

November 20, 2014

MEMORANDUM TO: Michael Norato, Chief
Materials Decommissioning Branch
Division of Decommissioning, Uranium Recovery,
and Waste Programs
Office of Nuclear Material Safety
and Safeguards

FROM: Karen Pinkston, Systems Performance Analyst */RAI/*
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Office of Nuclear Material Safety
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SUBJECT: PUBLICLY NOTICED MEETING SUMMARY

On October 9, 2014, a publicly noticed meeting was held regarding the Mallinckrodt facility located in St. Louis, Missouri. Participants included U.S. Nuclear Regulatory Commission (NRC) personnel from the Material Control, Independent Spent Fuel Storage Installation (ISFSI), and Decommissioning Branch of NRC Region III, the Reactor Decommissioning, Materials Decommissioning and Performance Assessment Branches of the Office of Nuclear Material Safety and Safeguards, the Office of General Counsel, the Oak Ridge Associated Universities as the NRC's consultant, and representatives of Mallinckrodt Pharmaceuticals and their consultant, Energy Solutions. The meeting was requested by Mallinckrodt. The purpose of the meeting was for Mallinckrodt to discuss their approaches to responding to the NRC staff's Requests for Additional Information (RAI) (ADAMS Accession No. ML14175A305). The RAIs were issued regarding the Final Status Survey Reports for the Columbium-Tantalum (C-T) Plant (ADAMS Accession No. ML14177A180). ADAMS is the NRC's Agencywide Document and Access Management System. Enclosure 1 is the agenda for the meeting. Enclosure 2 is a listing of the meeting's participants. Some individuals participated via teleconference.

In the introductory remarks, the NRC explained that the meeting was a Category 1 Public Meeting in which members of the public were invited to participate in the meeting consistent with past practice, and the public would be allotted the opportunity to communicate with the NRC after the business portion of the meeting, but before the meeting was adjourned. The NRC stated that there was nothing which required the licensee to respond to any comments or questions from members of the public. However, while there was no requirement to respond, there was also nothing which precluded the licensee from responding to questions if the licensee chose to do so.

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Following the introduction of the participants, various RAIs were discussed. This discussion focused primarily on the general comments and specific RAIs were discussed in less detail.

For General Comment 1 of the RAIs, Mallinckrodt provided several photos of survey units and a description of the location of residual contamination remaining on site as well as measurements that were performed in the elevated areas. Mallinckrodt stated that these survey units were evaluated using the index methodology which was approved in the decommissioning plan (DP). In the response to the RAIs, Mallinckrodt intends to assess these survey units using a dose assessment methodology instead. Mallinckrodt believes that using a dose assessment methodology that reflects the actual configuration of the residual material and cover would provide a degree of comfort to both the NRC and them because this would provide a better methodology for showing the 25 mrem/yr dose criteria will be met. Mallinckrodt indicated that they would provide more detail on defining the areas of elevated radiation readings. They indicated that some readings were the best that could be obtained considering physical limitations. Mallinckrodt also questioned whether the NRC's comment should have included Survey Unit 4 (SU4) in the list of survey units to which this comment pertains. The NRC agreed to confirm whether the comment pertained to SU4.

For General Comment 2.a, Mallinckrodt indicated that they had used deterministic models. They indicated that they would be changing the residency to 100% inside and apply a cover factor. The NRC staff clarified that the use of either deterministic or probabilistic models are acceptable. However, the parameters which Mallinckrodt selected were not the same parameters which were approved as part of the DP review. The staff stated that Mallinckrodt's dose assessment must take into account existing conditions and address potential future site changes (e.g., buried material with residual contamination is excavated).

NRC and Mallinckrodt also discussed whether the use of the dose assessment approach, instead of the DCGL approach, requires a license amendment. Mallinckrodt performed an analysis of whether a license amendment would be required. Mallinckrodt is to determine if this analysis was submitted to the NRC and docketed.

For General Comment 2.b, Mallinckrodt indicated that they had utilized the index value and had followed Chapter 14 of the DP. Chapter 14 drops out items with an index value less than 1. The staff asked where in Chapter 14 this information was provided. Mallinckrodt agreed to provide where in Chapter 14 this information was presented. As in the discussion of General Comment 1, Mallinckrodt and the NRC staff discussed the use of realistic modeling to address the dose from elevated areas instead of using the index methodology.

For General Comment 2.c, Mallinckrodt indicated that at 30 inches in depth, the dose effect is basically the same as if the distance were infinite. The NRC staff asked about the potential effect of a thicker layer of contamination on the dust loading and resulting worker dose. The staff also indicated that they would need a better justification for the assumed areas of the hot spots.

For General Comment 3, the NRC indicated that their concern was the subsurface material under the buildings and how the release criteria would be met. The NRC asked whether a historical search had been performed to ascertain where this material originated. The NRC staff noted that this type of information would be useful in understanding the origin of the subsurface

contamination and the potential extent of contamination. The NRC asked about the survey plan for this area and the basis for determining the number and location of samples.

Mallinckrodt indicated Survey Unit 22 (SU22) includes two buildings. They questioned the benefit of performing a gamma walk-over survey in the buildings as there was never any radioactivity in the buildings. Mallinckrodt stated that they had performed extensive sampling of soil under Buildings 240 and 250.

Building 240 was used strictly as an office building and as a maintenance shop. Building 250 is a pharmaceutical building and includes a couple of laboratories. These buildings were originally MARSSIM Class 3 survey units. However, elevated readings along the building foundation all the way to the footers and along C-T sewer lines passing by the buildings necessitated a change in classification. Mallinckrodt went as deep as 3 meters to sample the material and performed a 100% walkover of the alleyways by the buildings.

For General Comment 4, Mallinckrodt stated that the Plant 7 settlement agreement had been drafted. As part of this agreement, Mallinckrodt was going to remove the grit chamber in Plant 7. Mallinckrodt said that they expect this settlement agreement to be submitted soon.

Following the above discussions, there was no additional discussion since no members of the public participated in the call.

Enclosures:

1. Agenda
2. Attendee List

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