

Section A

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

Tremolite Asbestos Registry

OMB #0923-0039

Division of Health Studies
Agency for Toxic Substances and Disease Registry

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A. **Justification**

1. Circumstances Making the Collection of Information Necessary

Background

This is a request for a three-year extension for the Tremolite Asbestos Registry (TAR), OMB No. 0923-0039. The data collection instruments and the methods used to collect data remain unchanged. The TAR is a database of persons exposed to tremolite asbestos and other amphibole fibers found in vermiculite mined in Libby, Montana. The TAR contains information about exposure pathways for Libby amphibole and health outcomes.

As a consequence of relatively high occupational exposures, former Libby vermiculite workers are at much greater risk of developing asbestos-related disease than the general public. The household contacts of these vermiculite workers (e.g., immediate family members or roommates) may also have been exposed to asbestos brought home on the clothing of vermiculite workers, and also may have increased risk of developing asbestos-related disease. Further, residents of Libby who neither worked at the vermiculite mining and processing operation nor lived with a worker may also be at risk of developing asbestos-related disease due to other non-occupational exposure pathways in the community.

In 1999, the situation in Libby attracted significant local concern and media attention. Local and state health departments became involved, as well as the U.S. Environmental Protection Agency and the Agency for Toxic Substances and Disease Registry (ATSDR). In 2000 and 2001, ATSDR conducted community-based medical screening in Libby in which there were more than 7,000 participants. While the screening revealed excesses of asbestos-related abnormalities among participants, the long-term public health impact of asbestos exposures that occurred in Libby remains unknown, especially among potentially sensitive subgroups (e.g., children). ATSDR subsequently created the TAR to store and track information about former vermiculite workers, worker's household contacts, and persons who participated in the medical screening programs funded by ATSDR.

The purpose of the TAR is to improve communication with people at risk for developing asbestos-related disease resulting from asbestos exposure in Libby, and to support research activities related to TAR registrants. ATSDR wishes to continue to use TAR to mail information to registrants about the diagnosis and treatment of asbestos-related illness. In addition, several studies have been initiated using TAR data, such as examining mortality among vermiculite workers, autoimmune disease in Libby residents, and cancer incidence among registrants. Because vital status and contact information are part of the TAR, conducting health studies is facilitated with this potentially difficult and expensive task already completed.

The TAR was created in response to a legislative mandate. Section 104(i)(1) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (P.L. 96-510) authorizes the Agency for Toxic Substances and Disease Registry (ATSDR) to “in cooperation with the States, establish and maintain a national registry of serious diseases and illnesses and a national registry of persons exposed to toxic substances”. This mandate is restated under the authority of Section 110 (P.L. 99-499) of the Superfund Amendments and Reauthorization Act of 1986 (SARA) (Appendix A), which further states that when the results of a health assessment indicate a potential significant risk to human health, the establishment of a registry of exposed persons should be considered.

The legislative mandate for the TAR evolved from the need for basic information concerning the impact of toxic substances on the health of the general population. The establishment of the TAR is a long-term effort; the resulting data files are critical in the assessment of the long-term health consequences of exposure to Superfund-related hazardous chemicals. The TAR helps to address the concerns of individuals in communities where exposure to Libby vermiculite has occurred.

The 60 Day Federal Register Notice is located in Appendix B.

Privacy Impact Assessment

A PIA was conducted under the previous ICR for this project (Appendix C) and is still pertinent because methodology remains unchanged.

Overview of the Data Collection System

Information has been previously collected from participants in this information collection using computer-assisted personal and telephone survey instruments. These instruments have been administered by contractors acting on behalf of ATSDR and by the Montana Department of Public Health and Human Services. The survey instruments, interview methods, and partners for future information collection will remain the same. Because the TAR is being used to study the long-term health effects associated with exposure to Libby amphibole, the information will be maintained for 20 years.

Items of information collected

Categories of information collected for the TAR are:

1. Contact (IIF include name, mailing address and telephone number)
2. Identifying (IIF include date of birth and social security number)
3. Occupational history
4. Residential history
5. Exposure pathways
6. Tobacco use history
7. Health outcome

All information collected for the TAR is self-reported from participants.

Identification of Website and Website Content Directed at Children Under 13 Years of Age

This data collection does not involve web-based data collection methods or refer respondents to websites.

2. Purpose and Use of Information Collection

Initially, enrollment in the TAR was done via telephone interviews with former Libby vermiculite workers and their household contacts. Later, enrollment and the collection of data from face-to-face interviews were conducted as part of the ongoing screening process in Libby. Participants in the screening program are re-screened every one to five years, depending on individual risk category. On average, participants are re-screened every 3 years.

The purpose of the TAR is to facilitate rapid dissemination of information to registrants and to support surveillance of and research related to the health effects associated with exposure to Libby amphibole. To date, TAR data has been used to:

- o Educate registrants on health implications of asbestos-related disease
- o Educate registrants on health programs available to Libby residents
- o Select subjects for a study of autoimmune disease among Libby residents
- o Estimate the future public health impact of amphibole exposure to Libby residents
- o Select subjects for a study of health effects of persons with childhood exposure to Libby amphibole
- o Study patterns of mortality among Libby vermiculite workers
- o Study patterns of morbidity among Libby vermiculite workers
- o Monitor changes in the health of registrants.

The initial baseline data collection (Appendix D) is followed by a follow-up survey using the OMB-approved questionnaire instruments. The follow-up questionnaire (Appendix E) is a streamlined version of the baseline questionnaire that includes changes in lifestyle and health status since the previous interview. Optimally the follow-up survey will be administered every three years, contingent on available funding.

Registrants (or respondents) are followed longitudinally from baseline until a determination is made that further data collection is no longer necessary or expedient. Registrants age 18 years or older are asked to complete their own interview. Interviews for eligible registrants less than age 18 years or those mentally disabled are interviewed by proxy.

One of the major goals of the TAR is to minimize loss of registrants. The greatest source of loss is due to the inability to locate registrants; nonparticipation is minimal. To minimize this loss, ATSDR asks for the name of three persons who may know how to locate the registrant should his or her address or telephone number change. In many

cases the contacts listed are as mobile as the registrant providing the information; therefore, there is a need to obtain at least three contacts to minimize loss to follow-up.

TAR data are useful to local, state and federal governments and to researchers in assessing the long term health effects of exposure to Libby amphibole. The data can be used to ascertain disease prevalence, forecast health care needs, and facilitate studies attempted to link asbestos exposures with adverse health outcomes. The results from health studies based on TAR data may directly benefit the community reducing stress and anxiety resulting from data gaps of the effects of asbestos exposure by providing timely, factual information.

The public's concern for health consequences as a result of exposure to hazardous substances was, and continues to be, the major impetus for ATSDR's registry efforts mandated under CERCLA and, subsequently, SARA. Using information derived from the TAR, public health scientists will be better able to address public concerns for adverse health outcomes associated with long-term environmental exposure to asbestos in Libby.

In serving as a focal point for research related to the health of Libby residents, the TAR serves an important role in insuring the uniformity and quality of collected data and that data collection is not duplicative. In addition, ATSDR is in a position to evaluate data requests from outside researchers to insure they are not duplicative. ATSDR management review written requests for proposed research using TAR data. If the proposed research constitutes a potential breach of privacy protections, ATSDR will not share TAR data with the requestor. Examples of potential breaches of privacy protections include inadequate data security and high risk of conflict of interest. ATSDR will not share data containing IIF without the consent of individual registrants.

In addition to facilitating research, registry activities will further promote public health by being of direct service or benefit to the registrants. This is accomplished by keeping registrants informed of relevant research, medical interventions, or preventive measures related to their exposures.

Privacy Impact Assessment Information

A PIA was conducted under the previous ICR for this project (Appendix C) and is still pertinent because methodology remains unchanged.

Information is being collected for the TAR in order to provide a mechanism by which ATSDR can rapidly communicate with registrants, allow long-term surveillance of the health of registrants, and to facilitate the conduct of health studies of registrants. IIF is used to contact registrants, link the TAR with other surveillance databases (e.g., the National Death Index and the Montana Tumor Registry), and to invite registrants to participate in health studies. No data containing IIF will be released without a registrant's permission, with the exception of disclosure to the Montana Department of Health and Human Services. Some information contained in the TAR is highly sensitive;

a breach of confidentiality could potentially affect a respondent's privacy. To protect the privacy of TAR respondents, stringent safeguards have implemented; these safeguards are described in the PIA (refer to Appendix C).

3. Use of Improved Information Technology and Burden Reduction

Registrants will continue to be interviewed using computer-assisted survey instruments. Computer-assisted interviewing speeds data collection and processing, increases the accuracy of results, reduces respondent-interviewer burden by reducing the time of the interview, and enhances the researcher's ability to elicit appropriate information through detailed contingent questioning or branching systems.

4. Efforts to Identify Duplication and Use of Similar Information

There is no other registry of persons exposed to asbestos-contaminated vermiculite from Libby, Montana. The TAR was created with input from other federal government agencies and the appropriate state, county and city health and governmental officials. The scientific literature was searched before the TAR was created and no other similar registry found in the United States.

5. Impact on Small Businesses or Other Small Entities

No small businesses are involved in this study.

6. Consequences of Collecting the Information Less Frequently

Follow-up screening will continue to be performed by the Montana Department of Public Health and Human Services at scheduled three years intervals until a participant declines further participation or tests positive for asbestos-related disease, at which time the participant will be referred to a health services provider for treatment. Less frequent collection of information would result in reduced likelihood of detecting an asbestos-related abnormality (e.g., lung cancer) or an incidental medical finding (e.g., breast cancer) in time for the individual to obtain effective diagnosis and treatment.

Because the exact latency periods for diseases resulting from exposure to Libby amphibole are unknown, it will necessary to continue to carry out longitudinal data collection until sufficient information is amassed to make a judgment about what those diseases are or that there is no adverse outcome associated with amphibole exposure.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This data collection complies fully with the guidelines of 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

a. No public comments were received in response to the May 7, 2009 Federal Register Notice (Volume 74, Number 87, page 21369-21370).

b. The following are public meetings, peer review groups, and outside consultations that occurred prior to the establishing of the TAR.

ATSDR hosted panel of experts in February 2002 to discuss the Tremolite Asbestos Registry. After considerable discussion, the work group indicated that a design that would provide the greatest amount of both scientific knowledge and community service would encompass the following, in order of priority:

- Use the population of and information for each participant in the ATSDR Medical Testing Program as the core for the TAR;
- Locate and test (using the ATSDR Medical Testing Program protocol) former workers of W.R. Grace and the Zonolite Company and their household contacts;
- Locate and test current and former residents of Libby, Montana;
- Conduct follow-up data collection, including survey information and medical testing at specified intervals yet to be determined; and
- Consider including other sites in the TAR.

The panel concluded that ATSDR should attempt to collect the above information and develop the most feasible version of the TAR possible within resource constraints.

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9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be made to respondents.

10. Assurance of Confidentiality Provided to Respondents

The NCEH/ATSDR Privacy Act Officer has reviewed this OMB application and has determined that the Privacy Act is applicable. The applicable system of records is 09-19-0001, "Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances." Accordingly, ATSDR will adhere to the Privacy Act provisions concerning the protection of information collected on registrants. This responsibility for protection involves adopting policies and procedures for ATSDR employees involved in the operation and maintenance of the Registry, and establishing administrative, technical, and physical safeguards to ensure the security of the records.

The Privacy Act established the conditions for disclosure of individually identified data held by federal agencies, such as the information within the TAR database. ATSDR is generally prohibited from disclosing information kept in the TAR except with the prior written consent of registrants. However, the Privacy Act specifies certain parties to whom Registry data can be disclosed without the prior written consent of the registrant. The Privacy Act conditions of disclosure that are most likely to be invoked for the Registry data include:

1. To ATSDR personnel;

2. If required by the Freedom of Information Act (personal identifiers—i.e. name, date of birth, Social Security number, mailing address, phone number, and any data abstracted from a death certificate—removed);
3. To a researcher outside the government who has provided advance written assurance that the information released will be used solely for statistical research or as a reporting record. Personal identifiers will be removed from such datasets. ATSDR will review requests from outside researchers for data (refer to Part A, Section 2). Data will only be released in this manner after the findings of this review indicate privacy protections can be insured and that the use of the data is compatible with the purposes under which it was collected.
4. To a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if upon disclosure to the requestor, notification is transmitted to the last known address of the individual;
5. To Congress or the Comptroller General;
6. Pursuant to the order of a court of competent jurisdiction.

Prior to administering the Registry Questionnaire (both the Baseline and Follow-up), informed consent is obtained (Appendix G). The respondent reads the consent form and signs it if (s)he agrees to participate. The consent to participate in screening is separate from consent to participate in the TAR, and the respondent may opt to take part in screening but not in the TAR. Permission will be asked to request, within a 1-year period of time, the confirmation of the reported medical condition (from the medical care provider named by the registrant) (Appendix H). The limited purpose of the health condition form will be to confirm the date of onset of the reported condition(s) and to obtain a more precise diagnosis of the reported conditions(s) (i.e., mesothelioma and asbestosis). In the event of a CATI interview, the medical permission form will be mailed to the registrant or proxy.

All information conveyed to the registrant must comply with the Privacy Act, 5 USC 522a(e), which requires informing the participant about the Registry's principal purposes, the routine uses which might be made of the information, the authority for establishing a Registry, whether disclosure of information by the registrant is mandatory or voluntary, and the effects on the registrant, if any exist, should he or she not provide all or any part of the information solicited.

The institutional review board of the Centers for Disease Control and Prevention has approved the protocol for this data collection (Appendix F).

A PIA was conducted under the previous ICR for this project (Appendix C).

11. Justification of Sensitive Questions

The registrant's Social Security number (SSN) will be requested. The SSN is desirable to maintain contact with registrants to monitor their health status over time. The SSN is important for locating registrants for the update interviews and for conducting searches of the National Death Index and linking the TAR to the Montana Tumor Registry. It will be a unique identifier of an individual, whereas name and other identifiers can be replicated at a site, changed over time (for example, through marriage or divorce) or used inconsistently (for example, nicknames). The registrant's disclosure of the SSN will be voluntary. The registrant will be informed that the disclosure will not affect any benefits that may be received and the information will not be shared with any other government or non-government agency. The information will be collected under the authority of CERCLA.

Some registrants (those reporting health conditions) might be asked at the time of the baseline interview, (after the interview has been completed) to consent in writing for permission for ATSDR to review medical records (registrants provide the names of health care providers) for specific information only (usually the date of onset and more specific diagnoses of the reported condition; for example, if heart disease is reported, exactly what type of heart disease was experienced).

The registrant might be asked at a later time to give consent in writing to ATSDR giving permission to release their names and other personal identifiers for the purpose of conducting ATSDR Registry-related research. Registrants will be informed that neither of the consents will be necessary to be a part of the TAR and will receive a copy of the consent forms so stating. The medical permission forms are necessary to verify self-reported diagnostic or treatment information given at time of interview.

12. Estimates of Annualized Burden Hour and Costs

The number of annual respondents will vary little from year to year. We anticipate that 500 persons per year could be added during each of the next 3 years in addition to the 4,500 registrants already enrolled. These newly enrolled respondents will be interviewed using the Baseline interview instrument. Optimally, one third of the follow-up interviews will be conducted each year for the next three years using the Follow-up interview instrument. The maximum burden for the baseline survey is 30 minutes and 30 minutes for the follow-up survey.

A.12 -1 ESTIMATES OF ANNUALIZED BURDEN HOURS				
Data Collection Instruments	Number of Respondents	Frequency of Response	Average Time per Response (hour)	Annual Hour Burden
Baseline TAR	500	1	30/60	250
Follow-up TAR	1,500	1	30/60	750
TOTAL				1000

A.12 -2 ANNUALIZED COST TO RESPONDENTS¹				
Form	Number of Respondents	Hourly Wage	Avg. Time Per Response (in hrs.)	Total Respondent Costs
Baseline	500	\$17.83	30/60	\$ 4,458
Follow-up	1,500	\$17.83	30/60	\$ 13,373
TOTAL				\$17,831

¹According to the U.S. Department of Labor, Bureau of Labor Statistics, the average hourly salary (non-supervisory workers—seasonally adjusted) in the United States as of February 2008 was approximately \$17.83.

13. Estimates of Other Total Annualized Cost Burden to Respondents or Record keepers

There will be no respondent capital and maintenance costs for the TAR.

14. Annualized Cost to the Federal Government

The estimated annualized cost over three years of data gathering includes costs for equipment, overhead, printing, and support staff utilizing a private contractor. For detailed calculations of contractor and in-house cost, see Appendix I.

A.14 ANNUALIZED (ESTIMATED) COST TO THE FEDERAL GOVERNMENT			
Year	In-House Cost	Contractor Cost	Total Cost
FY10	\$ 97,219	\$ 15,000	\$ 112,219
FY11	\$ 97,219	\$ 16,000	\$ 113,219
FY12	\$ 97,219	\$ 17,000	\$ 114,219
SUBTOTAL	\$ 291,657	\$ 48,000	\$ 339,657
ANNUALIZED TOTAL			\$ 113,219

15. Explanation for Program Changes or Adjustments

No program changes are being proposed. Due to the nature of this data collection, the annual number of respondents will vary causing some adjustments in the burden from year to year. We anticipate that 500 persons per year could be added during each of the next 3 years in addition to the 4,500 registrants already enrolled. These newly enrolled respondents will be interviewed using the Baseline interview instrument. Optimally, one third of the follow-up interviews will be conducted each year for the next three years using the Follow-up interview instrument.

16. Plans for Tabulation and Publication and Project Time Schedule

- a. Analysis for TAR data continues to be done following completion of data collection.
- b. Timetable for publication and dissemination of the baseline and follow-up reports for the TAR continues to be set upon receipt of funding.
- c. Data collection for new participants will continue to occur each year. Follow-up data collection will occur every third year.
- d. Analysis timetable:

TREMOLITE ASBESTOS REGISTRY TIME SCHEDULE	
ACTIVITY	TIME SCHEDULE
BASELINE and Followup Surveys	
Letters to Registrants	2-3 months after OMB Approval
Data Collection	3-12 months after OMB Approval
Validation	12-15 months after OMB Approval
Analysis	15-24 months after OMB Approval
Publication of Study Results	25-36 months after OMB Approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

No expiration date will be displayed on the questionnaires due to repeated use of the questionnaires over the life of the TAR.

18. Exceptions to Certification for Paperwork Reduction Act

There will be no exceptions to certification for Paperwork Reduction Act.