

May 24, 2010

Mr. Robert Geller, Director
Hazardous Waste Program
Missouri Department of Natural Resources
State of Missouri
P.O. Box 176
Jefferson City, MO 65102

SUBJECT: RESPONSE TO STATE'S COMMENTS ON DRAFT ENVIRONMENTAL
ASSESSMENT AND SAFETY EVALUATION REPORT FOR THE PHASE 2
DECOMMISSIONING PLAN FOR THE MALLINCKRODT INC. SITE,
ST. LOUIS, MO

Dear Mr. Geller:

Thank you for your comments dated May 6, 2010, regarding the U.S. Nuclear Regulatory Commission's (NRC's) draft Safety Evaluation Report (SER) and Environmental Assessment (EA) supporting approval of the Mallinckrodt Inc. (Mallinckrodt) Phase 2 Decommissioning Plan (DP). As indicated in your letter, Missouri Department of Natural Resources (MDNR) and NRC staffs have interacted extensively during the review and approval process of this DP. Although most of the concerns presented in your letter were previously expressed by MDNR (ADAMS ML090790209) and addressed by NRC (ML 092030390), the enclosure provides a response to each of the concerns expressed in the May 6, 2010 letter.

NRC looks forward to continued interactions with MDNR staff during Mallinckrodt's decommissioning activities. If you have questions, please do not hesitate to contact me at (301) 415-6607.

Sincerely,

/RA/

John Buckley, Senior Project Manager
Reactor Decommissioning Branch
Division of Waste Management
and Environmental Protection
Office of Federal and State Materials
and Environmental Protection Programs

Enclosure:
NRC Response to MDNR Comments

cc: Mallinckrodt Distribution List

Docket: 40-6563
License: STB-401

Mr. Robert Geller, Director
 Hazardous Waste Program
 Missouri Department of Natural Resources
 State of Missouri
 P.O. Box 176
 Jefferson City, MO 65102

SUBJECT: RESPONSE TO STATE'S COMMENTS ON DRAFT ENVIRONMENTAL ASSESSMENT AND SAFETY EVALUATION REPORT FOR THE PHASE 2 DECOMMISSIONING PLAN FOR THE MALLINCKRODT INC. SITE, ST. LOUIS, MO

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NRC Response to MDNR Comments

1. MDNR Comment

We recognize that the Derived Concentration Guideline levels (DCGLs) are being targeted for an “unrestricted” release. The Department understands that this “unrestricted” designation is premised on NRC’s expectation that the Mallinckrodt site will remain an industrial, not a residential, scenario. The Department feels strongly that the public requires a full and persistent understanding of this as well. We are restating our concern that unless there is robust, enforceable, and effective land-use controls in place, reliance on zoning or historical land-use will not ensure the cleanup of the site will remain protective. The Department shares the same concern that the Environment protection Agency (EPA) voiced in their September 9, 2009, letter to Larry Camper of the NRC.

NRC Response

The NRC staff understands the state’s concern as we have discussed on several occasions (see March 22, 2010, NRC Response to MDNR Comment 3 – ML092030436). NRC staff continues to believe that the licensee provided adequate information to justify an industrial scenario as the most likely land use in the foreseeable future. Thus, the NRC staff concludes that an industrial scenario is the appropriate land use for demonstrating compliance with the requirements in Title 10 of the Code of Federal Regulations (CFR), Part 20, Subpart E. It should be noted that the DCGLs were derived from the licensee’s commitment to meeting an annual dose limit of 25 millirem (mrem) per year, which is prescribed in 10 CFR 20.1402, “Radiological Criteria for Unrestricted Use.” Remediation at the site will likely result in “as-left” residual concentrations well below the approved DCGLs, and therefore, the potential post-remediation dose to a member of the critical group will be some fraction of the annual dose limit of 25 mrem per year.

2. MDNR Comment

The NRC’s review of the Decommissioning Plan for this Environmental Assessment (EA) does cite four documents developed by the U.S. Army Corps of Engineers (USACE) for the FUSRAP portion of the site. Those documents are referenced for data and interpretation of the groundwater. The Department recommends that the legally binding decision document (Record of Decision (ROD)) signed by the EPA and the USACE, should also be included among the references. The ROD clearly states that groundwater in the “lower unit” **is a potential source of drinking water**. NRC staff state in the third sentence of the last paragraph, under section 3.5.6 Ground Water of the EA that “ nor will it {groundwater} likely be a source of drinking water in the future.” The Department suggests that this sentence be modified, for consistency with the ROD, for example: “The groundwater beneath the site is not a current source of drinking water. Based on current and projected needs, it is not anticipated that it will be used as a source of drinking water in the future.”

The Department further suggests that the USACE will not know if the groundwater (upper or lower) will be impacted by their remediation activities until after the soil cleanup has been completed and a long term post-remediation monitoring of the groundwater shows whether or not there has been an impact. That monitoring is focused on the MED-AEC issues; the Department also requests that the NRC clearly clarify whether they will require Mallinckrodt to employ a similar monitoring plan for the plant 5 area.

Enclosure

NRC Response

The staff will add the USACE Final ROD to the reference list.

With respect to the sentence in EA Section 3.5.6, the staff believes that the wording in the EA closely paraphrases the ROD. The EA makes no conclusions regarding the qualifications of the A and B Units as potential sources of drinking water under the “Guidelines for Groundwater Classification Under the EPA Groundwater protection Strategy.” Thus, no changes will be made to Section 3.5.6.

NRC will not require Mallinckrodt to employ long-term post-remediation monitoring. After remediation, the site will be released for unrestricted use and the license will be terminated. As stated in Section 3.6.7 of the SER Mallinckrodt will monitor water in the C-T process areas for radionuclide contamination as part of waste handling process. Water collected in excavations during remediation, either from runoff or groundwater, will be collected, sampled and discharged in accordance with 10 CFR 20.2003 and Mallinckrodt’s Metropolitan St. Louis Sewer District discharge permit. Mallinckrodt will be required, by license condition, to notify NRC if filtered water samples contain radionuclides exceeding the EPA MCLs.

3. MDNR Comment

The last sentence under Section 7. AGENCIES AND PERSONS CONCULTED AND SOURCES USED, of this EA says that the state’s concerns were addressed in this EA. The Department notes that while the NRC may have **addressed** the state’s concerns, these concerns have not necessarily been **resolved**.

NRC Response

The staff agrees with MDNR’s comment. The staff has worked closely with the state during the review of the Mallinckrodt DP, and the state’s concerns were discussed in detail during the April 24, 2009, public meeting. When possible, the staff incorporated the state’s concerns into the EA and SER.

4. MDNR Comment

Section 3.5.4.1 “Drains and Subsurface Sewerage That Served C-T Process Buildings” The Department suggest that a map of the sewerage system and building drains of Plant 5 would be helpful in the review of this section of the EA. We may have additional comments once the Final Site Survey (FSS) is provided and we can verify if remediation of these pipes meets the goal.

NRC Response

Figure 4-1 of the DP is a diagram showing the locations of the sewer lines in Plants 5 and 7W. A reference to this figure will be added to the EA and SER.

5. MDNR Comment

The Department requests some clarification in this document concerning the management of the cleanup for Plant 7. Some statements (i.e. next to last paragraph under Section 3.2.3 previous C-T and MED-AEC Decommissioning Activities) indicate that the USACE will remediate Plant 6 and 7. Section 3.4.3 Subsurface material and the last paragraph under Section 3.6.6 Soil) note that an agreement defining responsibility between the USACE and Mallinckrodt will need to be made.

NRC Response

We agree that the responsibility for the cleanup of Plant 7 is confusing. Plant 7 was used for MED-AEC and C-T processing activities. Therefore, USACE and Mallinckrodt have remediation responsibilities for Plant 7. To date, USACE and Mallinckrodt have not reached an agreement delineating responsibility for all areas of Plant 7. A delineation agreement must be reached between USACE and Mallinckrodt, and approved by NRC, before Mallinckrodt will be authorized to perform decommissioning activities in Plant 7. Section 3.2.3, Previous C-T and MED-AEC Decommissioning Activities of the SER/MED-AEC Decommissioning Activities, describes previous MED-AEC decommissioning activities in a very general way. Specific decommissioning activities planned for Plant 7 are described in Sections 3.6.1, 3.6.4, 3.6.5.4 and 3.6.6. In particular, Section 3.6.6 which addresses the soil beneath the wastewater neutralization basins states:

Mallinckrodt and USACE have not yet finalized an agreement delineating responsibility for soil beneath the former wastewater neutralization basins in Plant 7W. Mallinckrodt's license will be amended to state that Mallinckrodt must receive NRC approval of the Plant 7W delineation agreement before conducting any remediation activities in that area.

To address the state's comment, the same statement will be added to Section 3.6.4, Wastewater Neutralization Basins.

6. MDNR Comment

Referencing comment number 2 above, the statement in the last paragraph of Section 3.6.7 Groundwater "... nor will it (Groundwater) likely be a source..." is not consistent with the ROD language.

NRC Response

The staff believe that statements regarding future groundwater use are consistent with the ROD. See response to comment 2 above.

7. MDNR Comment

Section 3.11.1.1, Solid Radioactive Waste Management. This section notes that ... unimportant quantities of radioactive material can be managed by NRC-authorized transfer to a state-regulated disposal facility.” It should be noted that the state of Missouri’s solid waste rules and regulations specifically prohibit these types of materials in this state’s permitted facilities {10 CSR 80-3.010(3)(A)2}.

NRC Response

Comment noted. NRC is confident that Mallinckrodt understands that it must meet the state’s requirements for disposal of any solid waste at a state-regulated disposal facility. Section 12.1.6 of the DP provides Mallinckrodt’s plan for waste disposition. With regard to solid waste with unimportant quantities of radioactive material it says:

Material which is distinguishable from background but contains radioactivity concentrations less than the unimportant quantity of source material, as defined in 10 CFR 40.13, will be disposed of in accordance with an NRC-authorized transfer to a disposal facility, subject to the cognizant state regulatory agencies in which the disposal facility is located.

8. MDNR Comment

Section 4. Regulatory Evaluation, next to last paragraph, appears to state that decommissioning of the C-T process areas will be independent of the remediation of the MED-AEC areas. This is not the message the Department believes it was given in previous meetings with the NRC. It was and is our understanding that all areas of the Mallinckrodt plant would have to meet the NRC’s release criteria before the license would be terminated. The noted section further states the MED-AEC contamination will be remediated to meet the NRC unrestricted release standards: however, there will be some areas that will remain “inaccessible” which will have land-use controls and a management plan and ROD.

The Department again points out that the cleanup goals for the MED-AEC areas have a lower radioactive content than the NRC licensed areas. This difference may be addressed once the final site survey for the C-T area is available.

NRC Response

The decommissioning process for the Mallinckrodt site has not changed. Mallinckrodt is responsible for contamination associated with C-T processing and the U.S. Army Corps of Engineers (USACE) under the Formerly Utilized Sites Remedial Action Program (FUSRAP) is responsible for contamination associated with MED-AEC activities. In Plants 6 and 7 there is shared responsibility for contamination, resulting in the need for delineation agreements specifying cleanup responsibility. After delineation of responsibility for contamination in Plants 6 and 7, decommissioning of the C-T process areas will be independent of the MED-AEC areas.

Mallinckrodt’s cleanup criterion, provided in the DP, is based on meeting 25 mrem/yr plus ALARA. The cleanup criteria used by USACE at the Mallinckrodt site are provided in the existing ROD for accessible MED-AEC material. These criteria were developed to meet several objectives including

the requirements of 40 CFR 192 and the NRC's unrestricted release criteria of 10 CFR 20.1402. Specifically, the ROD states that 10 CFR Part 20, Subpart E, standards are relevant and appropriate to any FUSRAP materials similar to licensable materials under the Atomic Energy Act. Although Mallinckrodt and USACE have different clean-up criteria, the result is such that the unrestricted release dose criterion of 10 CFR Part 20.1402, are met.

In its DP, Mallinckrodt is requesting NRC to terminate its license after it completes decommissioning of C-T process areas on site such that these areas are suitable for unrestricted release in accordance with 10 CFR Part 20.1402. If USACE and Mallinckrodt independently demonstrate that the MED-AEC and C-T process areas, respectively, meet NRC's unrestricted release criteria, then the entire site should meet NRC's unrestricted release criteria at completion of site decommissioning activities. Therefore, the staff concludes that it is reasonable to terminate License STB-401 after Mallinckrodt completes decommissioning activities in the C-T process areas and demonstrates that the C-T process areas at the site meet NRC's unrestricted release criteria.