

Office of Compensation Analysis and Support
Program Evaluation Report

Document Number: OCAS-PER-015

Effective Date: 7/31/2007

Revision No. 0

Mallinckrodt TBD Revision

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RECORD OF ISSUE/REVISIONS

ISSUE AUTHORIZATION DATE	EFFECTIVE DATE	REV. NO.	DESCRIPTION
7/31/2007	7/31/2007	0	New document to determine which previously completed claims require evaluation for the effect of revising the Mallinckrodt TBD.

1.0 Description

The Mallinckrodt Technical Basis Document (ORAUT-TKBS-0005) was first issued on 10/23/2003. Since that time two revisions to the document have been approved. Revision 1 was approved on 3/10/2005 and revision 2 was approved on 6/14/2007. The last revision was made to address issues raised during a Special Exposure Cohort review of the TBD by the Advisory Board on Radiation and Worker Health.

2.0 Issue Evaluation

The revisions to the Mallinckrodt TBD changed the Dose Reconstruction methodology for several exposure pathways. Some of the changes to the methodology will increase radiation dose estimates. The latest revision also eliminates some exposure pathways where it was determined that the dose could not be estimated with sufficient accuracy. A Special Exposure Cohort (SEC) status was granted to employees of Mallinckrodt in two separate steps. Due to the nature of some of the changes, the magnitude of the effect on individual dose estimates will vary from claim to claim. It is therefore, not possible to determine the effect on the Probability of Causation without a new dose estimate.

3.0 Plan for Resolution or Corrective Action

It is not possible to determine the magnitude of the change to dose without a new dose estimate. Since (as of issuance of this PER) no Mallinckrodt claims have yet been completed with the newest revision to the TBD, NIOSH is requesting that all Mallinckrodt claims with a dose reconstruction performed using Revision 1 of ORAUT-TKBS-0005 that have a Probability of Causation less than 50% be returned for a new estimate. A list of the population of 16 potentially affected claims is attached. A new

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dose reconstruction will be completed for each of the claims using the latest revision to the Mallinckrodt TBD.