

<b>Division of Compensation Analysis and Support</b> <b>Program Evaluation Report</b>	Document Number: DCAS-PER-040 Effective Date: 9/10/2013 Revision No. 0
<b>Mallinckrodt TBD Revisions</b>	
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RECORD OF ISSUE/REVISIONS			
ISSUE AUTHORIZATION DATE	EFFECTIVE DATE	REV. NO.	DESCRIPTION
9/10/2013	9/10/2013	0	New document to determine the effect of revising the Mallinckrodt TBD on previously completed claims.

## 1.0 Description

The Mallinckrodt Technical Basis Document (ORAUT-TKBS-0005) was first issued on 10/24/2003. Since that time, the following revisions have been made:

- Revision 1 issued 3/10/2005
- Revision 2 issued 6/14/2007
- Revision 2 PC-1 issued 5/25/2009
- Revision 3 issued 11/22/2010

On 7/31/2007, OCAS-PER-015 was issued to evaluate the effect of revision 2 on previously completed claims. That PER resulted in NIOSH requesting the return of all previously completed Mallinckrodt dose reconstructions that resulted in a probability of causation (POC) less than 50%. Therefore, this PER considered only the effect of revision 3 on claims that were completed using revision 2 or revision 2 PC-1.

## 2.0 Issue Evaluation

The Mallinckrodt TBD also includes instructions for completing dose reconstructions for the St. Louis Airport Site (SLAPS). Several changes to the Mallinckrodt TBD may increase dose estimates for either Mallinckrodt or SLAPS.

Revision 2 of the TBD explained that no internal or external dose could be reconstructed for Mallinckrodt employment from 1942 through 1948 as a result of the SEC-00012 designation. However, in revision 3, it was clarified that external dose could be reconstructed for those with a record of external dose monitoring.

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In revision 2 PC-1, guidance was added after table A-40 describing appropriate isotopic ratios to use for internal dose at Mallinckrodt between 1959 and 1962. This change could increase dose for some organs.

Revision 3 increased external penetrating and non-penetrating dose at SLAPS for most years between 1947 and 1973 and between 1984 and 1998. Revision 3 also added a radon exposure estimate for SLAPS between 1971 and 1973 and an internal dose estimate from 1984 to 1998.

Additional changes were made to the Mallinckrodt TBD that reduced the estimated dose. Those are not itemized here but are accounted for in any new estimate of dose.

### **3.0 Plan for Resolution or Corrective Action**

Based on the conditions described above, a text search of previously completed dose reconstructions was performed that searched for any mention of “Mallinckrodt”, “Destrehan”, “Louis Airport” or “SLAP”. From the list generated using these search criteria, dose reconstructions were eliminated that:

- Were completed prior to 6/14/2007 (The date of revision 2. Claims prior to that were requested to be returned to NIOSH in OCAS-PER-015)
- Were completed after 11/22/2010 (The date of revision 3 which is the current revision of the TBD)
- Claims that had been pulled from Dose Reconstruction by the Department of Labor.
- Had a probability of causation greater than 50%
- Qualified for compensation under an existing SEC (except those that potentially required a dose reconstruction for medical benefits)
- Those that did not use the Mallinckrodt TBD in calculating dose (For example, some claims from other sites were flagged only because the text of the dose reconstruction mentioned the site performing work for Mallinckrodt)

This process resulted in a total of 91 claims to be reviewed.

#### **3.1 Determination of claims which will not change due to TBD revision.**

For the ninety-one claims requiring further evaluation, dose was recalculated using all current dose reconstruction methods, including those in the current version of the TBD. From that recalculated dose, a new probability of causation was determined. The

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probability of causation remained below 45% for 86 of the 91 claims. For three of the remaining five claims, the probability of causation fell between 45% and 50%. In accordance with NIOSH procedures, IREP was run 30 times with 10,000 iterations for each run. The final probability of causation remained below 50% for all three claims. The final two resulted in a probability of causation greater than 50%. In both cases, this resulted primarily from the inclusion of monitored external dose between 1942 and 1948 that had not previously been included. NIOSH will notify DOL of all these results and request a return of the two claims that would now be greater than 50%.