September 15, 2005

The Honorable Michael O. Leavitt
Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Mr. Secretary:

The Advisory Board on Radiation and Worker Health (The Board) has evaluated SEC Petition -00012-2 concerning workers at the Uranium Division at the Mallinckrodt facility under the statutory requirements established by EEOICPA and incorporated into 42 CFR Sec. 83.13 (c) (1) and 42 CFR Sec. 83.13 (c) (3). The Board respectfully recommends a Special Exposure Cohort be accorded to all Department of Energy (DOE) employees or its contractor or subcontractor employees who worked as at the Uranium Division at the Mallinckrodt Destrehan Street facility from 1949 to1957 and who were employed for a number of work days aggregating at least 250 work days, occurring under this employment or in combination with work days of employment occurring within the parameters (excluding aggregate work day requirements) established for other classes of employees included in the SEC. This recommendation is based on the following factors:

- These workers were employed at a facility that processed materials during the early time period for the production of nuclear weapons. Radiation monitoring methods for all isotopes were under development at that time leading to significant gaps in the monitoring of these workers in comparison to current monitoring programs.

- There is relatively little information available for estimating thorium, actinium, and protactinium. NIOSH’s approach to dose reconstruction no longer relies on individual monitoring but rather plant-wide air monitoring data, which is, itself, not even isotope specific. These data have to be converted into isotope specific activity using residue fraction values which have not been validated. As such, NIOSH has not demonstrated that it can conduct individual dose reconstructions with sufficient accuracy.
• While there are many internal exposure monitoring records for uranium and some for radium, there are no individual bioassay records for Plant 6 workers for high consequence isotopes extracted from the pitchblende ores and contained in the AM-7 and Sperry Cake residues (Thorium 230, Actinium 227, and Protactinium 231). There are only bioassay data for two months in March and April 1955 for the Plant 7E workers (thorium recovery operations) although operations continued in 1956 and 1957.

• There are concerns about the lack of a method to adjust for the angle of incidence of external dose monitoring. This adjustment has a significant impact on the interpretation of the monitoring data, and a final method needed for individual dose reconstruction is not yet available.

• There are concerns about the validity of the radon breath data being used for dose reconstruction. Radium intakes based on radon breath data were taken from a secondary data source, and they have not been validated against source data. In response to questions about the validity of the data, NIOSH has just started an effort to obtain the data from the original records. This effort has not been completed, and the Board has not been able to evaluate the results of this effort.

• The Board has reviewed data which confirms that radiation exposures at the Mallinckrodt facility during the time period in question could have endangered the health of members of this class.

The Board has been deliberating for over 6 months on the Mallinckrodt SEC petition for the period 1949-1957. There have been 4 separate audit reports, 4 Board meetings, 4 subcommittee or working group meetings and many conference calls and memos. NIOSH staff, the staff of their contractor, and the contractor for the Advisory Board have spent hundreds of hours working on this effort. Despite many meetings and two years of work on the site profile for this site, new data continue to emerge on the site including some first revealed to the Board during this most recent meeting. Efforts to find new data on this site could continue for years. However, the Board also recognizes the need to make timely decisions. EEIOCPA requires that this program should produce a defensible radiation dose reconstruction in a reasonable period of time, and Congress has recently reinforced this objective in the FY 05 Defense Authorization Act and the Labor HHS Appropriations Act.

Based on these considerations, the Board recommends that this Special Exposure Cohort petition be granted. It should be noted that the Board believes that the exposure information available is adequate for the reconstruction of individual external exposures, and where appropriate for specific types of cancer (e.g., skin) those individual doses can be reconstructed.

Enclosed is supporting documentation from the Advisory Board Meetings held April 25 to 27, 2005 in Cedar Rapids, Iowa, July 5 to 7, 2005 in St. Louis, Missouri, and August 24 to 26, 2005 in St. Louis, Missouri. This documentation includes transcripts of public comments on
the petition, copies of the petition and the NIOSH review thereof, and related documents distributed by NIOSH and the petitioners. If any of these items are unavailable at this time, they will follow shortly.

Sincerely,

[Signature]

Paul L. Ziemer, Ph.D.
Chairman,
Advisory Board on Radiation and Worker Health

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