



A Review of NIOSH's Program Evaluation Report DCAS-PER-040, “Mallinckrodt TBD Revisions”

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MCW site profile revisions

- ◆ Mallinckrodt Chemical Works (MCW) technical basis document (TBD), ORAUT-TKBS-0005:
 - Rev. 00, issued October 24, 2003
 - Rev. 01, issued March 10, 2005
 - Rev. 02, issued June 14, 2007
 - Rev. 02 PC-1, issued May 25, 2009
 - Rev. 03, issued November 22, 2010
- ◆ OCAS-PER-015, issued July 31, 2007, to address changes in dose reconstruction (DR) procedures using rev. 02 of ORAUT-TKBS-0005.
- ◆ OCAS-PER-015 resulted in NIOSH evaluating all previous completed claims with a probability of causation (POC) of <50%.

DCAS-PER-040

- ◆ Issued September 20, 2013
- ◆ Addressed changes in DR procedures introduced in rev. 03 of ORAUT-TKBS-0005
- ◆ Reassessed previous claims completed using rev. 02 or rev. 02 PC-1 of MCW TBD

MCW operations

- ◆ Mallinckrodt Chemical Company, also known as Mallinckrodt Chemical Works (MCW), Destrehan Street (downtown site), St. Louis, Missouri
- ◆ MCW began research on uranium refining and processing operations in April 1942 under the direction of the Manhattan Engineer District, predecessor agency to the U.S. Atomic Energy Commission
- ◆ By July 1942, MCW was producing nearly 1 ton of uranium dioxide (UO_2) per day
- ◆ Other activities included:
 - production of uranium trioxide (UO_3), uranium tetrafluoride (UF_4)
 - uranium derby metal and vacuum recasting of ingot metal
 - recovery of scrap uranium metal
 - reprocessing of pitchblende residues to recover uranium
- ◆ St. Louis Airport (Storage) Site (SLAPS) received residues from MCW operations during 1946–1958; thereafter, site used for residual storage and disposal until 1967



EEOICPA coverage

- ◆ MCW covered DR periods were 1942–1962 and 1995
- ◆ SLAPS covered DR periods were January 3, 1947–1973 and 1984–1998

Radionuclides of dose significance

- ◆ A variety of uranium refining processes resulted in changing source terms and exposure potential.
- ◆ Most ore processed at MCW was pitchblende ores from the Belgian Congo.
- ◆ To produce UO_2 , feed materials of pitchblende ores contained up to 65% to 70% triuranium octoxide (U_3O_8) by weight.
- ◆ This pitchblende ore contained high levels of radium (Ra)-226 and other radiological daughter products.
 - Most external doses were from Ra-226 in equilibrium with its daughter products.
 - Thorium (Th)-234 and protactinium (Pa)-234 produced most of the extremity doses.
 - Radon and radioactive dust resulted in internal doses due to inhalation.
- ◆ Table A-4 of ORAUT-TKBS-0005, rev. 03, lists the types and quantities of material produced in association with the uranium refining and related operations.

Internal monitoring

- ◆ During the years of UO_2 production, energy employees (EEs) were monitored via urinalysis for uranium and thorium.
- ◆ EEs who processed uranium were given a pre-employment urinalysis and annual urine samples thereafter.
- ◆ Radon breath analysis was performed for EEs potentially exposed to Ra-226.
- ◆ For assessing exposure to radon, area radon data were used.
- ◆ Special Exposure Cohorts (SECs) were issued because NIOSH determined:
 - It is not feasible to reconstruct internal dose prior to 1949.
 - It is not feasible to reconstruct internal radiation doses from non-uranium radionuclides (Th-230, Pa-231, and actinium (Ac)-227) through 1958.
 - Internal dose at the SLAPS cannot be reconstructed with sufficient accuracy for the period January 3, 1947, through November 2, 1971.

External monitoring

- ◆ EEs were not individually monitored for external dose prior to June 1945.
- ◆ Starting in June 1945, film badges were issued to all EEs cleared to have access to production areas.
- ◆ Weekly film badge records are available from 1946–1948, 1950–1951, 1952, and 1954–1958, with some gaps in monitoring data.
- ◆ Film badge records for the post-operations period at MCW may not be available.
- ◆ NIOSH issued an SEC that states it is not feasible to reconstruct external radiation doses for individuals who worked at MCW prior to 1949.
- ◆ Although sources of neutron exposures existed at MCW, no neutron monitoring was performed. Neutron doses are derived based on neutron-to-photon ratios.

SC&A's review of PER-040

- ◆ SC&A tasked to review PER-040, “Mallinckrodt TBD Revisions,” on February 16, 2023
- ◆ SC&A issued “A Review of NIOSH’s Program Evaluation Report DCAS PER-040, “Mallinckrodt TBD Revisions” on August 11, 2023
- ◆ SC&A issued revision 1 of our review of DCAS-PER-040 on September 21, 2023

Reason for issuance of DCAS-PER-040

- ◆ TBD rev. 03 contains several changes in DR covering the MCW downtown (Destrehan Street) St. Louis site and the SLAPS.
- ◆ Changes include:
 - Rev. 02 stated no internal or external dose could be reconstructed from 1942 through 1948 as a result of SEC-00012. However, rev. 03 clarified that external dose could be reconstructed for EEs with a record of external dose monitoring.
 - Rev. 02 PC-1 added guidance after table A-40 to include isotopic ratios for internal dose between 1959 and 1962, which could increase dose for some organs.
 - Rev. 03 increased external dose at SLAPS for most years between 1947 and 1973 and between 1984 and 1998. Rev. 03 also added a radon exposure estimate for SLAPS.

SC&A's subtask 1 review of PER-040

- ◆ **Subtask 1:** Identify the circumstances that necessitated DCAS-PER-040.
- ◆ SC&A reviewed ORAUT-TKBS-0005, rev. 02, 02 PC-1, and 03, and PER-040.
- ◆ SC&A found that PER-040 addressed the changes in rev. 03 that could potentially result in increased internal and external dose assignments.
- ◆ Additional changes in the revisions were for other purposes and did not result in a potential increase in assigned dose.
- ◆ SC&A had no findings or observations pertaining to subtask 1.

SC&A's subtask 2 review of PER-040

- ◆ **Subtask 2:** Assess NIOSH's specific methods for corrective action.
- ◆ SC&A reviewed rev. 03 of the TBD and compared the text, figures, and tables in it to rev. 02 of 2007 and rev. 02 PC-1 of 2009.
- ◆ Since SC&A had only reviewed TBD rev. 00, the subtask 2 review evaluated the technical accuracy of the changes made in TBD rev. 03.
- ◆ SC&A found that these changes were correctly captured in DCAS-PER-040.
- ◆ SC&A had no findings but did have two observations.

SC&A's subtask 2 observation 1: Table A-40 text clarification (PER-040)

- Table A-40 of TBD rev. 03 lists intake values for the period 1959–1962 and 1995.
- PER-040 indicates that the guidance following table A-40 could increase internal dose during 1959–1962.
- SC&A believes PER-040 should also include 1995.
- Table A-40 of TBD rev. 02 lists the correct units of picocuries (pCi) for inhalation and ingestion in the left-hand column.
- Rev. 02 PC-1 and rev. 03 list incorrect units of “phi” for left-hand column in table A-40.

SC&A's subtask 2 observation 2: Periods of assigning beta dose at SLAPS (TBD rev. 03)

In TBD rev. 03, NIOSH recommends:

- Assigning beta dose for January 3, 1947–November 2, 1971
- Not assigning beta dose for November 3, 1971–December 31, 1973
- Assigning beta dose for January 1, 1984–December 31, 1998

SC&A questions what occurred at SLAPS during January 1, 1974–December 31, 1983, that warranted beta dose assignment during the period January 1, 1984–December 31, 1998, when it was not to be assigned for the prior period of November 3, 1971–December 31, 1973.

SC&A's subtask 3 review of PER-040

- ◆ **Subtask 3:** Evaluate the PER's stated approach for identifying the number of DRs requiring reevaluation of dose.
- ◆ NIOSH queried the database of completed DRs for the words "Mallinckrodt," "Destrehan," "Louis Airport," or "SLAP" to create a list of potential cases for review.
- ◆ SC&A does not have access to the database used by NIOSH to identify and quantify those cases that qualified for reevaluation.
- ◆ However, SC&A concluded that the search terms are appropriate and all-inclusive.
- ◆ Note: PER-040 did not provide the total number of cases that met NIOSH's query, or the number of cases removed.

Subtask 3: NIOSH claim elimination process

- ◆ From the total number of potentially impacted cases, NIOSH eliminated cases for the following reasons:
 - DR completed prior to June 14, 2007 (the date of TBD rev. 02; claims prior to that date were reevaluated under PER-015)
 - DR completed after November 22, 2010 (the date of TBD rev. 03)
 - Case had been pulled from DR by the U.S. Department of Labor
 - Case had a POC greater than 50%
 - Case qualified for compensation under an existing SEC (except those that potentially required a DR for medical benefits)
 - DR did not use the MCW TBD in calculating dose
- ◆ This process resulted in a total of 91 cases to be reevaluated

Subtask 3: Reevaluation of remaining claims

- ◆ Doses for the remaining 91 cases were recalculated using rev. 03 of the TBD and other applicable documents.
- ◆ Rework of the 91 cases resulted in:
 - 86 cases had POCs less than 45%.
 - 3 cases had POCs between 45% and 50%. The Interactive RadioEpidemiological Program (IREP) was run 30 times with 10,000 iterations for each run. The final POCs for these three cases remained below 50%.
 - 2 cases resulted in a POC greater than 50%.

Subtask 3: SC&A's evaluation of case elimination process

- ◆ SC&A concluded the screening criteria used to eliminate cases from the total number of identified cases are valid.
- ◆ There are no findings or observations associated with subtask 3.

SC&A's recommendation for PER-040 subtask 4 case reviews

- ◆ **Subtask 4:** Conduct audits of a sample set of reevaluated DRs mandated by PER-040.
- ◆ SC&A recommends that cases be selected for our review that reflect these changes and meet the following criteria:
 - Employment between 1942 through 1948 where external dose was assigned
 - Internal dose assigned at MCW between 1959 and 1962 and in 1995
 - External penetrating and/or nonpenetrating doses at SLAPS for years 1947–1973 and/or 1984–1998
 - Radon exposure assigned for SLAPS between 1971 and 1973, and/or between 1984 and 1998
 - Internal dose assigned for SLAPS within the timeframe 1984–1998

Summary of SC&A's evaluation of PER-040

- ◆ SC&A reviewed PER-040 and identified no findings but had one observation:

Observation 1: Table A-40 text clarification

Summary of SC&A's evaluation of site profile

- ◆ SC&A reviewed ORAUT-TKBS-0005, rev. 03, and identified no findings but did have one observation:

Observation 2: Periods of assigning beta dose at SLAPS



Questions?