by procedures.

[20] C-T Phase I DP, §5, Jan. 9, 2002.

URO source removal activities will be performed in a manner to ensure the results are accurate and that uncertainties have been adequately considered. The quality assurance program will operate in all stages of URO removal, through validation of the data and the interpretation of the results to verify that this has occurred.

Persons or organizations responsible for ensuring that the quality assurance program has been established and verifying that activities affecting quality have been correctly performed will have sufficient authority, access to work areas, and organizational freedom to:

- identify quality problems;
- initiate, recommend, or provide solutions to quality problems through designated channels;
- verify implementation of solutions; and,
- ensure that further URO removal activities are controlled until proper disposition of a nonconformance or deficiency has occurred.

Such persons or organizations will have direct access to responsible management at a level where appropriate action can be taken. Such persons or organizations will report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations.
The major aspects of the quality assurance program for the URO removal activities are discussed in the following sections.

9.2. QUALITY ASSURANCE PROJECT PLAN

For execution of URO removal activities at the Mallinckrodt URO Project, a Quality Assurance Project Plan (QAPP), consistent with applicable guidelines will be developed. The QAPP will be reviewed and approved by Mallinckrodt prior to implementation. The objective of the QAPP is to ensure confidence in the sampling, analysis, interpretation and use of radiological data generated during the URO removal project.

The QAPP will ensure collection of reliable data by serving as the instrument of control for field and analytical activities associated with the project. Stated within the QAPP are the quality assurance policies, quality control criteria, and reporting requirements that must be followed by all site and contractor personnel when carrying out their assigned responsibilities on this project. The QAPP describes the functional activities and quality assurance/quality control (QA/QC) protocols necessary to collect data of adequate quality.

9.3. PROCEDURES

Supporting Quality Implementing Procedures (QIPs) will provide step-by-step details for complying with project QA requirements. Each radiological survey, including development of sampling plans, direct measurements, sample analysis, instrument calibration, daily functional checks of instruments, and sampling methods will be performed according to written procedures. These written procedures will be reviewed and approved by the Mallinckrodt project manager.

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[21] C-T Phase I DP, §5 Quality Assurance, Jan. 9, 2002.

9.4. SUBCONTRACTORS

The activities to be conducted during URO removal will require the services of a contractor and various specialty subcontractors such as a qualified drilling contractor or a licensed surveyor. Contractor activities will be under the direct supervision of Mallinckrodt personnel in accordance with the QAPP. Subcontractor activities will be under the direct supervision of the contractor personnel, also in accordance with the QAPP.

9.5. LABORATORY SERVICES

In the event off-site analysis of a sample is required, a qualified laboratory recommended by the URO removal contractor and approved by Mallinckrodt will perform those radiological analytical laboratory services for the project. The laboratory will be responsible for all bench level QA/QC, data reduction, data reporting, and analytical performance monitoring. Laboratory accuracy will be evaluated by the analysis of blank and spiked samples. Sample handling protocols, analytical procedures, and reporting procedures employed by the analytical laboratory will be described in the laboratory's Quality Assurance Plan.

The off-site laboratory will be responsible for assuring that all appropriate laboratory personnel are thoroughly familiar with the Quality Assurance Project Plan and good laboratory practices, and that all appropriate laboratory personnel meet the requisite qualifications for their positions within the laboratory. The laboratory Director, or his equivalent/representative, will review and approve all reports. The Director will also be responsible for assuring laboratory personnel have appropriate training to perform assigned responsibilities, and for daily management of the laboratory and its staff.

The off-site laboratory will have a QA designee who will be responsible for assuring that the QA/QC requirements of the QAPP, the laboratory Quality Assurance Plan, and its associated operating procedures are strictly followed. The QA designee will be responsible for review of data, alerting the Mallinckrodt URO removal project Manager and the Contractor Project Manager of the need for corrective action (when necessary), performing internal audits as specified by the QAPP, and maintenance of the QC records. The QA designee will also be responsible for preparing project specific QA/QC plans, as necessary.

9.6. SURVEYS AND SAMPLING ACTIVITIES

Trained individuals following written procedures will perform surveys using properly calibrated instruments. The custody of samples will be tracked from collection to analysis. Final survey data will be retained until License STB-401 is terminated by the NRC.[22] The designated sampler or analytical laboratory will collect a split sample when desired by the NRC to obtain samples that are duplicates of those to be analyzed. When this operation is performed, the procedure for obtaining duplicate samples will be followed.

[22] 10 CFR Part 40.36(f)

QC hold points will be utilized as necessary to ensure quality of surveys and sampling. Hold points will also be used to ensure that debris is moved only after QA has verified that the proper sampling and survey information for the debris in question has been obtained.

9.7. DOCUMENTATION

Data will be recorded and documented in a data management system. Entries will include the location of the survey or sampling point on the appropriate land grid. Data management personnel will also ensure that chain-of-custody and data management procedures are followed for URO removal-related samples. The contractor's procedures for proper handling, shipping and storage of samples will be used.

Both direct measurements and analytical results will be documented. The results for each survey measurement or sample and its grid block location, will be listed in tabular form (*i.e.*, result versus sample or survey location).

Data will be recorded in an orderly and verifiable way and reviewed for accuracy and consistency. Every step of the URO removal process, from training personnel to calculating and interpreting the data, shall be documented in a way that lends itself to audit. Records of training to demonstrate qualification will also be maintained.

9.8. EQUIPMENT MAINTENANCE AND CALIBRATION

Measuring equipment will be maintained, calibrated, and tested according to Regulatory Guides 4.15 and 4.16 recommendations. Further, the procedures, responsibilities, and schedules for calibrating and testing equipment will be documented.

Proper maintenance of equipment varies, but maintenance information and use limitations are provided in the vendor documentation. Measuring and analyzing equipment will be tested and calibrated before initial use and will be recalibrated if maintenance or modifications could invalidate earlier calibrations. Field and laboratory equipment, specifically used for obtaining final radiological survey data, will be calibrated based on standards traceable to NIST. In those cases where NIST-traceable standards are not available, standards of an industry-recognized organization (for example, the New Brunswick Laboratory for various uranium standards) will be used. Minimum frequencies for calibrating equipment will be established and documented. Measuring equipment will be tested at least once on each day the equipment is used. Test results will be recorded in tabular or graphic form and compared to predetermined, acceptable performance ranges. Equipment that does not conform to the performance criteria will be promptly removed from service until the deficiencies can be resolved.

9.9. DATA MANAGEMENT

9.9.1. Laboratory Data

Data reduction, QC review, and reporting will be the responsibility of the analytical laboratory. Data reduction includes all automated and manual processes for reducing or organizing raw data generated by the laboratory. The laboratory will provide a data package for each set of analyses that will include a copy of the raw data in electronic format, and any other information needed to check and recalculate the analytical results.

Once a data package is received from the laboratory, the analytical results and pertinent QA/QC data will be compiled onto standardized data formats. The data packages will serve as basic reference sheets for data validation, as well as for project data use.

9.9.2. Field Survey Data

The generation, handling, computations, evaluation and reporting of final radiological survey data will be as specified in the contractor's procedures. Included in these procedures will be a system for data review and validation to ensure consistency, thoroughness and acceptability. Qualified health and safety, operations, and/or engineering personnel will review and evaluate survey data.

9.9.3. Data Evaluation

Prior to releasing data for use by project staff, selected data will undergo data evaluation based on intended end use of the data. Data points chosen for evaluation will be examined to determine compliance with QA requirements and other factors that determine the quality of the data. Data taken during a prior survey, *e.g.*, characterization survey, may be usable provided the data are subjected to quality verification and satisfy data quality objectives.

If sample data are rejected or data omissions are identified during the data validation, this data will be evaluated to judge the impact on the project. Other corrective action may include re-sampling and analyzing, evaluating and amending sampling and analytical procedures and accepting data acknowledging the level of uncertainty.

In the event survey data are processed by computer, the application program[23] and each modification thereof will be verified to perform as intended before its initial use. A knowledgeable person will verify that the algorithms are as intended and will compare an instance of computer-generated result and an independently derived result of the same process. Mallinckrodt or its contractor will document the application program, including its algorithms and a listing or copy of the program.

9.10. SAMPLE CHAIN-OF-CUSTODY

One of the most important aspects of sample management is to ensure that the integrity of the sample is maintained; that is, that there is an accurate record of sample collection, transport, analysis, and disposal. This ensures that samples are neither lost nor tampered with and that the sample analyzed in the laboratory is actually and verifiably the sample taken from a specific location in the field.

Sample custody will be assigned to one individual at a time. This will prevent confusion of responsibility. Custody is maintained when (1) the sample is under direct surveillance by the

[23] An *application program* consists of instructions and or algorithms created specifically for processing data for the URO removal project. It does not pertain to generic software, including for example, a spreadsheet program such as Microsoft EXCEL™ or a database program such as Microsoft ACCESS.™

assigned individual, (2) the sample is maintained in a tamper-free container, or (3) the sample is within a controlled-access facility.

The individual responsible for sample collection will initiate a chain-of-custody record using a standard form provided by the URO removal contractor. A copy of this form will accompany the samples throughout transportation and analyses; and any breach in custody or evidence of tampering will be documented.

9.11. AUDITS

Periodic audits will be performed to verify that URO removal activities comply with established procedures and other aspects of the QAPP and to evaluate the overall effectiveness of the QA program. Mallinckrodt and Contractor Quality Assurance personnel will verify that qualified personnel are used to conduct audits to ensure that the applicable procedures are being properly implemented. The audits will be conducted on at least a quarterly basis, in accordance with written guidelines or checklists. Health and safety personnel will also conduct semiannual audits in their area of concern. External program audits may also be used at the discretion of either Mallinckrodt or contractor management. Audit results will be reported to both Mallinckrodt and contractor management in writing, and actions to resolve identified deficiencies will be tracked and appropriately documented.

10. SAFETY ANALYSIS

Radiological safety of workers performing URO removal has been evaluated. An occupational dose evaluation was modeled using the RESRAD computer code and site-specific information or estimates of input parameters. The modeling yielded an estimate of 83 mrem for a representative remediation worker, which is less than 10% of the maximum tolerable radiological dose to a worker annually.

An ALARA evaluation was performed to assess defensible cost-benefit balance for averting dose. Based upon an estimate of 10 workers subject to exposure on the project, the prospective collective dose was estimated to be 0.83 person-rem. This evaluation suggests that routine health physics measures already planned for the project should be acceptable to maintain doses ALARA during the URO removal project.

A safety evaluation report for the URO removal project is provided as Appendix 1 herewith.

11. ENVIRONMENTAL REPORT

An environmental report for the URO removal project is provided as Appendix 2 herewith.