

Section B

**SUPPORTING STATEMENT OF THE REQUEST FOR
OMB REVIEW AND APPROVAL
FOR REINSTATEMENT OF**

Tremolite Asbestos Registry

OMB #0923-0039

Division of Health Studies
Agency for Toxic Substances and Disease Registry

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B. Collection of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

ATSDR used documents from the company that ran the Libby vermiculite operation to recreate the worker cohort. From this cohort 791 living vermiculite workers were identified. ATSDR was also able to identify 1,680 household contacts of vermiculite workers. In addition, there are 5,299 other Libby residents who participated in the 2000/2001 ATSDR community screening who are also eligible to be enrolled in the TAR. Thus, the combined universe of potential TAR registrants is 7,770. To date, 664 workers (84%), 1,354 household contacts (81%) and 2905 (55%) residents have been enrolled and interviewed by combined efforts of the Montana Department of Public Health and Human Services (MDPHHS) and ATSDR. MDPHHS is continuing to enroll registrants in the TAR as they participate in its community screening program. All registrants will be administered the same survey.

One hypothesis related to TAR data is that an excess of asbestos-related mortality among former Libby vermiculite workers with high asbestos exposure levels exists. ATSDR was able to reconstruct the entire Libby vermiculite worker cohort (n=1,862) as well as the asbestos exposure level for each individual worker from company documents. Members of the cohort can be categorized as living (n=791), deceased (n=876), and vital status unknown (n=195). If the proportion of deceased workers with an asbestos-related cause of death among those workers with asbestos exposure levels greater than or equal to 100 fiber-years/mL (n=60) is 0.40, and among workers with less than 100 fiber-years/mL (n=816) is 0.15 and assuming $\alpha=0.05$, the power to detect significant difference between the two groups would be $\beta > 0.99$.

Outside researchers may have their own hypotheses regarding TAR data. Before any TAR data are released to outside researchers, ATSDR management will evaluate each data request as described in Part A, Section 2.

2. Procedures for the Collection of Information

The data collection effort began in September 2002 and has continued under the OMB approval (0923-0006). Initially, a National Death Index search was conducted to identify decedents in this cohort. Next, various other databases (e.g., LexisNexis) were used to locate living cohort members. ATSDR then contacted these persons telephonically to confirm their identity and status as either a worker or household contact.

An advance letter explaining the purposes and goals of the TAR will be sent to all newly identified eligible persons. Next, recruitment of medical testing participants will begin as those persons return for their first follow-up screening. At that time, they will be invited to participate in the TAR. If they consent to participate by signing the appropriate section of the MASSA consent form, their medical testing data (i.e., survey responses, pulmonary function test results, and chest radiograph results) will be added to the TAR. If the candidate consents to be added to the TAR, the appropriate survey will be administered using CAPI.

3. Methods to Maximize Response Rates and Deal with Non-response

The TAR respondents are identified and asked to participate. The outreach program will involve efforts to notify and inform all potential registrants; interaction with and cooperation of health professionals and government officials at the federal, state and local levels; community meetings; and radio, television, and newspaper publicity. The respondents will be assured that ATSDR will provide updated information regarding exposures, their confidentiality will be maintained, and there will be a long term follow-up, as funding allows, to update information provided during the baseline data collection.

All interactions with the registrants have proceeded through or with the knowledge of the regional, state, county, and local officials and health professionals.

4. Test of Procedures or Methods to Be Undertaken

The TAR survey instrument continues to be the same as the one used in community screening conducted by ATSDR in Libby in 2000/2001. The survey instrument uses symptom and tobacco use questions standardized by the American Thoracic Society. Other questions were developed using input from experts from academia, the Centers for Disease Control and Prevention, the Montana Department of Public Health and Human Services, U.S. Environmental Protection Agency, and the U.S. Department of Health and Human Services.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The Surveillance and Registries Branch (SRB) in ATSDR's Division of Health Studies (DHS), is in charge of monitoring the Tremolite Asbestos Registry. The branch includes Statisticians and Epidemiologists (3 Statisticians and 4 Epidemiologists).

1. Data will continue to be analyzed by SRB Epidemiologists and Statisticians.
2. Questions regarding data collection procedures should be addressed to Mr. Theodore Larson at 770-488-3695 or thl3@cdc.gov.
3. Questions regarding statistical methods should be addressed to Mr. James Sapp at 770-488-3814 or JSapp@cdc.gov.