U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Better Planning, Execution and Communication Could Have Reduced the Delays in Completing a Toxicity Assessment of the Libby, Montana, Superfund Site

Report No. 13-P-0221 **April 17, 2013**

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Abbreviations

ATSDR	Agency for Toxic Substances and Disease Registry
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act (Superfund)
EPA	U.S. Environmental Protection Agency
FAR	Federal Acquisition Regulations
FY	Fiscal Year
IRIS	Integrated Risk Information System
IUR	Inhalation Unit Risk
LAA	Libby Amphibole Asbestos
LAP	Libby Action Plan
LATAG	Libby Area Technical Assistance Group
NCEA	National Center for Environmental Assessment
NHEERL	National Health Effects and Environmental Research Laboratory
NIOSH	National Institute for Occupational Safety and Health
NTP	National Toxicology Program
OARM	Office of Administration and Resources Management
OIG	Office of Inspector General
ORD	Office of Research and Development
OSWER	Office of Solid Waste and Emergency Response
PCM	Phased Contract Microscopy
RfC	Reference Concentration
SAB	Science Advisory Board
SOW	Statement of Work
USGS	U.S. Geological Survey

Cover photo: Exterior removal of contaminated soil from a residential area in Libby, Montana. (EPA photo)

U.S. Environmental Protection Agency
Office of Inspector General

13-P-0221
April 17, 2013

At a Glance

Why We Did This Review

We performed fieldwork to determine why the EPA did not meet planned corrective-action milestones for completing a comprehensive toxicity assessment of asbestos necessary to determine the cleanup level for the Libby, Montana, Superfund site. We also determined whether EPA informed appropriate officials about the delays in a timely manner. In 1999, EPA began investigating local concerns about asbestos contamination in Libby. EPA designated the Libby site a national priority in the Superfund program in 2002; and in December 2006, the EPA OIG recommended that the EPA perform a comprehensive toxicity assessment of amphibole asbestos to determine the safe level for human exposure. EPA submitted its Libby Action Plan in 2007 to address the OIG recommendations. In June 2009, the EPA Administrator declared a public-health emergency in Libby due to the number of deaths and illnesses reported in the town.

This report addresses the following EPA Goal or Cross-Cutting Strategy:

- *Cleaning up communities and advancing sustainable development.*

For further information, contact our Office of Congressional and Public Affairs at (202) 566-2391.

The full report is at:
www.epa.gov/oig/reports/2013/20130417-13-P-0221.pdf

Better Planning, Execution and Communication Could Have Reduced the Delays in Completing a Toxicity Assessment of the Libby, Montana, Superfund Site

What We Found

U.S. Environmental Protection Agency (EPA) action officials did not complete planned corrective actions under its Libby Action Plan in a timely manner. This occurred because the scope of the work was larger than originally thought; there was no established charter; and there were contracting delays, competing priorities, unanticipated work, and poor communication with stakeholders. Consequently, the Agency has twice revised its estimates for completing actions in response to our December 2006 report.

The toxicity assessment is one of two components (an exposure assessment being the other) that makes up the health risk assessment for determining cleanup levels in Libby. In December 2011, EPA informed us that the health risk assessment would be substantially delayed. As a result, the Agency's final determinations that the completed and ongoing cleanup actions are sufficient to address the health risks from site contamination have been delayed from 2 to 6 years, depending on the studies being performed. This is a significant concern, considering that the EPA Administrator declared a public-health emergency at the Libby site in 2009 and the Agency has spent over $400 million on cleanup. Communications about delays in completing Libby Action Plan items, and the reasons for those delays, were not always timely or clearly communicated to stakeholders; and EPA officials failed to update the Agency's follow-up system or notify the Office of Inspector General (OIG) about known delays until planned corrective actions under the Libby Action Plan could not be met.

Recommendations

We recommend that EPA: (1) require action officials to disclose risks to completing corrective-action plans, and update and distribute original and revised plans to stakeholders; (2) establish a charter to define project roles and responsibilities for completing remaining corrective actions under the Libby Action Plan, and determine whether the Science Advisory Board (SAB) or another organization will review the completed risk assessment; (3) direct the SAB to determine whether EPA has followed guidance sufficiently to support the findings in the toxicity assessment, and whether other possible limitations exist when applying cancer and noncancer values to determine acceptable levels of exposure to asbestos in Libby; (4) ensure that future contracts issued through interagency agreements are within the scope of those agreements; and (5) develop a priority list for pending and ongoing research work.

The Agency agreed with part of one recommendation and disagreed with other recommendations. The recommendations are unresolved, pending estimated completion dates or an action plan for the agreed-to recommendation, and dispute-resolution actions for recommendations with no agreement.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE INSPECTOR GENERAL

April 17, 2013

MEMORANDUM

SUBJECT: Better Planning, Execution and Communication Could Have Reduced the Delays in Completing a Toxicity Assessment of the Libby, Montana, Superfund Site
Report No. 13-P-0221

FROM: Arthur A. Elkins Jr.

TO: *See Below*

This is our report on the subject evaluation conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and does not necessarily represent the EPA position. This report contains part of a recommendation that the Agency agreed with, but the Agency did not provide estimated completion dates or an action plan. Therefore, this recommendation is unresolved. The report also contains recommendations where the Agency and OIG disagreed. These recommendations are also considered unresolved.

Action Required

In accordance with EPA Manual 2750, resolution should begin immediately upon issuance of the report. We are requesting a meeting of action officials from the Office of Solid Waste and Emergency Response, the Office of Research and Development, EPA Region 8, and the Assistant Inspector General for the Office of Program Evaluation, to start the resolution process and attempt to obtain resolution. If resolution is still not reached within 30 days, these action officials are required to complete and submit a dispute-resolution request to the Chief Financial Officer to continue the resolution process.

Please email your response to Carolyn Copper at copper.carolyn@epa.gov. The final response should not contain data that you do not want to be released to the public. If your response contains such data, you should identify the data for redaction or removal. We have no objections

to the further release of this report to the public. We will post this report to our website at http://www.epa.gov/oig.

Should you have any questions, please contact Carolyn Copper, Assistant Inspector General for Program Evaluation, at (202) 566-0829 or copper.carolyn@epa.gov; or Eric Lewis, Director, Special Reviews, at (202) 566-2664 or lewis.eric@epa.gov.

Addressees:
Bob Perciasepe, Deputy Administrator
Mathy Stanislaus, Assistant Administrator, Office of Solid Waste and Emergency Response
Lek Kadeli, Acting Assistant Administrator, Office of Research and Development
Howard Cantor, Acting Regional Administrator, Region 8

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Chapter 1
Introduction

Purpose

The U.S. Environmental Protection Agency (EPA), Office of Inspector General (OIG), conducted this review as a follow-up to EPA OIG Report No. 2007-P-00002, *EPA Needs to Plan and Complete a Toxicity Assessment for the Libby Asbestos Cleanup*, December 5, 2006. Our objectives were to:

- Conclude why the Agency did not meet planned corrective-action milestones in response to the recommendations in the OIG's December 2006 report.

- Determine whether appropriate Agency officials were properly informed of the breaches in these milestones for the purpose of updating stakeholders (e.g., Congress; OIG; residents of Libby, Montana) in a timely manner.

Background

The town of Libby is located in the northwest corner of Montana. EPA has been working in Libby since 1999, when the Agency sent an emergency-response team to investigate local concerns and news articles about asbestos-contaminated vermiculite. In January 2000, due to citizen concerns, EPA started sampling and analyzing lawn and garden products from Libby, which contained vermiculite. In 2002, EPA began an emergency-response cleanup of Libby residential and commercial properties, and that same year the Libby site was added to the National Priorities List of Superfund sites. In June 2009, the EPA Administrator declared a public-health emergency at the Libby site due to the number of deaths and illnesses reported in the town.

The OIG's 2006 Report

We conducted our 2006 review in response to inquiries received from the two U.S. senators from Montana, who requested information regarding cleanup activities of asbestos material in Libby, Montana. Our December 2006 report identified two significant issues critical to a successful cleanup in Libby. First, EPA had not completed a toxicity assessment of amphibole asbestos to determine the safe level for human exposure. Therefore, EPA could not be sure that the Libby cleanup sufficiently reduced the risk that humans may become ill or, if ill already, get worse. Second, EPA's public-information documents *Living with Vermiculite* and *Asbestos in Your Home* were inconsistent about safety concerns.

The OIG report included two recommendations to the Assistant Administrator for the Office of Solid Waste and Emergency Response (OSWER) and the Regional Administrator for EPA Region 8:

1. Fund and execute a comprehensive amphibole asbestos toxicity assessment to determine (1) the effectiveness of the Libby removal actions, and (2) whether more actions are necessary. The toxicity assessment should include the effects of asbestos exposure on children. The EPA Science Advisory Board (SAB) should review the toxicity assessment and report to the Office of the Administrator and the Libby Community Advisory Group whether the proposed toxicity assessment can sufficiently protect human health.

2. Review and correct any statements that cannot be supported in any documentation mailed or made available to Libby residents regarding the safety of living with or handling asbestos, until EPA confirms those facts through a toxicity assessment.

Agency Response to the OIG's 2006 Report

By removing inconsistent documentation or communications provided to Libby residents, the Agency satisfied recommendation 2 prior to issuance of the December 2006 report.

To satisfy OIG recommendation 1, a meeting was held in January 2007 with EPA and other federal scientists from the Agency for Toxic Substances and Disease Registry (ATSDR) and the National Toxicology Program (NTP), to identify data gaps that needed to be addressed to complete a toxicity assessment of the mixture of fibrous amphibole minerals found in Libby (Libby amphibole). The group developed a list of 12 studies needed to complete this assessment. These studies are collectively referred to as the Libby Action Plan.

In April 2007, OSWER and EPA Region 8 provided the OIG with their specific corrective actions under the Libby Action Plan. They committed to completing the EPA Office of Research and Development's (ORD's) National Health Effects and Environmental Research Laboratory (NHEERL) animal toxicity studies by September 30, 2009; and to completing a baseline risk assessment, including a comprehensive toxicity assessment, by September 30, 2010.

To carry out the list of 12 studies developed during the meeting held in January 2007, a steering committee[1] was established to develop a draft action plan. The toxicity assessment, coupled with an exposure assessment, would comprise the baseline risk assessment needed to support the Record of Decision for the Libby site. Our review did not address the Agency's efforts related to

[1] Members of this steering committee included representatives from NHEERL, the National Center for Environmental Assessment (NCEA), OSWER, and EPA Region 8.

completing the exposure assessment, because this assessment did not fall under the scope of our review.

Libby Action Plan Studies, Responsibilities, and Milestones

Appendix A lists 12 studies that constitute the Libby Action Plan, the responsible parties for conducting these studies, and the estimated milestone dates for their completion. This appendix lists these studies in the order to be performed and their relative priority for completing the Libby toxicity assessment. This order was established by EPA and other federal scientists in January 2007.

Responsibility for carrying out the studies under the Libby Action Plan were given to EPA's OSWER, ORD, and Region 8, with assistance to be provided by the U.S. Geological Survey (USGS), the National Institute for Occupational Safety and Health (NIOSH), and ATSDR. The Agency's April 2007 Libby Action Plan called for all planned studies to be completed by the fourth quarter of fiscal year (FY) 2009.

OSWER

OSWER's responsibilities involved developing the methodology for estimating the risk of lung cancer and mesothelioma from inhalation exposure to different forms of asbestos. OSWER was also responsible for oversight of the Libby Action Plan and reporting progress made to internal and external stakeholders, including:

- Senior Agency officials (EPA Administrator, Assistant Administrators for OSWER and ORD, and Region 8 Regional Administrator)
- OIG
- Congressional staff of Montana's U.S. senators
- Libby residents

ORD

ORD/NCEA was responsible for conducting a cancer assessment specifically for Libby amphibole for the Integrated Risk Information System (IRIS). Responsibilities of the ORD/NHEERL included developing a dosimetry model and simulation studies, conducting in vitro dissolution assays, evaluating in vitro toxicity endpoints, conducting comparative toxicology in mice and rats, and conducting inhalation toxicology studies in rats.

Region 8

EPA Region 8, with assistance from ORD/NCEA, was responsible for developing the site-specific reference concentration (RfC) for the Libby amphibole asbestos. The RfC applies to noncancer health effects and is the

concentration of a substance that is likely to be without an appreciable risk of adverse health effects over a lifetime. Region 8 was also one of the organizations—along with ORD/NCEA, NIOSH, and ATSDR—responsible for developing epidemiological information from cohorts exposed to Libby amphibole. The cohort used to develop the RfC was the Marysville, Ohio, cohort. Workers in that cohort were exposed to the Libby amphibole. The region was also responsible for verifying fiber-size distribution of Libby amphibole and assisting ORD/NCEA, NIOSH, and ATSDR with developing epidemiologic information from other cohorts exposed to Libby amphibole.

Scope and Methodology

We conducted our review from December 2010 through July 2012. Our review was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the review to provide a reasonable basis for its findings and conclusions. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our review objectives. To complete our work we:

- Interviewed appropriate EPA personnel from OSWER, ORD/NCEA, the Office of Administration and Resources Management (OARM), and Region 8, who were involved with oversight and coordination of the Agency's efforts under its Libby Action Plan.

- Held briefings with senior managers from OSWER, ORD, SAB, and EPA Region 8.

- Interviewed U.S. Department of Transportation/Volpe Center[2] personnel involved with the contract award to the University of Cincinnati for Libby noncancer studies.

- Evaluated work performed by other government agencies assisting EPA with the completion of tasks under its Libby Action Plan. These agencies included the USGS, ATSDR, and the Volpe Center.

- Obtained and reviewed the following documents to determine the Agency's timeliness in meeting Libby Action Plan project milestones:

    - Examples of monthly progress reports prepared by EPA and submitted to the congressional staff of U.S. senators from Montana.

[2] The center is part of the U.S. Department of Transportation's Research and Innovative Technology Administration and is an innovative, federal, fee-for-service organization. Its mission is to improve the nation's transportation system. The center performs work for the U.S. Department of Transportation, as well as for other federal, state, local, and international agencies and entities.

- Annual progress reports on accomplishments under the Libby Action Plan to determine whether the Agency was adequately managing activities in order to meet established milestones.

- Peer-reviewer comments rendered about studies under the Agency's Libby Action Plan to determine whether any concerns were noted regarding the Agency's ability to complete study milestones in a timely manner.

- Funding and budget information for implementing the 2007 Libby Action Plan to determine whether there were any funding issues that may have impeded progress under the plan.

- Contract award documents issued via interagency agreement for studies related to the Marysville, Ohio, cohort and maintained by OARM.

Chapter 2
Improved Management Controls Needed to Ensure Completion of Corrective Actions Under the Libby Action Plan

EPA action officials did not complete planned corrective actions under its Libby Action Plan in a timely manner. This occurred because:

- EPA did not develop a charter that would have established a single authority responsible for completing the milestones.
- EPA took almost 2 years to issue a sole-source contract to support the noncancer study.
- EPA had other priorities that delayed completion of the cancer study.
- EPA encountered unforeseen problems preparing dosing material for animal studies; delays in government contracting; and revisions to experimental designs, which have prevented the completion of the remaining studies until 2015.

Agency action officials are ultimately responsible for establishing reasonable timeframes for completing corrective actions, and for ensuring that corrective actions are implemented. However, action officials in OSWER and Region 8 did not ensure that corrective actions under their Libby Action Plan were monitored and completed in accordance with initially planned milestones. As a result, the Agency's efforts to complete Libby Action Plan studies in support of a comprehensive amphibole asbestos toxicity assessment have been delayed 2 years for key cancer and noncancer studies, and 6 years for all other studies. This is a significant concern considering that the EPA Administrator declared a public-health emergency at the Libby site in 2009, and the Agency has spent over $400 million of the funds obtained from the responsible party.

In addition, outside of OSWER, ORD and Region 8, no one was informed of the reasons for the delays. EPA officials failed to update the Agency's follow-up system or notify the Office of Inspector General (OIG) about known delays until planned corrective actions under the Libby Action Plan could not be met.

Original Project Milestones Were Overly Ambitious

EPA's Libby Action Plan called for all studies to be completed by the fourth quarter of FY 2009. This included all individual project plans, peer reviews, contract awards, and the completion of all tasks involving cancer and noncancer assessments and animal studies. We found that the milestones established for accomplishing these studies were ambitious, and there was a high risk of the milestones not being completed on time. Consequently, since establishing corrective actions under its April 2007 follow-up response, EPA has twice revised these milestones.

Overly Ambitious Timetable

The original Libby Action Plan had an overly ambitious timetable and required coordination and oversight to meet that timetable. In addition, there was intense stakeholder interest. From the beginning, it appears that there was not sufficient time built into the timetable to complete the individual tasks that comprised the plan. OSWER and Region 8 managers told us that the Agency had significantly underestimated the magnitude of effort that would be needed to achieve the agreed-to corrective action. The Region 8 Libby on-scene coordinator, who attended the Agency's planning meeting held in January 2007, stated that the Libby Action Plan was "doomed to fail from the start," with respect to meeting the original project milestones because:

- EPA was trying to be responsive to external pressure when the Libby Action Plan was first put together; and
- EPA officials from OSWER and Region 8 had made promises to Montana politicians and to the residents of Libby to come up with a baseline risk assessment. This promise included a comprehensive toxicity assessment to support a Record of Decision for ongoing cleanup activities at the Libby Superfund site. EPA staff involved with developing the Libby Action Plan tried to deliver on those promises.

OSWER managers stated that:

- OSWER had never executed such a complex research project.
- The initial milestone dates had to be extended due to the depth and breadth of the studies that had to be performed.
- Preparation of the Libby amphibole test material was essentially a research project in itself, and was needed to provide a consistent dosing to animals in terms of both the quantity of Libby amphibole and the character of fibers provided.

Concerns over projected milestone dates were also noted during the initial peer review of planned animal toxicity studies to be performed under the Libby Action Plan. Proposed methods for conducting these animal toxicity studies were peer

reviewed externally in May 2007 by experts from academia, ATSDR, the National Institute of Environmental Health Sciences, and the Libby Area Technical Assistance Group (LATAG).[3] Peer reviewers stated that some animal studies were overly ambitious and perhaps unattainable within the proposed time frames.

Milestone Revisions

EPA revised its estimated milestones on two separate occasions after providing the OIG its first plan in April 2007. In its April 2007 response, EPA estimated:

- The completion of a baseline risk assessment, including a comprehensive toxicity assessment by September 30, 2010.
- The completion of NHEERL animal toxicity studies by September 30, 2009.

However, in October 2009, OSWER informed the OIG that the estimated date for completing the comprehensive toxicity assessment was revised from September 30, 2010, to September 30, 2012; and from September 30, 2009, to September 2015 for the NHEERL animal toxicity studies. At the time, OSWER cited the following reasons for the delays:

- Substantial analytical and statistical complexities associated with exposure limits characterization using new activity-based sampling techniques.
- Contracting delays for additional epidemiological work related to the Marysville, Ohio, cohort that supports the development of the RfC for Libby amphibole.
- Unforeseen problems in preparing the dosing material for animal studies.
- Delays in government contracting.
- Revisions to experimental designs.

EPA provided its second estimates in December 2011 when the Assistant Administrator for OSWER informed the OIG that the milestone date for the completion of the health risk assessment would likely be delayed beyond the September 30, 2012, date. The Assistant Administrator stated that the health risk assessment relies upon two components: (1) a toxicological assessment of Libby amphibole asbestos led by ORD and EPA Region 8, and (2) a site-specific exposure assessment by EPA Region 8. According to the Assistant Administrator, neither component was complete and both would entail significant effort in 2012. The Assistant Administrator stated the schedules for completion remain highly uncertain for both components.

[3] The focus of the LATAG is to make certain that the cleanup of Libby amphibole contamination is comprehensive, complete, and timely, resulting in the elimination of the Libby amphibole threat to human health and environment.

No Charter Established

The accomplishment of the Agency's Libby Action Plan required a collaborative effort. The Agency chose to use a group comprised of the Assistant Administrators for OSWER and ORD, and the Regional Administrator for EPA Region 8 to manage the project. EPA considered developing a charter but decided against it. The project charter could have addressed the purpose, measurable objectives, a high-level description of what is to be done, risks, summary milestones, initial budgets, approvals required, and project manager authority and responsibility.

OSWER, ORD, and Region 8 oversaw initial efforts under the Libby Action Plan, discussed cross-coordination efforts within EPA, and approved funding. However, each member was only responsible for the Libby Action Plan studies assigned to them (see appendix A). No office had authority over the level of staff participation from other EPA program offices. This management approach did not have a single figure who had the authority to ensure project milestones were being met, or who had the ability to delineate responsibilities, oversee funding, and ensure proper channels of communications.

Contracting Issues Delayed Noncancer Assessment

The *RfC Development* study was ranked number one by the Agency for its importance in completing the Libby toxicity assessment. EPA Region 8, with assistance from ORD/NCEA, was responsible for carrying out the *RfC Development* study. This study would develop a site-specific noncancer toxicity value for Libby amphibole from the Marysville, Ohio, cohort. According to the Agency's Libby Action Plan, all contracts were to be drafted by the third quarter of FY 2007, or no later than June 2007. However, the sole-source contract for the *RfC Development* study was not awarded until May 2009. Consequently, it took almost 2 years from the time the sole-source contract should have been drafted and when it was actually awarded.

Contract Award

The University of Cincinnati completed studies on the effects of Libby asbestos on the Marysville, Ohio, workers in 1984. Because the university owned this data, EPA Region 8 wanted to contract with the university to update, compile, and provide the Marysville, Ohio, cohort data in a format that could be used for developing the RfC in support of the Libby toxicity assessment.

Instead of using the Agency's contracting resources, Region 8 used an existing interagency agreement with the U.S. Department of Transportation Volpe Center to award the sole-source contract to the University of Cincinnati. However, we believe that Region 8's use of the Libby cleanup interagency agreement to award a contract to the University of Cincinnati exceeded the scope of work under the

agreement between Region 8 and the Volpe Center. Region 8's interagency agreement with the Volpe Center is site specific and the scope of work describes authority for work to be done at Libby, Montana, and not at the University of Cincinnati. The Region 8 Libby on-scene coordinator who made this decision stated that the Volpe Center had assisted Region 8 with cleanup efforts at the Libby asbestos site since 1999; and, at the time, he considered them better, faster, and more innovative at contracting than EPA.

In a May 2009, Libby Action Plan meeting, EPA cited getting the sole-source contract in place with the University of Cincinnati as a reason for the delay under the *RfC Development* study. Managers with OSWER's Office of Superfund Remediation and Technology Innovation also attributed the delay to the time it took the Volpe Center to award the sole-source contract.

However, Volpe Center personnel stated that EPA did not readily know what the Agency wanted in the contract with the University of Cincinnati. According to Volpe Center personnel, the contract was originally estimated at $2.1 million and included seven tasks. However, EPA could not decide whether all seven tasks would be done by the university. When the contract was awarded, Region 8 decided that only two tasks would be completed at a cost of $410,000. Volpe Center personnel described the following timeline for awarding the contract to the University of Cincinnati:

- Initial technical discussions began between EPA Region 8 and Volpe Center technical staff in November 2007.
- EPA provided a draft statement of work (SOW) to Volpe Center technical staff around the December 2007/January 2008 timeframe.
- Between January 2008 and April 2008, Volpe Center technical staff and EPA worked cooperatively on refining the SOW, and in April 2008 the SOW was finalized.
- The Volpe Center's Acquisition Division received the purchase request package, including the finalized SOW, in April 2008.
- Once in the Acquisition Division, Acquisition staff, along with advice from the legal advisor, worked on the justification required to support a sole-source procurement.
- The justification for a sole-source procurement was approved on July 22, 2008. The solicitation was drafted, finalized, and issued on October 29, 2008.
- The contract was awarded to the University of Cincinnati on May 4, 2009.

We asked Volpe Center personnel how they kept the Agency informed about the progress for awarding the contract, and whether there were any problems with meeting deliverables. We were told that there were monthly meetings with the University of Cincinnati, technical staff of the Volpe Center, and EPA Region 8. Volpe Center personnel stated the milestones for deliverables were agreed to by EPA Region 8 and the University of Cincinnati at the kick-off in May 2009.

Volpe Center personnel could only recall one deliverable that needed to be adjusted due to the volume of data encountered. In this instance, Volpe indicated that EPA was informed and agreed to extend the deliverable schedule. Volpe Center personnel said the final deliverable for tasks 1 and 2 were delivered to the Agency in August 2010. These deliverables were used by EPA to develop an exposure-response relationship RfC report for peer review.

Although the Region 8 on-scene coordinator claimed that the use of the Volpe Center services through the interagency agreement would provide better, faster, and more innovative contracting, this did not occur. Rather, the process took more time than planned, and the EPA and the Volpe Center blamed each other for the delays.

Risk and Toxicity Assessment Guidance and Reviews

The Agency's April 2007 response stated that it would complete a baseline risk assessment, including a comprehensive toxicity assessment, in response to recommendation 1 in our December 2006 report. This recommendation also required EPA's SAB to review the Libby toxicity assessment. Since the final site-specific assessments have not been developed, EPA will, at a minimum, develop the risk assessment based on guidance listed in appendix B. EPA developed the draft *IRIS Toxicological Review of Libby Amphibole Asbestos* in support of a toxicity assessment based on the 14 guidance documents found in appendix C.

We requested that the former SAB director, who put together a panel to review EPA's work, provide the SAB's perspective on the quality of the toxicity assessment. The former director stated that:

- The SAB has not been charged to review the risk assessment when it is completed.
- The SAB has received charge questions from EPA to guide the focus of the review of the draft *IRIS Toxicological Review of Libby Amphibole Asbestos.* However, the SAB director stated that the SAB review will go beyond the charge questions as they deem appropriate.
- The SAB looks for the best experts with no conflicts of interests to provide different scientific perspectives on a particular review. Additionally, all reviewers of the draft *IRIS Toxicological Review of Libby Amphibole Asbestos* document are from outside of EPA.
- The SAB panel supports the selection of the Marysville, Ohio, cohort for the noncancer assessment, although uncertainties exist with the small size of the cohort to accurately represent the general population. However, with regard to the Marysville cohort, the SAB has asked EPA to conduct additional analyses, which include chest X-ray abnormalities other than localized pleural thickening. In addition, the SAB has asked EPA to do

analyses on more recent published cohorts (e.g., Minneapolis). This would provide more scientific support for the calculated RfC.

- The RfC risk is stated in terms of phased contract microscopy (PCM).[4]
- For years the SAB has asked the Agency to be more transparent in describing the rationale for choosing or excluding studies (i.e., selection criteria) and the choice of statistical models that support the dose-response assessment for cancer and noncancer health endpoints.
- External reviewers should have all available information at their disposal at the beginning of the review; this is necessary to verify the results of the EPA analysis. However, EPA only provides the information upon request.

The Libby Action Plan states that the baseline risk assessment would include the toxicity assessment. However, while the toxicity assessment will be reviewed by the SAB, the overall risk assessment will not. EPA should determine whether the SAB or another organization should review the risk assessment. That review should be an assessment of the risk involved with not completing all the required studies of the Libby Action Plan. EPA and the SAB should resolve issues relating to developing specific guidance on study selection and dose-response model selection to improve the toxicity assessment process. We also agree with the SAB that external reviewers should receive all available documentation at the start of their review. This will avoid delays and make the Agency's work transparent.

Competing Priorities and Unanticipated Work Delayed Cancer Assessment

The *Libby Amphibole Cancer Assessment* study[5] was conducted by EPA's ORD/NCEA. According to milestones stated in the Libby Action Plan, this study was supposed to be completed by the fourth quarter of FY 2009. Completion of this study was ranked second in terms of importance by the Agency for completing the Libby toxicity assessment. Although this study is now complete, it was delayed due to ORD/NCEA competing priorities and to unanticipated work that ORD/NCEA personnel realized was needed.

Competing Priorities

ORD/NCEA senior managers stated that:

- Determining a cancer value for Libby asbestos was not their only ongoing work priority at the time. ORD usually listed Libby asbestos, perchloroethylene, and formaldehyde as the top three priority assessments.

[4] The current IRIS value for asbestos states that unit risk is based on fiber counts made by PCM and should not be applied directly to measurements made by other analytical techniques. Many environmental monitoring measurements are reported in terms of fiber counts or mass as determined by transmission electron microscopy. The correlation between PCM fiber counts and transmission electron microscopy mass measurements is very poor.
[5] Appendix A, study 2.

- Depending on events, sometimes ORD had to put emphasis on one chemical assessment over another; making a choice was difficult because they were all high priorities with significant public health consequences.
- In 2008, the former ORD/NCEA director decided that it was important to complete the formaldehyde assessment in a timely fashion. Consequently, in the fall of 2009, ORD/NCEA decided to focus on getting the formaldehyde assessment completed and into the review/revision steps, even if that meant some delay in the Libby cancer assessment.

Unanticipated Work and Other Priorities

NCEA personnel stated that assessment projects are scientifically complex and milestone timelines are unpredictable, especially with regard to the time needed to complete the base scientific work and to develop a draft to put into the first formal review steps. Most of these large, complex projects and related peer-review procedures take longer than originally forecast. For example:

- Primary research took longer than anticipated because NCEA did not have adequate published data. NCEA had to perform its own research on the data provided by NIOSH.
- To obtain the data, NIOSH and EPA entered into an interagency agreement. However, the interagency agreement was delayed 6 months until EPA and NIOSH attorneys agreed on privacy issues related to individuals in the data.
- NCEA researchers also obtained updated National Death Index[6] data, which was unplanned. This data also had privacy issues and added 6 to 8 months to the schedule.

No analysis was performed to determine whether the formaldehyde and Libby assessments had equivalent concerns. For Libby, EPA reported deaths, illness, an expensive clean-up, and continued asbestos exposure. EPA did not have similar data on formaldehyde; therefore, we could not determine how EPA set it priorities for determining which chemical assessment took precedence over the other. Additionally, given the relative priority of the *Libby Amphibole Cancer Assessment* study for completing the Libby toxicity assessment, the delays should have been explicitly shared with stakeholders through the monthly status reports.

Communication of Plan Execution Could Be Improved

We found that communications regarding delays in completing the Libby Action Plan items, and the reasons for those delays, were not always timely or clearly communicated. After it was clear that delays were inevitable, EPA officials responsible for completing the actions failed to explicitly update internal and

[6] The National Death Index is provided by the Centers for Disease Control and Prevention and is a central computerized index of death-record information on file in states' vital statistics offices.

external stakeholders until the due dates had passed. Further, EPA officials responsible for the actions failed to update the Agency's follow-up system or notify the OIG about known delays until it was clear that planned corrective actions under the Libby Action Plan could not be met.

Incomplete and Untimely Communication Within EPA

We reviewed documents, such as Gantt charts, which OSWER and Region 8 used to brief senior Agency officials, including the EPA Administrator, about progress on the Libby Action Plan. The Gantt charts had completion dates later than the dates the Agency committed to in its April 2007 response to OIG. After mid-January 2008, the Gantt charts no longer showed the dates the Agency committed to for responding to OIG recommendations. Also, a May 2009 OSWER document used to brief the EPA Administrator did not address the original planned milestones under the Libby Action Plan. These documents did not discuss the delays or reasons why the delays occurred.

Also, OSWER staff responsible for tracking OSWER action on OIG recommendations (audit follow-up personnel) had requested periodic updates from appropriate officials, but it was not until September 2009 that audit follow-up personnel learned of the delays. Moreover, the OIG was not formally notified that the Agency had missed the planned milestone dates under the Agency's Libby Action Plan until October 2009 (the first quarter of FY 2010), even though the 12 tasks in the Libby Action Plan were to be completed by the fourth quarter of FY 2009 (see appendix A).

Incomplete and Untimely Communication to Members of Congress and Their Staff

During an April 5, 2007, congressional hearing on the Libby site, a U.S. senator from Montana asked the OSWER Assistant Administrator to provide monthly status reports on toxicity studies being conducted in response to the recommendation in our December 2006 report. The OSWER Assistant Administrator agreed and in June 2007, OSWER began submitting monthly progress reports to the senator's office. Each progress report included a short statement describing activity for Libby Action Plan studies.

Our review of the progress reports issued from June 2007 through June 2011 show no explicit description of the Agency's change in planned milestones for the completion of the toxicity studies or the reason for the changes. For example, the OSWER monthly updates to the senator's office for the noncancer study remained unchanged from December 2007 through September 2009. This information was incomplete, considering the Agency did not award the contract for the study to the University of Cincinnati until May of 2009.

Managers with OSWER's Office of Superfund Remediation and Technology Innovation acknowledged that their monthly progress reports to the senator did

not explicitly mention delays to original corrective-action milestones. These managers also provided briefing materials for the EPA Administrator to use to brief the senator in March 2010. The briefing materials still included a timeline indicating anticipated completion of the analytical studies supporting the completion of the comprehensive toxicity assessment in 2010. Region 8 personnel informed us that they agreed with the information OSWER provided to the senator and his staff. However, the previous Region 8 administrator provided the OIG with a schedule of undocumented meetings and discussions with the senator during April and May 2010. While this document did show dates where Libby issues were addressed, we could not determine that these discussions explicitly addressed cause for delays.

To clarify, in June 2012, we spoke with three staffers for the two senators from Montana, who either (1) participated in meetings with the Agency involving discussions with Libby; or (2) reviewed monthly progress reports from the Agency on the status of Libby cleanup activities. The purpose of our inquiry was to determine whether EPA informed the Montana senators or their staff about the delay in meeting corrective-action milestones for completing a toxicity assessment for Libby amphibole. The scope of our inquiry went from June 2007, when OSWER began submitting monthly progress reports about activities for the Libby Action Plan to the senators' offices, through June 2012. We were told the following by the senators' staff:

- Two staffers did not recall any discussions that explicitly pertained to milestone delays or reasons for delays in completing the Libby toxicity assessment. A third staffer vaguely remembered being told about milestone delays in completing the toxicity assessment during informal discussions regarding the overall cleanup effort at Libby.
- None of the three staffers recalled ever being told the reasons for the milestone delays in completing the Libby toxicity assessment.
- All three staffers stated that discussions with the Agency mainly involved what was happening with the overall cleanup effort at the Libby Superfund site.

Other Issues

Current Status of Peer Reviews

The external review of the Agency's draft *IRIS Toxicological Review of Libby Amphibole Asbestos*, on the results of the *Libby Amphibole Cancer Assessment* study and the *Libby Amphibole RfC Development* study, were posted for public comment on August 25, 2011. A public listening session was held October 6, 2011. The public comment period closed October 24, 2011. On February 23, 2012, an independent peer-review panel under the EPA SAB convened to review the Agency's draft *IRIS Toxicological Review of Libby Amphibole Asbestos*. This effort was necessary for the Agency to complete the toxicity assessment.

We spoke with the former SAB director regarding the status of the SAB's peer-review efforts. The director told us that in response to ORD's request, the SAB staff office established an expert panel to conduct an independent peer review of the Agency's draft *IRIS Toxicological Review of Libby Amphibole Asbestos*. The review panel held a public meeting February 6–8, 2012, to discuss its review comments in response to EPA's charge questions. The former director also told us that on May 1 and May 8, the panel held two public teleconferences to discuss the SAB's first draft report. In early December 2012, the former director said the SAB panel held a public teleconference on July 25, 2012, to discuss its revised draft report. The panel's report was considered by the chartered SAB (Board) on September 25, 2012, via a public teleconference. The Board tentatively approved the report, provided that revisions are made based on the Board's comments. The SAB's final report was presented to EPA on January 30, 2013.

Milestones for NHEERL and Epidemiology Studies Had to Be Revised

The Agency's Libby Action Plan also included NHEERL and NCEA/Region 8 epidemiology studies[7] contributing to the development of the final Record of Decision and the 5-year review requirements for the Libby Superfund site. We noted that these studies have been delayed as well. For instance, the NHEERL *In Vitro Dissolution Assays* studies were set back due to the delay in the preparation of testing samples. We also noted that a project scope change caused by the addition of the NHEERL fiber separation studies also contributed to the delay in the initial completion date for these studies.

Contracting delays also prevented EPA from completing the NCEA/Region 8 *Dosimetry Model Development and Simulation Studies* and the *Inhalation Toxicology in Rats* studies based on planned milestones. The *Dosimetry Model Development and Simulation Studies* contract was awarded 3 years late, and the *Inhalation Toxicology in Rats* contract was awarded 15 months late.

Based on revised estimates by OSWER, the NHEERL animal toxicity studies will be 6 years late from the original baseline date. In its correspondence dated October 2009, OSWER informed the OIG that the estimated date for completing the NHEERL animal toxicity studies is now September 2015. OSWER's initial estimate for completing the NHEERL animal toxicity studies was September 2009. The Region 8/NCEA epidemiology studies are ongoing, and several studies have been published already. These studies will continue for many years to come, and will help to improve knowledge about the health effects of asbestos exposure. However, OSWER's *Interim Risk Methodology for Quantification of Cancer Risk from Inhalation Exposure to Asbestos* study[8] was dropped due to an unfavorable peer review. The SAB identified significant concerns with this model so EPA decided not to pursue it further.

[7] Appendix A, studies 3, 5, 6, 7, 8, 9, 10, and 11.
[8] Appendix A, study 12.

Conclusion

EPA has taken steps to plan and implement a toxicity assessment for Libby asbestos as we recommended in our 2006 report. We believe EPA could have made better progress to complete its work through improved communication, planning and execution of actions. EPA should have been clear and provided complete information on the challenges it was experiencing in meeting milestones. This could have allowed the Administrator, other senior EPA officials, or congressional staff to provide needed focus, assistance, or priority-setting direction. EPA should have issued a charter designating a project manager to expedite the completion of the toxicity assessment, to manage communication of action plan status within and outside EPA, and to keep contracting matters on track.

EPA's lack of transparency and timely, full disclosure regarding its delays and challenges in addressing the Libby Action Plan could reduce public confidence in EPA's work and decision. As a result, residents affected by the Libby site contamination may think that EPA did not act as urgently as possible to address the significant human health and environmental risks present at the Libby site.

Recommendations

We recommend that the:

1. Assistant Administrator for Solid Waste and Emergency Response, and Region 8 Regional Administrator, require action officials to:

    a. Disclose significant risks to completing the Libby Action Plan.
    b. Update the Libby Action Plan to reflect changes in milestone dates.
    c. Distribute original and revised plans to stakeholders.

2. Assistant Administrator for Solid Waste and Emergency Response, Assistant Administrator for Research and Development, and Region 8 Regional Administrator:

    a. Establish a charter to define project roles and responsibilities for completing the remaining corrective actions under the Libby Action Plan.
    b. Determine whether the SAB or another organization will review the completed risk assessment.

3. Deputy Administrator direct the SAB to determine and report on whether:

    a. EPA has followed guidance sufficient to support the findings in the Libby toxicity assessment.
    b. Limitations exist in applying the cancer and noncancer values to the determination of acceptable levels of exposure to asbestos in Libby.

4. Region 8 Regional Administrator ensure that future contracts issued through interagency agreements are within the scope of those agreements.

5. Assistant Administrator for Research and Development require the development of a priority ranking list among the ongoing IRIS assessments, and that the Assistant Administrator be informed of any recommended changes in those priorities. The rankings should consider human health consequences.

Agency Response to Draft Report and OIG Evaluation

The EPA stated that, in general, it had significant concerns about the OIG draft report. The Agency also stated that our draft report primarily focused on EPA not meeting the initial draft Libby Action Plan project timelines, but did not acknowledge accomplishments or the fact that EPA's delay in meeting research timelines did not impede the extensive cleanup activities that have occurred to date. One of the objectives of our review was to determine how EPA had satisfied a previous OIG recommendation to conduct and complete a toxicity assessment of Libby asbestos. Our report does acknowledge the Agency's completion of its draft *IRIS Toxicological Review of Libby Amphibole Asbestos* on the results of the Agency's cancer and noncancer studies in support of its Libby toxicity assessment. The OIG did not review Libby cleanup actions and our report makes no representations about the Libby site cleanup efforts.

In response to our draft report, the Agency agreed with Recommendation 1a, and disagreed with Recommendations 1b, 1c, 2a, 2b, 3a, 3b, 4 and 5. Recommendation 1a remains unresolved until the Agency provides sufficient information to determine whether the intent of this recommendation has been satisfied. In accordance with EPA Manual 2750, and its instructions for unresolved recommendations, the Agency is required to provide a written response to Recommendation 1a, including a proposed action plan and completions dates, within 60 calendar days of the report issuance.

However, Recommendations 1b, 1c, 2a, 2b, 3a, 3b, 4 and 5 remain unresolved, pending dispute-resolution actions. The dispute-resolution process starts immediately upon report issuance.

We reviewed the Agency's comments and made changes to the report as needed. Appendix D provides a condensed version of the Agency's comments and the OIG's responses. The condensed version was necessary due to the voluminous size of the Agency's comments concerning the draft report. We provide the Agency's comments in their entirety as a stand-alone document separate from this report. Comments are available at http://www.epa.gov/oig.

Developments Since Issuing Our Draft Report

Claimed Libby Action Plan Accomplishments

In response to our draft report, Agency officials stated that substantial and significant progress has been achieved on important Libby Action Plan projects.

- EPA has developed improved analytical methods, identified adverse health effects from exposure to Libby amphibole asbestos, researched the mechanisms of injury, and developed a better understanding of the exposure response relationships in epidemiological studies.
- Basic research conducted under the Libby Action Plan has resulted in 19 peer-reviewed publications.
- The draft *IRIS Toxicological Review of Libby Amphibole Asbestos* was made available to the public in August 2011. This toxicity assessment provides a Libby amphibole asbestos-specific RfC to evaluate noncancer health effects and an Inhalation Unit Risk (IUR) to assess the potential cancer risk from exposure to Libby amphibole asbestos in the environment.

According to EPA officials, together with site-exposure characterizations based on activity-based sampling, the upcoming risk assessment(s) for the Libby Superfund site will assess the risk to the Libby community from exposure to Libby amphibole asbestos, and inform site risk-management decisions and future site remedies.

The Agency also stated that the Libby cleanup has substantially reduced the exposure levels of Libby citizens and that EPA's delay in meeting research timelines did not impede the conduct of extensive cleanup activities that have occurred to date.

The OIG did not substantiate these claims by the Agency.

The SAB's Final Report on the Agency's Toxicity Assessment

The SAB reviewed the Agency's toxicity assessment, and the Board presented its final report to EPA on January 30, 2013. The SAB's report cited several areas that need more consideration, and provided recommendations to further enhance the clarity and strengthen the scientific basis for the conclusions presented. This

included additional analysis using cohorts other than the Marysville, Ohio, cohort, and to use different statistical sampling models. In response to the OIG draft report, the Agency said the LATAG will review the overall risk assessment and EPA will make the risk assessment available to the public. Review of the risk assessment was not within the scope of our review.

On April 4, 2013, the director for ORD/NCEA in Washington, D.C., provided the OIG with developed milestones based on a review of the SAB's January 30, 2013, report, and an examination of what work the ORD expects to do in response to the SAB's recommendations. The director stated ORD/NCEA's schedule includes some uncertainties that could result in additional modifications to the schedule. Below we provide the director's verbatim response for the estimated schedule and potential uncertainties:

Developed Milestones

- September 30, 2013—First complete draft of revised toxicological review and comment disposition.
- January 14, 2014—Revised draft to go to Interagency and Agency reviewers.
- April 25, 2014—Revised draft to final clearance.
- June 24, 2014—Post final toxicological review (current estimate of when the final Libby Amphibole Asbestos Toxicity Review would be released to the public, assuming unknown events).

Uncertainties

Estimating the timeline for further modeling work in response to the SAB peer review

In their peer review report, the SAB agreed with many of the choices EPA made on how to assess the toxicity and dose-response of Libby amphibole asbestos. However, the SAB recommended that EPA conduct extensive and innovative additional modeling and sensitivity analyses, which EPA plans to do. These types of modeling and analyses are complex, and it is difficult to predict exactly how long it will take to successfully complete such modeling and analysis.

Potential for further peer review

At this point, EPA does not think that the revised IRIS assessment of LAA will require additional peer review. The additional analysis being conducted is directly responsive to specific SAB peer review recommendations and will not need further peer review. The SAB agreed that EPA should use the cohorts and endpoints used in the draft assessment. After responding to the SAB recommendations, it is possible

that EPA may decide that some portions of the work (e.g., new modeling or analysis) needs further targeted peer review. If EPA makes such a decision, this may add time to the projected timeline.

Clearance

Because of the very high profile nature of the Libby, Montana, site, and by extension, the IRIS assessment of LAA, it is possible that additional effort related to briefings and communication will be needed before releasing the final assessment. EPA's projected schedule provided above allows for 2 months to complete formal review and final clearance, including all of the requisite communications tasks and briefings. The timing of final reviews and clearances are often variable with very high profile work, and this step may take longer than projected.

Litigation

EPA could be required to respond to potential litigation related to Libby amphibole asbestos. In the event this happens, EPA may need to devote significant time to address issues which may extend the timeline.

Libby Versus the Formaldehyde Assessment

In November 2012, ORD personnel provided additional information regarding the selection of the formaldehyde assessment work over Libby work. Specifically, in September 2009, NCEA management requested that two scientists working on both the Libby and formaldehyde assessments temporarily focus only on completing the formaldehyde assessment so that staff could later focus on the Libby assessment without distraction. During our exit conference, ORD agreed to consider establishing a priority list of EPA projects with milestones that would require senior management review if any changes occurred with the milestones.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in $000s)	
Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Claimed Amount	Agreed-To Amount
1	17	Require action officials to: a. Disclose significant risks to completing the Libby Action Plan. b. Update the Libby Action Plan to reflect changes in milestone dates. c. Distribute original and revised plans to stakeholders.	U U U	Assistant Administrator for Solid Waste and Emergency Response, and Region 8 Regional Administrator			
2	17	a. Establish a charter to define project roles and responsibilities for completing the remaining corrective actions under the Libby Action Plan. b. Determine whether the SAB or another organization will review the completed risk assessment.	U U	Assistant Administrator for Solid Waste and Emergency Response, Assistant Administrator for Research and Development, and Region 8 Regional Administrator			
3	18	Direct the SAB to determine and report on whether: a. EPA has followed guidance sufficient to support the findings in the Libby toxicity assessment. b. Limitations exist in applying the cancer and noncancer values to the determination of acceptable levels of exposure to asbestos in Libby.	 U U	Deputy Administrator			
4	18	Ensure that future contracts issued through interagency agreements are within the scope of those agreements.	U	Region 8 Regional Administrator			
5	18	Require the development of a priority ranking list among IRIS assessments, and ensure that the Assistant Administrator be informed of any recommended changes in those priorities. The rankings should consider human health consequences.	U	Assistant Administrator for Research and Development			

[1] O = Recommendation is open with agreed-to corrective actions pending.
C = Recommendation is resolved with all agreed-to actions completed.
U = Recommendation is unresolved with resolution efforts in progress.

Appendix A

Name and Ranking of Studies Under the Agency's Libby Action Plan

(as of April 2007)

Name of Study	Responsible Party	Original Milestone Date
1. *Libby Amphibole Reference Concentration (RfC) Development (noncancer)*	Region 8/ NCEA	4th Quarter -FY 2009
2. *Libby Amphibole Cancer Assessment*	ORD/NCEA	4th Quarter -FY 2009
3. *Preparation of Libby Testing Material*	USGS	4th Quarter -FY 2007
4. *Fiber Size Distribution in Libby Vermiculite*	Region 8	4th Quarter -FY 2007
5. *Dosimetry Model Development and Simulation Studies*	NHEERL*	4th Quarter -FY 2009
6. *In Vitro Dissolution Assays*	NHEERL	2nd Quarter -FY 2009
7. *In Vitro Toxicity Endpoints*	NHEERL	2nd Quarter -FY 2009
8. *Comparative Toxicology in Mice and Rats*	NHEERL	4th Quarter -FY 2009
9. *Inhalation Toxicology in Rats*	NHEERL	3rd Quarter -FY 2009
10. *New Epidemiologic Information from Libby Cohort*	Region 8/NCEA	2nd Quarter -FY 2009
11. *Region 8/NCEA, New Epidemiologic Information From Other Cohorts*	Region 8/NCEA	3rd Quarter -FY 2009
12. *Interim Risk Methodology for Quantification of Cancer Risk From Inhalation Exposure to Asbestos*	OSWER	4th Quarter -FY 2009

Source: EPA's April 2007 follow-up response.

***** The National Health Effects and Environmental Research Laboratory (NHEERL) is located in Research Triangle Park, North Carolina.

Risk Assessment Guidance

The guidance documents listed below are general in nature. As the final site-specific risk assessments have not yet been developed (awaiting final toxicity values and complete site-specific exposure data), it is not possible at this time to determine exactly which additional guidance documents may be eventually referenced.

1. **EPA. 1989. Risk Assessment Guidance for Superfund, Human Health Evaluation Manual, Part A. (EPA/540/1-89/002. Washington, D.C.: EPA, Office of Emergency and Remedial Response.http://www.epa.gov/oswer/riskassessment/ragsa/index.htm**

   The guidance for the development of a site-specific risk assessment. As stated in the document: The policies and procedures set forth here are intended solely as guidance to EPA and other government employee and contractors. This guidance does not constitute rulemaking by the Agency… EPA may take action that is at variance with the policies and procedures in this manual….”

2. **EPA. 2008. Framework for investigating asbestos-contaminated superfund sites. Washington, D.C. http://www.epa.gov/superfund/health/contaminants/asbestos/pdfs/framework_asbestos_guidance.pdf.**

   This guidance provides the methods for the calculation of cancer risk from asbestos exposure. This guidance also recommends methods for the statistical summary of activity-based sampling data.

3. **EPA. 2009a. Risk assessment guidance for superfund volume I: Human health evaluation manual (Part F, supplemental guidance for inhalation risk assessment): Final. (EPA/540/-R-070/002). Washington, D.C.: EPA, Office of Superfund Remediation and Technology Innovation. http://www.epa.gov/oswer/riskassessment/ragsf/index.htm.**

   This guidance is part of the overall risk assessment guidance for superfund giving more specific recommendations regarding the assessment of risk and hazard from inhalation exposures.

4. **EPA. 2001b. Risk assessment guidance for superfund: Volume III part A, process for conducting probabilistic risk assessment. (EPA 540-R-02-002). Washington, D.C.: EPA, Office of Solid Waste and Emergency Response. http://www.epa.gov/oswer/riskassessment/rags3adt/index.htm**

   This guidance provides methods for alternative approaches for the calculation of exposure and risk estimates based on statistical distributions rather than single point estimates.

Toxicity Assessment Guidance

1. **EPA. 1986b. Guidelines for mutagenicity risk assessment [EPA Report]. (EPA/630/R-98/003). Washington, D.C. http://www.epa.gov/iris/backgrd.html.**

   These guidelines informed the evaluation of available scientific information regarding the potential mutagenicity of the Libby Amphibole asbestos fibers. (Section 4.4.2)

   The evaluation of mutagenic potential primarily applies to the cancer assessment.

2. **EPA. 1991a. Guidelines for developmental toxicity risk assessment [EPA Report]. (EPA/600/FR-91/001). Washington, D.C.: EPA, Risk Assessment Forum. http://www.epa.gov/iris/backgrd.html.**

   Although there are no developmental data specific to the Libby Amphibole, the potential for developmental effects is discussed in Section 4.7 addressing susceptible populations (including life stages). These guidelines would apply to the general data on asbestos which may address the potential for developmental effects.

3. **EPA. 1994a. Interim policy for particle size and limit concentration issues in inhalation toxicity studies [EPA Report]. Washington, D,C.: EPA, Office of Pesticide Products, Health Effects Division. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=186068.**

   These are general guidelines for evaluating exposure conditions for animal inhalation studies and were used in evaluating the studies in Appendix D of the Toxicological Review where applicable.

4. **EPA. 1994b. Methods for derivation of inhalation reference concentrations and application of inhalation dosimetry. (EPA/600/8-90/066F). Research Triangle Park, N.C.: EPA, Office of Research and Development, Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=71993.**

   This guidance was used in derivation of an RfC for the Libby Amphibole (Section 5.2), as it provides the primary guidance for establishing reference concentrations under the IRIS Program.

   This guidance was used to calculate the exposure estimates for the occupational cohorts which were the basis of both the RfC and IUR (Sections 5.2.3.1 and 5.4). {Although the Guidance was written specifically for the RfC process, the 2005 EPA Cancer Guidelines recommend the same procedures be employed in inhalation cancer assessments (see section 3.1.1.2 of the cancer guidelines, EPA, 2005)}

5. **EPA. 1995. The use of the benchmark dose approach in health risk assessment [EPA Report]. (EPA/630/R-94/007). Washington, D.C. http://www.epa.gov/raf/publications/useof-bda-healthrisk.htm.**

   Although this guidance is being updated (see EPA 2000a), this technical guidance provides the foundation for the exposure-response modeling of the noncancer health effects observed in the O.M. Scott cohort and used as the basis for the RfC.

   The guidance also informed some of the decisions in the exposure-response modeling in support of IUR derivation.

6. **EPA. 1996. Guidelines for reproductive toxicity risk assessment [EPA Report]. (EPA/630/R-96/009). Washington, D.C.: EPA, Risk Assessment Forum. http://www.epa.gov/raf/publications/pdfs/REPRO51.PDF.**

   Although there are no reproductive data specific to the Libby Amphibole, the potential for reproductive effects is discussed in Section 4.7 addressing susceptible populations. These guidelines would apply to the general data on asbestos, which may address the potential for reproductive effects.

7. **EPA. 2000a). Benchmark dose technical guidance document [external review draft]. (EPA/630/R-00/001). Washington, D.C.: EPA, Risk Assessment Forum. http://www.epa.gov/raf/publications/benchmark-dose-doc-draft.htm.**

   This technical guidance was applied to the exposure-response modeling of the noncancer health effects observed in the O.M.Scott cohort and used as the basis for the RfC. (Sections 5.2.3–5.2.5)

   The guidance also informed some of the decisions in the exposure-response modeling in support of IUR derivation. (Sections 5.4.3–5.4.5)

8. **EPA. 2000c. Science policy council handbook: Risk characterization. (EPA 100-B-00-002). Washington, D.C.: EPA, Office of Research and Development, Office of Science Policy. http://www.epa.gov/osa/spc/pdfs/rchandbk.pdf.**

   This general guidance document informed the scientific evaluations and decisions in both the cancer and noncancer portions of the toxicological review.

9. **EPA. 2002. A review of the reference dose and reference concentration processes. (EPA/630/P-02/002F). Washington, D.C. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=51717.**

   This review provides a summary of current practices as well as recommendations for the IRIS Program where setting reverence values, and informs the RfC derivation for Libby Amphibole asbestos. (Section 5.2)

10. **EPA. 2005a. Guidelines for carcinogen risk assessment. (EPA/630/P-03/001F). Washington, D.C. http://www.epa.gov/cancerguidelines/.**

The Cancer Guidelines were followed for all aspects of the Libby Amphibole asbestos cancer assessment: hazard identification, discussion of Mode of Action, determination of carcinogenicity (carcinogenic to humans), exposure-response modeling and IUR derivation from the chosen exposure-response model(s). (Sections 4.4, 4.6 and 5.4)

11. **EPA. 2005b. Supplemental guidance for assessing susceptibility from early-life exposure to carcinogens. (EPA/630/R-03/003F). Washington, D.C.: EPA, Risk Assessment Forum. http://www.epa.gov/cancerguidelines/guidelines-carcinogensupplement.htm.**

The supplemental guidance was employed in Section 4.6.2, where the mode of action information is reviewed to determine if the adjustment factors for early-life exposure should be applied.

12. **EPA. 2006b. A framework for assessing health risk of environmental exposures to children. (EPA/600/R-05/093F). Washington, D.C. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=158363.**

This guidance was applied in those sections which discuss the exposures to children (Section 2.3 exposure potential, Section 4.7 susceptible populations).

13. **EPA. 2006d. Science policy council handbook: Peer review, 3rd edition. (EPA/100/B-06/002). Washington, D.C.: EPA, Science Policy Council. http://www.epa.gov/OSA/spc/2peerrev.htm.**

The external peer review of the Libby Amphibole Asbestos Toxicological Review is being conducted by the EPA Science Advisory Board.

14. **International Labour Organization (ILO), World Health Organization (WHO). (2002). International classification of radiographs of pneumoconioses. In (Rev. Ed. 2000 ed., Vol. 22). Geneva, Switzerland: International Labour Office.**

This guidance document was cited in Section 5.2.2 where the noncancer health effects providing the basis of the RfC are evaluated. As this WHO publication is the standard for describing the noncancer health effects of asbestos exposures based on standard radiographs, these guidelines were used in evaluating and describing the critical health effect on which the RfC is based.

OIG Consolidated Responses to Agency's Comments on Libby Draft Report

The Agency provided extensive comments to the draft report in three separate documents. This included main comments dated September 5, 2012 from the Assistant Administrators for OSWER and ORD, and the Region 8 Administrator. Additional attachments included comments rendered by the Agency's Deputy Chief of Staff on August 10, 2012, and the Agency's NHEERL on or about September 5, 2012. We summarize and respond to those comments below. We have organized them into the following topics: general comments, charter comments, cancer study comments, noncancer study comments, communications comments, interagency agreement comments, Science Advisory Board comments, NHEERL comments, recommendation comments, and EPA Deputy Chief of Staff Comments. We provide these 3 sets of comments in their entirety as a stand-alone document separate from this report at website (http://www.epa.gov/oig).

General Comments.

Understanding Health Effects. EPA stated that the draft report did not acknowledge EPA's major strides in improving the understanding of health effects of exposure to Libby asbestos.

> **OIG Response 1**: The purpose of this review was to determine how EPA had satisfied our previous recommendation to conduct and complete a toxicity assessment of Libby asbestos. However, we have included information in our report provided by the Agency in response to our draft report on progress made under the Libby Action Plan projects.

Reducing Exposure Levels. EPA stated the draft report did not acknowledge that EPA had substantially reduced exposure levels of Libby citizens through the cleanup efforts.

> **OIG Response 2**: The purpose of this review was to determine how EPA had satisfied our previous recommendation to conduct and complete a toxicity assessment of Libby asbestos. The OIG did not review the effectiveness of the cleanup.

Delays Did Not Impede the Cleanup. EPA stated the draft report did not state that the delays in meeting the research timelines did not impede the cleanup.

> **OIG Response 3**: The draft report makes no inference that the delays in completing the toxicity assessment delayed the cleanup. We did not review the cleanup, which is a separate activity from the toxicity assessment.

Draft Report Focused Primarily On Meeting Draft Milestones. EPA stated that the draft report focused primarily on EPA not meeting the initial draft Libby Action Plans milestones.

OIG Response 4: We disagree that the draft report focused primarily on EPA not meeting the LAP milestones. The focus of the findings and recommendations is on how EPA established the milestones and why EPA experienced delays.

The OIG Acknowledges that the Draft Milestones Were Unachievable. EPA stated that the OIG acknowledges that the milestones were unachievable.

OIG Response 5: We disagree that the draft report acknowledges the LAP milestones were not achievable. The OIG reports that EPA personnel stated at the initiation of the OIG review that EPA knew the LAP milestones were not achievable when EPA presented them to stakeholders. Further, the milestones were the estimates that the action official agreed to. In an April 2007 memorandum, EPA informed the OIG that:

- The milestone for the completion of the baseline risk assessment including a comprehensive toxicity assessment would be September 30, 2010.
- The tentative date to complete the NHEERL animal studies was September 30, 2009.
- In an attachment to the memorandum, EPA provided tentative completion dates for each of the 12 individual studies supporting the toxicity assessment, which ranges from the fourth quarter of FY 2007 to the fourth quarter of FY 2009.

EPA did not update the milestones until October 20, 2009. At that time, they informed the OIG that the milestone to complete the baseline risk assessment including a comprehensive toxicity assessment changed from September 30, 2010 to September 30, 2012. EPA also informed the OIG that the baseline to complete the NHEERL animal studies changed from September 30, 2009 to September 30, 2015.

The OIG Uses the Term "Toxicity Assessment" Incorrectly. EPA stated that despite the detailed information they provided and the availability of numerous EPA program and guidance documents, the term "toxicity assessment is used to convey three different meanings, only one of which is correct. Further EPA stated that the OIG draft report in several places continues to confuse an agent-specific toxicity assessment and a site-specific risk assessment.

OIG Response 6: We disagree. We reviewed each instance of the term toxicity assessment in the draft report and all refer to the work EPA committed to perform to satisfy the report recommendation or are statements made by EPA personnel. The term agent-specific toxicity assessment is a term EPA uses in its comments to this report. It is not a term the OIG uses. The OIG does not refer to the term site-specific risk assessment in the introduction or other part of the report. Appendix A, Risk Assessment Guidance, provided by the Agency, provides the only mention of a site-specific risk assessment. The Agency identified twelve studies that comprise the toxicity assessment (see appendix A); however, the report is clear that the work accomplished by EPA to date will only reflect two, the cancer and noncancer studies due to EPA delays in completing all the toxicity work.

EPA Milestones Should Not Be Used as Baselines. EPA states that it does not agree with the OIG's interpretation that the draft timelines provided in April 2007 should be the baseline against which the EPA's progress on LAP projects should be evaluated.

> **OIG Response 7**: We disagree with the EPA interpretation that the report findings are based primarily on EPA not meeting the LAP milestones. The original baselines show that EPA experienced significant delays in completing the toxicity assessment. OSWER informed the OIG that the estimated date for completing the comprehensive toxicity assessment was revised from September 30, 2010 to September 30, 2012 (two year delay), and September 2015 (initially September 2009) for the NHEERL animal toxicity studies (6 year delay). However, the report findings are based upon the EPA management actions that contributed to the delays.

Revisions Did Not Cause Delays. EPA stated that the action of revising the timelines did not affect the execution of the LAP projects. The action of revising the timelines reflected – not caused – project delays.

> **OIG Response 8**: We agree that the sentence stating that is unnecessary and confusing. Therefore, we are removing it from the report.

Title Page and Cover: EPA states the OIG's field investigation and review seems to have addressed all projects under the Libby Action Plan (LAP). As such they recommend the title reflect this is a report on the progress of all LAP projects, not just the toxicity assessment.

> **OIG Response 9**: The title of the report accurately reflects progress made under the Agency's Libby Action Plan. EPA characterization of the OIG review is incorrect. The 12 LAP studies did comprise of the toxicity assessment. For example in her April 2007 Congressional testimony the former OSWER assistant administrator stated, "…the Agency has identified and is implementing a comprehensive program of 12 studies to support the development of the Libby toxicity assessment. The cancer and noncancer work are clearly listed as two of the studies. This is also consistent with the information EPA provided to the OIG.

At A Glance and Chapter 1, Background: EPA states that the OIG draft report indicates the concerns of the Libby community centered around "lawn and garden products from Libby." The concerns of the citizens include potential exposures and environmental contamination from past mine operations, waste materials used as fill in the community, use of expanded vermiculite in buildings (e.g. homes, schools) for insulation and use of both waste materials and expanded vermiculite as a soil amender. The Libby Superfund site is not focused only on contaminated lawn and garden products.

OIG Response 10: The EPA characterization of the report is not correct. The report language is as follows*: In 2000, due to citizen concerns, EPA started sampling and analyzing lawn and garden products from Libby that contained vermiculite*. The report does not state that the concerns of Libby citizens centered on lawn and garden products. Rather, it states the action EPA took.

LAP Projects. EPA states that the list of LAP projects provided to the OIG as shown in Appendix A of the draft report are not in order of priority, and requests that the statement making reference to the order of priority of these projects be removed for accuracy.

OIG Response 11: EPA personnel provided this information. More specifically, EPA's documentation states the RfC development study was ranked number one by the Agency relative to its priority for completing the Libby toxicity assessment; and, completion of the Libby Amphibole cancer assessment study was ranked second in terms of relative priority by the Agency for completing the Libby toxicity assessment. EPA has not stated why the information is not correct or provided a new list arranged in accordance with priority. EPA should provide justification for this change in the 60 day comments to the final report. That justification should include the priority ranking of the remaining studies.

Unclear Statement. EPA states the following statement is unclear "We were told by OSWER managers that the derivation of the reference concentration (RfC) and inhalation unit risk (IUR) for Libby amphibole asbestos were needed for completion of the site-specific risk assessment."

OIG Response 12: We disagree that the statement as written by EPA was in the draft report. The closest report language to the EPA statement is as follows. "*We were told by OSWER managers that studies 1 and 2 were especially critical to completing the toxicity assessment in response to OIG recommendation 1 based on their priority ranking.*" This particular statement is supported by evidence gathered during our evaluation.

The Libby Action Plan Coordinator Is Not Recognized. EPA states the OIG Draft Report does not acknowledge the Libby Action Plan Coordinator, who had the primary responsibility for coordination of the projects among the offices. As this was a key aspect of LAP management, this information needs to be included.

OIG Response 13: The report addresses the responsibilities of OSWER, ORD and Region 8 in carrying out the Libby Action Plan. As such, we spoke with the Action Officials for OSWER, ORD and EPA Region 8 during meetings leading up to the issuance of the draft.

Personnel Not Interviewed. EPA stated that no NHEERL personnel were interviewed during this field investigation including the first two LAP coordinators who were responsible for planning and coordinating the overall NHEERL research effort. Nor were personnel in ATSDR, the lead Agency for projects 10 and 11 contacted in the field investigation.

OIG Response 14: The OIG conducted an entrance conference with EPA to discuss the review and to determine whom the OIG needs to interview. We saw no benefit to interviewing these personnel. The purpose of the review was to determine EPA efforts in developing and completing the toxicity assessment.

The Term "Listing" Has a Specific CERCLA Meaning. EPA states that "Listing "has a specific meaning in the context of CERCLA and is used to refer to a site being added to the National Priorities list. It is not appropriately used in the OIG report. EPA recommends the reference to "listed" be removed.

OIG Response 15: The report is not a CERCLA document and the term "listed" is used appropriately. The term is used several times and in no way conveys that the subject of conversation refers to listing on the National Priorities List in the draft report. Where necessary, we have used the term National Priority Listing in reference to Libby as a Superfund site.

Specific Word Changes to Draft Report.

Page 3, line 44: strike "determining" replace with "conducting."
Page 4, line 2: Should read "… conducting inhalation toxicology **studies** in rats."
Page 4, line 7: Should read "site-specific reference concentration (RfC) for the Libby amphibole asbestos…"
Page 5 and 6, Scope and methodology: Add the following bullet "Briefings to senior managers."

OIG Response 16: We agreed with each word change request. All changes are reflected in the final report.

Charter Comments

No Charter Necessary to Complete Libby Work. A LAP Coordinator was appointed from management of one of the participating offices and was responsible for cross-Agency coordination of all of the individual projects within the LAP

OIG Response 17: Our report addresses the role and responsibilities of the Assistant Administrator for OSWER and ORD, and the Region 8 Administrator whom, according the Agency managers, served as the senior Agency officials ultimately responsible for ensuring the completion of corrective actions under the LAP. In this structure, each office was only responsible to itself.

OIG Response 17 Continued

- OSWER was responsible for oversight of the Libby Action Plan and reporting progress made to internal and external stakeholders.
- ORD's National Center for Environmental Assessment (NCEA) was responsible for conducting a cancer assessment specifically for Libby amphibole for the Integrated Risk Information System (IRIS).
- EPA Region 8, with assistance from ORD/NCEA, was responsible for developing the Libby reference concentration (RfC) for Libby amphibole.

However, our review revealed the Agency's efforts to carry out its Libby Action Plan experienced significant delays with this management structure. OSWER oversight was not sufficient or empowered to ensure that:

- ORD and Region 8 estimates to complete the studies were reasonable.
- ORD did not postpone Libby work to complete another assessment without justification.
- EPA and University of Cincinnati scientists began work on the non-cancer study as soon as possible rather than spend 19 months issuing the contract.

Cancer Study Comments

Libby Should Not Be The Sole EPA Priority. EPA stated that it is incorrect that the declaration of the public health emergency in Libby Montana should have made the Toxicological Review of Libby Asbestos the sole priority toxicity assessment for EPA.

OIG Response 18: We disagree that the report states that Libby should be the sole EPA priority. The OIG does not state that the declaration of the public health emergency required EPA to make Libby the top priority. Rather, the OIG found that the Agency could not provide criteria to make one assessment a priority over the other. Specifically, EPA data acknowledges death and illness due to exposure to Libby asbestos, over $400 million spent on the cleanup, Libby asbestos is in millions of American homes, and EPA's only issuance of a public health emergency as reasons to make Libby a priority. At the time of the review, responsible EPA personnel could not provide similar reasons for other assessments. Therefore, we recommended that the Assistant Administrator for Research and Development develop a priority list for pending and ongoing research, not to make Libby the sole priority. During our exit conference, an ORD official stated ORD would consider establishing a priority list of EPA projects with milestones that would require senior management review of any changes in the milestones. We believe it is consistent with EPA's mission to clearly factor in human health risks when deciding on priorities.

Competing Demands Not the Sole Reason for Delays in the Cancer Study. EPA disagrees with any implied finding that the delay in completing the *Toxicological Review of Libby Amphibole Asbestos* was due solely to competing demands.

> **OIG Response 19**: We disagree that the report makes that statement. The report clearly states that competing priorities and unplanned work caused delays in completing the cancer study. The specific details of each as provided by EPA personnel are included in the report. However, we have changed the wording from unplanned work to unanticipated work.

Noncancer Study Comments

Contracting Issues Did Not Delay the Noncancer Study. EPA stated that it did take action to try to expedite contracting procedures by choosing to use an existing contract mechanism through the Volpe Center.

> **OIG Response 20**: EPA's response does not reflect the Agency's Interagency Policy and Procedures Compendium, which states that the agreement must be for-an independent and distinct project. The scope of work listed in the agreement was for the Volpe Center to perform site-specific clean-up work at the Libby site, not to develop a noncancer value with the University of Cincinnati. Further, EPA's response does not recognize that the Volpe Center provided no technical work in developing the noncancer value. Specifically, the EPA staff member-who chose the Volpe Center believed that the Volpe Center was better at contracting and was faster and more innovative than EPA in getting contracts done. EPA's response also does not account for the fact that performing pass through acquisitions, as defined by the Volpe center, was against Volpe Center Policy. The Volpe Center stated that their work on the interagency agreement must be technical in nature but the statement of work states that Volpe would facilitate communication between EPA and University of Cincinnati scientists. In our opinion, facilitating communication is not a technical role in developing a noncancer toxicity value.

Communications Comments

EPA Communications with the Senate. EPA states the OIG should reconsider their statements that EPA communications to the Senate were "misleading."

> **OIG Response 21**: We concur. We have made changes to the report, as appropriate. Specifically, the report now states that reports provided to the senators were incomplete rather than misleading.

EPA Provided Information to Internal and External Stakeholders. EPA has briefed community stakeholders on LAP project status and timelines across the course of the projects. Although EPA did not contrast the timelines to the draft timelines provided in the Agency's response to the OIG (April 2007), community stakeholders had the best available current project status and timelines well before September 2009.

> **OIG Response 22**: The report does not dispute that EPA provided information to stakeholders. The report does show that the information provided was not always complete and in the case of the LAP, the information was incomplete.

InterAgency Agreement Comments

The Volpe Center Did Not Perform a Pass Through Acquisition for EPA. EPA did not use Volpe as a pass-through vehicle for contracting. Volpe Center provides EPA with technical assistance in Superfund site cleanup to include site assessment and remedy selection.

> **OIG Response 23**: We disagree. The EPA comment does not reflect that:
>
> - EPA staff admitted they used the Volpe Center for contracting support to avoid using EPA contracting.
> - The Volpe Center performed no technical work in developing the noncancer value.
> - The agreement must be for an independent and distinct project.
>
> We believe Region 8's use of the Libby Clean-up IAG to award a contract to the University of Cincinnati exceeded the scope of work under the agreement between Region 8 and the Volpe Center. Region 8's interagency agreement with the Volpe Center is site specific and the scope of work describes authority for work to be done at Libby, Montana, and not at the University of Cincinnati in Ohio.

EPA and Volpe Do Not Fault Each Other for the Delays. EPA disagrees with the OIG statement "Rather, EPA and the Volpe Center fault each other for the delays."

> **OIG Response 24**: The draft report statement is accurate. EPA and the Department of Transportation Volpe Center personnel provided contrary opinions as to who was at fault for the delay in issuing the contact awarded for the noncancer assessment study under the Libby Action Plan. EPA personnel faulted the Volpe Center for delays in completing the noncancer study. In turn, the Volpe Center responded that EPA did not know what tasks it wanted to complete under the contract and that contributed to the delays.

Science Advisory Board Comments

The Role of the SAB. EPA stated there are critical flaws in the findings and recommendations of the OIG Draft Report with respect to external peer review and the role of the EPA SAB. This issue has been independently addressed by the Office of the Administrator. The EPA Deputy Chief of Staff responded for the Office of Administrator stating that the SAB review is still ongoing and, therefore, it is not appropriate to include SAB review comments in the OIG report.

> **OIG Response 25**: In response to the EPA Deputy Chief of Staff comments regarding this issue, we note that the statements made by the SAB Staff Director are in response to questions posed by the OIG and are not taken from the SAB draft report. However, the SAB's final report is public. The SAB's report cited several areas that need more consideration, and provided recommendations to further enhance the clarity and strengthen the scientific basis for the conclusions presented in the draft toxicity assessment. Also note that the OIG report does not recommend that the SAB direct EPA actions. The EPA has turned to the SAB for scientific review of its risk assessments. It does not appear constructive for EPA to engage expert SAB panels but deny the panel information they believe is necessary to do their jobs effectively. Resolution of the issues could reduce the limitations associated with SAB reviews of future EPA risk assessments. Additionally, resolution of these issues could improve public confidence in EPA risk assessments.

NHEERL Comments

EPA Was Responsive to Reviewer Comments. The OIG does not acknowledge that EPA was responsive to the reviewer comments and EPA revised the project plans accordingly.

> **OIG Response 26**: Our review objectives were to determine why the Agency did not meet planned corrective action milestones in response to the recommendations in the OIG's December 2006 report. EPA provided documentation to the OIG in October 2009 stating that the laboratory studies are expected to be completed in 2012; however, EPA anticipated that an additional two to three years was necessary to assess results, develop technical summary reports, and have the reports peer reviewed. The report does not infer that EPA was non-responsive.

Delays in Government Contracting on the NHEERL Studies. EPA states that the OIG should acknowledge that although true, these contracting delays (delays is government contracting) were not the critical factor to delays in the NHEERL research projects. The unforeseen technical difficulties in producing adequate quantities of test material were the rate limiting factor.

> **OIG Response 27**: The OIG did not rate the factors limiting the completion of the NHEERL studies. However, EPA cannot ignore certain factors that cause delays.

Fiber Separation Studies. EPA states the need for fiber separation studies only resulted in minor project delays (a few months).

> **OIG Response 28**: The report does not attempt to post the time caused by each delay. Rather, it lists the causes of the delay as stated by EPA.

Dosimetry Delays. EPA states that the dosimetry contract was delayed because it was initially developed as a desired sole source contract. It was eventually awarded based on open competition.

> **OIG Response 29**: As the report states, EPA informed the OIG that multiple actions contributed to the delays the cumulative effect being a 6 year delay. The OIG did not attempt to rank the amount of delay attributed to each action. However, EPA cannot state that the contracting delay was not consequential. EPA could not conduct the tests without the proper material. It also could not conduct the tests without having the contract in place.

NHEERL Delays. EPA states although the completion of all animal toxicity studies is projected for 2015, this date reflects completion of all laboratory studies as well as completion of all project reports and publications. The OIG report should acknowledge that many of the subject studies have been completed and that results have published in peer reviewed scientific journal demonstrating significant progress.

> **OIG Response 30**: The draft report lists the delays and causes of the delays EPA presented in completing the NHEERL studies. Specifically, in October 2009 EPA informed the OIG that the time frame for these studies have been extended due to unforeseen problems in preparing the dosing material for animals studies, delays in government contracting, and revisions to the experimental designs. While EPA states that many of the studies have been done or will be completed in 2012, EPA also states that assessing the results would take another two to three years. Therefore, EPA established a new completion date of September 2015 versus September 2009 (6 years). Further, the report correctly states the studies are 6 years late based upon the information EPA provided. While it is good to know that EPA is making progress it does not change the fact that stakeholders will have to wait 6 years before the information can be used.

Recommendation Comments

1a) Assistant Administrator for Solid Waste and Emergency Response and Region 8 Regional Administrator require action officials to: Disclose significant risks to completing the Libby Action Plan.

EPA Response: Concur
When and if, EPA is aware of factors that have the potential to affect the current project milestones, this information will be shared with stakeholders.

OIG Response 31: The OIG acknowledges the Agency's concurrence. In response to our draft report, Agency officials stated when, and if, EPA is aware of factors that have the potential to affect the current project milestones, this information will be shared with stakeholders. However, the Agency has not provided an action plan with the mechanism for contacting the stakeholders and specifying how soon after the delays are known that the stakeholders would be informed. Therefore, Recommendation 1a status is unresolved pending an action plan with completion dates (when determined) for the agreed-to recommendations.

1b) Assistant Administrator for Solid Waste and Emergency Response and Region 8 Regional Administrator require action officials to: Update the Libby Action Plan to reflect changes in milestone dates.

EPA Response: Nonconcur.

Alternative text: "OIG finds that the LAP coordinator maintains a current timeline for all LAP activities conducted across the Agency and that senior management from ORD, OSWER, and Region 8 is regularly updated of LAP project status."

OIG Response 32: The Agency disagreed with Recommendation 1b, even though they have agreed to keep stakeholders informed in Recommendation 1.a. Therefore, Recommendations 1b is unresolved with dispute actions pending. The dispute resolution process starts within 30 calendar days of the report issuance.

1c) Assistant Administrator for Solid Waste and Emergency Response and Region 8 Regional Administrator require action officials to: Distribute original and revised plans to stakeholders.

EPA Response: Nonconcur

EPA believes it has kept stakeholders informed. Specifically, EPA stated it has provided monthly status reports to Congress, addressed LAP status in Senate testimony, attended regular meetings with interested Senate staff, responded to all requests for information on

LAP projects, and has briefed community stakeholders on LAP project status and timelines across the course of the projects.

Alternative Remedy: EPA will continue to provide updates of schedules to stakeholders as the progress on the LAP continues. In future updates, EPA will provide clear information on schedule changes to the current project milestones of LAP projects.

OIG Response 33: The Agency disagreed with Recommendation 1c. However, we do concur that the Agency has provided information to stakeholders although our report does not fully support that complete information has always been provided. Therefore, Recommendations 1c is unresolved with dispute actions pending.

2a) Assistant Administrator for Solid Waste and Emergency Response, Assistant Administrator for Research and Development, and Region 8 Regional Administrator: Establish a charter to define project roles and responsibilities for completing the remaining corrective actions under the Libby Action Plan.

EPA Response: Nonconcur
The OIG Draft Report does not support a finding that the current tri-chair structure with a LAP Coordinator is ineffective.

Alternative Remedy: No corrective action needed. EPA does not believe establishing a formal charter is necessary to address the OIG's concern with respect to communicating project milestones.

OIG Response 34: The Agency disagreed with Recommendation 2a. We disagree that the purpose of the charter is to communicate project milestones. The purpose of the recommendation is to help EPA improve its management of the completion of the remaining LAP studies. The report shows that OSWER, ORD, and Region 8 oversaw initial efforts under the Libby Action Plan, discussed cross-coordination efforts within EPA, and approved funding. However, each member was only responsible for the Libby Action Plan studies assigned to them and no office has the authority to oversee the actions of all offices. Therefore, a single entity did not have the authority to review the causes for the delays and to offer remedies. As a result, EPA distributed the LAP to stakeholders with the knowledge that the milestones were not achievable, contracting issues delayed the development of the noncancer value, an interagency agreement was used to avoid EPA contracting personnel, competing priorities and unanticipated work delayed development of the cancer value, and communications with stakeholders could be improved. Therefore, Recommendation 2a is unresolved with dispute actions pending.

2b) Assistant Administrator for Solid Waste and Emergency Response, Assistant Administrator for Research and Development, and Region 8 Regional Administrator: Determine whether the SAB or another organization will review the completed risk assessment.

EPA Response: Nonconcur
An additional peer review is unnecessary and would delay final remedy selection and finalization of the Record of Decision for the Libby Superfund site. Site-specific risk assessments represent the application of EPA policies and guidance. They are released for public comment but do not undergo a separate expert peer review since any influential scientific information on which they rely has already undergone peer review. As the Libby amphibole asbestos toxicity assessment is currently being reviewed by the SAB and the Libby site-specific risk assessment will be based on the peer-reviewed toxicity values, it is unclear what would be accomplished by a second SAB review.

Alternative Remedy: No corrective action needed.

OIG Response 35: The Agency disagreed with Recommendation 2b. However, the Agency proposed action is responsive to the recommendation as the Agency has committed to have the LATAG review and comment on the risk assessment. Therefore, Recommendation 2b is unresolved with dispute actions pending.

3a) Deputy Administrator Direct the SAB to determine and report on whether EPA has followed guidance sufficient to support the findings in the Libby toxicity assessment.

EPA Response: Nonconcur
The SAB is currently conducting an independent scientific peer review of the External Review draft of the *Toxicological Review of Libby Amphibole Asbestos.* The SAB conducts its peer review in the context of EPA guidelines on risk assessment along with their own expert knowledge of the characteristics of asbestos, toxicity assessment, and exposure-response analysis done for purposes of cancer and non-cancer risk evaluation. The questions posed by EPA to the SAB are presented in the public "charge" to the Board. That charge includes specific questions on the key issues in the assessment and makes explicit reference to EPA guidances, such as the *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005) and to EPA's Draft *Benchmark Dose Technical Guidance* (EPA, 2000).

The OIG provides no rationale as to why an additional or different peer review of the Toxicity Assessment by the SAB is needed. The SAB is anticipating making their final recommendations to the EPA Administrator in December, 2012. EPA does not agree that any additional review of the Toxicity Assessment is needed from the SAB.

Alternative Remedy: No corrective action needed. EPA's position is that an additional review by the SAB is neither warranted nor necessary.

OIG Response 36: The Agency disagreed with Recommendation 3a. We note that the recommendation does not require the SAB to perform an additional review. The recommendation requires the SAB to comment on whether EPA followed sufficient guidance to support the findings in the Libby toxicity assessment. The Agency disagreed but stated that the information would be in the final SAB report regardless of the OIG recommendation. Further, despite its disagreement, the Agency's proposed action is responsive to the recommendation. Therefore, Recommendation 3a is unresolved with dispute actions pending.

3b) Deputy Administrator direct the SAB to determine and report on whether limitations exist in applying the cancer and noncancer values to the determination of acceptable levels of exposure to asbestos in Libby.

EPA Response: Nonconcur
EPA is unclear what the OIG intends with the specific wording in the draft Recommendation 3b.

If the OIG intends that the SAB should provide advice on limitations of the Toxicological Review or difficulties in its application; that issue is already being addressed per the specific charge questions given to the SAB for their review of the Toxicological Review of Libby amphibole asbestos. Response D.1 provides details of these questions with respect to the SAB's assessment of the "uncertainties and limitations" of the results of the toxicological review.

Alternative Remedy: No corrective action needed. The SAB has already reviewed the toxicity assessment and was asked by the Agency to identify "uncertainties and limitations." The toxicity assessment does not set "acceptable levels" for specific sites.

OIG Response 37: The Agency disagreed with Recommendation 3b despite the EPA Deputy Chief of Staff stating that the requested information would be in the final SAB report. Therefore, Recommendation 3b is unresolved with dispute actions pending.

4) Region 8 Regional Administrator ensure that future contracts issued through interagency agreements are within the scope of those agreements.

EPA Response: Nonconcur
Region 8 adheres to the Federal Acquisition Regulations (FAR) with regard to Interagency Agreements (IAs). As such, Region 8 has ensured that work assignments issued through IAs are within the scope of those agreements and will continue to do so. The EPA disagrees with the OIG finding that the contract work was outside of the scope of the IA.

Alternative Remedy: No corrective action needed. Region 8 adheres to the FAR with regard to IAs.

OIG Response 38: The Agency disagreed with Recommendation 4. In response to the OIG finding, Region 8 officials stated they adhered to the Federal Acquisition Regulations (FAR) as authority for using the Volpe Center interagency agreement to award the contract to the University of Cincinnati. The Agency did not adhere to FAR Subpart 17.5, "Interagency Agreements Under the Economy Act." The Economy Act applies when specific statutory authority does not exist. The report indicates that the Agency use of the Libby Clean-up IAG to award a contract to the University of Cincinnati exceeded the scope of work under the agreement between Region 8 and the Volpe Center. The Agency also does not cite compliance with any particular FAR requirement that would override the Compendium and the interagency agreement terms. Therefore, this recommendation is unresolved with dispute actions pending.

5) Assistant Administrator for Research and Development develop a priority list for pending and ongoing research.

EPA Response: Nonconcur

EPA strongly disagrees with any OIG findings or implications that other toxicity assessments being conducted by ORD were not of equally high public health consequence. The OIG did not evaluate the public health impacts of any of the other Toxicological Assessments being conducted by EPA. They did not, for example, evaluate the public health significance of completing assessments of the toxicity of formaldehyde, trichloroethylene (TCE), or perchloroethylene (PERC). TCE and PERC are constituents of concern at over 700 sites on the National Priorities List, and formaldehyde is a chemical with very widespread exposure in both indoor and outdoor air. All of these assessments were nominated and selected per the IRIS process described above.

Alternative Remedy: No corrective action needed. EPA believes the existing prioritization approach used by ORD/ National Center for Environmental Assessment (NCEA) is appropriate and adequate. In November 2012, EPA reconsidered this response. EPA provided additional information for the selection of formaldehyde work over Libby work and requested a change to the recommendation to require the Assistant Administrator for ORD to review priority ranking among the ongoing IRIS assessments and that he be informed of any recommended changes in those relative priorities.

OIG Response 39: The Agency disagreed with Recommendation 5. We disagree that the report states that other assessments were not of an equally high public health consequence. Rather, EPA could not tell the OIG what the existing prioritization approach was and how EPA made the determination to complete other work instead of the Libby cancer study. Specifically, EPA made the management decision to complete formaldehyde work, which resulted in some delay in completing the Libby cancer study**.** We requested that EPA provide the rationale for this decision given the noted health implications of the Libby cancer study. During the review, EPA responded that the NCEA Director made the decision to complete the formaldehyde assessment even if that meant some delays in the Libby cancer assessment. In these comments, EPA states that the OIG did not evaluate the public health impacts of any of the other Toxicological Assessments being conducted by EPA. However, this concerns the EPA rationale for a decision that it had already made. Given that EPA could not provide a health based rationale, we recommended that EPA develop a process to determine priority in completing assessments. Therefore, Recommendation 5 is unresolved with dispute actions pending.

Deputy Chief of Staff Comments

That OIG recommended that the Deputy Administrator direct the Science Advisory Board (SAB) to determine whether:

a. EPA has followed guidance sufficient to support the findings in the toxicity assessment; and
b. Limitations exist in applying the cancer and noncancer values to the determination of safe levels in Libby.

1. Review Comment: We do not concur with the recommendation. The recommendation is not warranted because the SAB is in the process of completing a peer review of ORD's *Draft Toxicological Review of Libby Amphibole Asbestos*. The SAB review report will address strengths and limitations of ORD's draft assessment for the derivation on noncancer and cancer toxicity values.

OIG Response 40: Although EPA does not agree with our Recommendations (3a and 3b), the action specified through information to be addressed in the SAB report meets the intent of the recommendation. These Recommendations requires the SAB to comment on whether EPA followed sufficient guidance to support the findings in the Libby toxicity assessment; and, whether limitations exist in applying the cancer and non-cancer values to the determination of safe levels in Libby. Therefore, Recommendation 3a and 3b remain unresolved pending dispute resolution actions.

2. Review Comment: The OIG draft report includes certain statements made by the SAB Staff Office Director concerning some preliminary SAB review comments on the *Draft Toxicological Review of Libby Amphibole Asbestos*. The SAB review is still ongoing and, therefore, it is not

appropriate to include SAB review comments in the OIG report. The SAB review report is expected to be completed in October 2012. We strongly recommend deletion of the 4th, 5th, and 6th bullets on p.13 of the draft report.

OIG Response 41: The statements made by the former SAB Director are in response to questions posed by the OIG and are not taken from the SAB draft report. However, the SAB's final report is public. The SAB's report cited several areas that need more consideration, and provided recommendations to further enhance the clarity and strengthen the scientific basis for the conclusions presented in the draft toxicity assessment. Therefore, we find no justification to delete the text.

3. **Review Comment**: The first bullet on page 14 referring to the former SAB Director's statement about availability of information and data for SAB review is not specific to the Libby Asbestos toxicity assessment and should be deleted. This is a general statement about SAB experience in reviewing many EPA technical documents over the years. With regard to the ongoing SAB review of Libby Asbestos toxicity assessment, the SAB panel has requested additional data to verify the results of EPA analysis, and the Agency has been very responsive to the SAB request.

OIG Response 42: The OIG does not ignore systemic weakness observed (EPA does not provide all data to the SAB) when reviewing a specific topic such as the SAB review of the toxicity assessment. The issue affects all assessments the SAB performs for EPA as evidenced by the Deputy Chief of Staff who states, "This is a general statement about SAB experience in reviewing many EPA technical documents over the years." The former SAB Director stated that EPA did not provide all the data available on the toxicity assessment without a specific request from them.

4. Review Comment: The OIG report states on page 14 (third paragraph) the *"EPA and the SAB should resolve issues relating to developing specific guidance on study selection and dose response selection to improve the toxicity assessment*." As an external advisory body, the SAB provides review comments and makes recommendations through written reports. The SAB reports are advisory in nature, and the SAB has no(t) the authority to direct the agency or negotiate with the agency regarding the SAB recommendations. Should SAB make specific recommendations on this issue in its report, it is incumbent upon the agency to decide how to implement the recommendations.

OIG Response 43: The report makes no such recommendation, as the OIG is aware that the SAB has no authority to direct EPA actions. However, the EPA has turned to the SAB for scientific review of its risk assessments. It does not appear constructive for EPA to engage expert SAB panels but deny the panel information they believe is necessary to do their jobs effectively. This is an insufficient response to address such a serious issue. Resolution of the issues could reduce the limitations associated with SAB reviews of future EPA risk assessments. Additionally, resolution of these issues could improve public confidence in EPA risk assessments.

Appendix E

Distribution

Office of the Administrator
Deputy Administrator
Assistant Administrator, Office of Solid Waste and Emergency Response
Assistant Administrator, Office of Research and Development
Regional Administrator, Region 8
Agency Follow-Up Official (CFO)
Agency Follow-Up Coordinator
General Counsel
Associate Administrator for Congressional and Intergovernmental Relations
Associate Administrator for External Affairs and Environmental Education
Principal Deputy Assistant Administrator, Office of Solid Waste and Emergency Response
Deputy Assistant Administrator, Office of Research and Development
Deputy Regional Administrator, Region 8
Director, Washington Division, National Center for Environmental Assessment, Office of Research and Development
Director, Office of Superfund Remediation and Technology Innovation, Office of Solid Waste and Emergency Response
Public Affairs Officer, Region 8
Audit Follow-Up Coordinator, Office of the Administrator
Audit Follow-Up Coordinator, Office of Solid Waste and Emergency Response
Audit Follow-Up Coordinator, Office of Research and Development
Audit Follow-Up Coordinator, Region 8