



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

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MEMORANDUM

SUBJECT: Response to the OIG Draft Report, "Follow-Up Report: Better Planning, Execution, and Communication Could Have Reduced Delays in Completing the Libby Asbestos Toxicity Assessment (Assignment No. OPE-FY10-0012)"

FROM: Mathy Stanislaus, Assistant Administrator
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TO: Arthur Elkins, Jr., Inspector General
Office of Inspector General (OIG)

The memorandum transmits the Environmental Protection Agency's (EPA's) response to the Office of Inspector General (OIG) Draft Report entitled, "Follow-Up Report: Better Planning, Execution, and Communication Could Have Reduced Delays in Completing the Libby Asbestos Toxicity Assessment (Assignment No. OPE-FY10-0012)." EPA appreciates the opportunity to comment; however, in general, we have significant concerns with the OIG's Draft Report. The OIG Draft Report fails to acknowledge EPA's major strides in improving the understanding of the health effects of exposure to Libby amphibole asbestos, substantially reducing the exposure levels of the citizens of Libby through our cleanup efforts, and coordinating with community health organizations and the Agency for Toxic Substances and Disease Registry (ATSDR) to address the Public Health Emergency (PHE) in Libby, MT and the surrounding communities. Instead, the OIG Draft Report focuses primarily on EPA not meeting the initial draft Libby Action Plan (LAP) project timelines, which the OIG acknowledges as unachievable, without acknowledging our accomplishments or the fact that EPA's delay in meeting research timelines did not impede the conduct of the extensive cleanup activities that have occurred to date. While EPA appreciates the diligence with which the OIG has conducted their review of the LAP

progress and recognizes that there have been many challenges to conducting this review given the technical nature of individual projects within the LAP, EPA is unable to concur with most of the OIG's findings, conclusions, and recommendations due to the factual inaccuracies in the report and the lack of understanding about key EPA products and programs associated with the Agency's cleanup efforts in Libby, MT.

As requested, our response addresses the factual accuracy of the OIG Draft Report and provides concurrence or nonconcurrence with each recommendation, finding, and conclusion as directed by the OIG. Where EPA nonconcur, alternative language and/or an alternative remedy is provided. In addition to this response, we are providing several attachments: specific text corrections (Attachment 1), supporting information about site-specific cleanup activities in Libby, MT (Attachment 2), a list of peer-reviewed publications resulting from LAP studies (Attachment 3), the August 10, 2012 Memo from the Office of the Administrator to the OIG regarding comments in the OIG Draft Report on the EPA Science Advisory Board (SAB) review of Agency products (Attachment 4), and additional information regarding presentations EPA provided to stakeholders in 2007 and 2008 (Attachment 5). In our general comments below, we summarize EPA's significant accomplishments and paramount concerns.

EPA's Accomplishments

- **Substantial and significant progress has been achieved on important LAP Projects:**

The body of work completed under the LAP to date is significant. The 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. The basic research conducted under the LAP has resulted in 19 peer reviewed publications, eight of which were listed in the September 2011 LAP monthly report provided to the OIG. The Draft Toxicological Review of Libby Amphibole Asbestos was made available to the public in August, 2011. This toxicity assessment provides a Libby amphibole asbestos-specific Reference Concentration (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. 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. EPA has worked with ATSDR to define additional community health studies to investigate the health effects from nonoccupational exposure as well as to continue ongoing research of the health effects in workers previously exposed to Libby amphibole asbestos. Progress on these longer-term studies is described in the LAP monthly reports, all of which – through September 2011 – were provided to the OIG. Thus, while acknowledging that individual LAP projects have taken longer than initially anticipated, the EPA recommends the OIG Draft Report balance the OIG's concerns about meeting project milestones with recognition of the substantial and significant progress achieved to date on important LAP projects.

- **Substantial progress has been made in reducing asbestos exposure at the Libby Superfund site:** The EPA has been working in the Libby community since 1999 to characterize Libby amphibole asbestos in the environment, reduce environmental asbestos contamination, and evaluate the potential for human exposure. These cleanup actions are not dependent on the LAP

research agenda or the site-specific risk assessment and, therefore, have not been impeded by delays in LAP projects. The EPA has completed numerous cleanup actions to reduce community exposures at the Libby Superfund site including: removal of asbestos/vermiculite-contaminated soil from over 1600 properties (1.2 million tons of contaminated soil) and removal of asbestos/vermiculite-contaminated soil from major source areas (e.g., production, distribution, and storage facilities). These cleanup actions have focused on areas of highest contamination and have significantly reduced asbestos levels in Libby. However, cases of lung disease in citizens historically exposed to asbestos may not decrease in number or severity due to the long latency periods associated with asbestos-related disease. The cleanup activities are described in the Report to Congress on "Known Health Effects, Baseline Risk Assessment Approach, and On-Going Cleanup Activities at the Libby Asbestos Superfund Site, Libby, Montana" (May 2010) provided to the OIG. The EPA is addressing each operable unit (OU) through the Superfund process where remedial investigations and feasibility studies support proposed plans and Record of Decisions for final cleanup. Recently, the remediation of the former export plant (OU1) was completed, and the Riverfront Park was refurbished and opened for public use. Additional information on these and other site remedial actions are included in Attachment 2. **The EPA believes it is important for the OIG to convey that although individual LAP research projects have taken longer than initially anticipated, the additional time needed to complete these projects has not adversely affected the Agency's cleanup efforts to reduce exposures in Libby, MT.**

- **Significant progress towards addressing community health concerns has been made:** The determination of a PHE by the EPA and Department of Health and Human Services (DHHS) in June 2009 recognized the serious impact to the public health from the contamination at Libby and Troy (a town located near Libby) and underscored the need to provide health care for area residents who have been or may be exposed to asbestos and continued cleanup actions to reduce asbestos exposures. The primary consequence of this PHE is delivery of health care services. As part of the Libby Community Environmental Health Project, the DHHS has provided funding for asbestos-related medical care to Libby and Troy residents and has been coordinating with community health organizations to increase the community's capacity to provide health care. Further information about the PHE, DHS's Libby Community Environmental Health Project activities, and EPA's efforts to address the contamination that resulted in the determination of a PHE is available to the public at <http://www.epa.gov/libby/phe.html>. EPA disagrees with any implication that the declaration of a PHE made completion of the *Toxicological Review of Libby Amphibole Asbestos* the sole priority toxicity assessment for EPA. The PHE declaration accomplished its main purpose, which is to trigger provisions under CERCLA to allow the Federal government to provide medical care to the population in Libby, MT. **The EPA believes it is important for the OIG to convey that the longer than initially anticipated timelines for individual LAP research projects have not adversely affected the Agency's, ATSDR's, or the community's ability to address the contamination that led to the determination of the PHE or the public health needs in Libby, MT.**

As evidenced by progress in the site cleanup, LAP projects, and actions addressing the PHE, the EPA is committed to environmental restoration of the Libby Superfund sites. This includes assessing and mitigating potential health risks and reaching final remedy decisions as soon as possible. The EPA believes it is important for the OIG Draft Report to reflect the many EPA accomplishments, as well as

accurately identify issues of concern and areas for improvement. As a result, the EPA requests the OIG Draft Report disclose the EPA's progress on the LAP projects, accomplishments on site cleanup, and actions taken to address public health concerns, as outlined above. The OIG Draft Report uses the declaration of the PHE in Libby, MT, as a basis for recommendations regarding the relative priority and urgency of the Libby work, yet the OIG Draft Report does not document achievements and the progress of EPA programs that have actively addressed community health in Libby, MT. **It is important that the OIG Draft Report provides a complete and accurate accounting of EPA's progress.**

The Agency recognizes the importance of oversight on Agency functions. In reviewing the OIG Draft Report, however, we find numerous factual inaccuracies that challenge the utility of the OIG findings, conclusions, and recommendations. The text does not adequately represent the record and comments provided to the OIG by Agency staff. In addition the OIG Draft Report does not reflect a full understanding of key aspects of the LAP projects, the Libby Superfund Site cleanup, and the relationship of these activities to the Federal government's ability to address the PHE in Libby, MT. Thus in addition to the detailed responses below, we offer the following paramount concerns with the OIG's investigation, evaluation, and draft report.

Paramount Concerns

- **The OIG used draft timelines it recognized as unachievable as the basis for evaluating EPA progress:** The OIG Draft Report acknowledges that the initial draft LAP "milestones were not achievable," yet the investigation and resulting OIG Draft Report gauges the Agency's performance against these preliminary milestones. EPA clearly indicated in its April 2007 memo that the completion date was "tentative pending the completion of the detailed workplans." The tentative dates were revised once project scoping was completed and detailed workplans were developed. In order to provide a meaningful evaluation of EPA's progress and to determine which factors contributed to project delays, the OIG should gauge EPA's progress against project timelines developed after project scoping and detailed workplans were completed. An evaluation of why the initial draft timelines were not met, when the OIG (and EPA) considered them unachievable, is of little utility to the Agency or its interested stakeholders. Of greater utility would be an examination of LAP progress against the more developed timelines which reflect completed project scoping.
- **The OIG provides no foundation for its assertion that establishing a charter and single authority over LAP activities would have avoided project delays:** The OIG Draft Report does not document where lack of coordination affected the progress of LAP activities. Although the OIG does discuss many of the factors that challenged specific project timelines, the OIG Draft Report does not cite lack of coordination as a factor for any of the specific projects reviewed. In fact, the record demonstrates cross-Agency coordination in every stage of the LAP (see response B.1 below), including project definition and planning to identify and obtain needed resources as well as coordinate among the program offices to resolve issues that arose in conducting this research program. EPA has provided information documenting that revisions to project timelines were needed because of technical difficulties and the complexity of the projects, not because of a lack of coordination. The information provided in the OIG Draft Report does not support the OIG's conclusion and recommendation that EPA should establish a charter and single authority

to manage LAP activities.

- **The OIG Draft Report does not consistently use the term “toxicity assessment” correctly:** Despite detailed information provided by our offices 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. The OIG Draft Report in several places continues to confuse an agent-specific toxicity assessment and a site-specific risk assessment. Although the OIG correctly indicates that a toxicity assessment is distinct from a site-specific risk assessment in the introductory sections of the report, these terms are confused in later sections. Additionally, the term “toxicity assessment” is sometimes used in the OIG Draft Report to refer to the whole of the LAP activities. The terminology used by the OIG in later sections is so inconsistent it is difficult to understand the intended meaning of many passages (i.e. recommendation 2b, recommendation 3b, findings A.2, D.1, G.1, G2). As these Agency’s products are the heart of the purpose of the LAP, it is unclear how the OIG can evaluate our progress and adequately communicate their findings without a working understanding of these EPA products. Changes to the OIG Draft Report, including the title, main text, conclusions, and recommendations, are needed in order to rectify this misunderstanding.
- **OIG discussion of external peer review and SAB activities:** 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 (see Attachment 4). The SAB is charged by EPA to coordinate independent external peer reviews of Agency documents. As such, EPA cannot direct the SAB panels as recommended in the OIG Draft Report. Additionally, it is premature for the OIG Draft Report to cite findings of the SAB review of the External Draft Toxicological Review of Libby Amphibole Asbestos as the SAB has not finalized its review.

As requested by the OIG, and in order to improve the factual accuracy and utility of the OIG Draft Report, EPA has provided specific responses to the recommendations, findings and conclusions, as well as specific changes and corrections to the text (Attachment 1). EPA maintains that with additional consideration of the record and the facts at hand, and a better understanding of the LAP projects, the OIG’s evaluation of EPA’s activities will be more useful and better serve both the public and the Agency with an accurate and useful assessment of EPA’s progress on the LAP activities. Specifically, the OIG should reconsider their statements that EPA communications to the Senate were “misleading”. **Therefore, the EPA requests the OIG incorporate the provided responses and reconsider the findings, conclusions, and recommendations of the OIG Draft Report in light of this information.**

Agency Responses to Main Recommendations of the OIG Draft Report (Page 21).

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.

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.

EPA does not agree with the recommendation as written, as it suggests that EPA does not already keep an up-to-date schedule. The LAP coordinator maintains a current schedule of all LAP activities and advises senior management of the current schedule during regular updates. The OIG does not offer information in the OIG Draft Report that supports a need for the above recommendation.

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."

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 does not agree that providing original and revised plans to the stakeholders is a useful or productive endeavor. As pointed out by the OIG, the original draft timelines for the LAP individual projects were greatly underestimated in most cases. Thus, providing these original schedules to stakeholders at this junction would provide no benefit. Considering the progress EPA has made, this information would be confusing rather than clarifying or helpful at this time.

We believe the EPA has kept stakeholders informed. The record shows that EPA has provided monthly status reports to Congress, addressed LAP status in Senate testimony, attended regular meetings with interested Senate staff, and responded to all requests for information on LAP projects. EPA has briefed community stakeholders on LAP project status and timelines across the course of the projects. Specifically, Agency officials briefed community stakeholders in a variety of forums on all LAP projects in September 2007, February 2008, May 2008, September 2008, and May 2009, providing project descriptions, progress, dates for interim milestones, and available schedules (see response to F.1 for details). The online minutes of the Libby Asbestos Technical Advisory Group (LATAG) reflect those briefings. Although EPA did not contrast these timelines and milestones to the draft timelines provided in the Agency's response to the OIG (April 2007), community stakeholders had the best available project status and timelines well before September 2009. Additionally, ATSDR provided a fact sheet in June 2008 on their research (Projects 10 and 11 of the LAP) indicating research would take 5 years. Thus, community stakeholders did have information available to them indicating LAP projects would not be complete by September 2009.

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.

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. EPA staff have provided documentation of the ongoing project coordination between the AA-ships conducting LAP projects. The roles and responsibilities for LAP projects have always been clear. Project planning or execution has not been adversely affected by not having a formal charter. The OIG has offered no specific incidence or example of a project milestone being negatively impacted through lack of coordination or a misunderstanding of roles and responsibilities within the Agency. [Response B.1 provides details of the intra-agency LAP project coordination.]

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.

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.

The integrative site-specific risk assessment will be released as a draft document for public review and comment. All interested parties including community and industry stakeholders may review the document and provide comments to the EPA at that time. To aid in the technical review of the risk assessment in the interest of the community, the LATAG has been established and is funded by an EPA grant. The LATAG is a standing organization for external technical review and comment on EPA documents, actions, and issues resulting from the Superfund process at the Libby Superfund site. Therefore EPA will continue to adhere to its process with respect to review of site-specific risk assessments.

Alternative Remedy: No corrective action needed.

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.

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.

If the OIG intends that the SAB should review how EPA determines “acceptable levels,” that is a risk management decision that considers not just risk but other factors such as engineering feasibility, background levels, or other factors as defined in the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) statute and implementing regulations. It is beyond the scope of the SAB to offer comment on such risk management decisions.

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.

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. The contract with the University of Cincinnati (UC) included work essential to the development of a site-specific RfC for use in the Libby, MT risk assessment and in support of risk management decisions and remedy selection. As such, the work was integral to Superfund site cleanup actions. The site-specific risk assessment includes site-specific exposure measurements and toxicity values. Where no toxicity values are available, site-specific values are needed. Development of the RfC was initially scoped as a site-specific endeavor. This work was and continues to be as important and relevant to site cleanup and remedy selection as was the site exposure monitoring and could be carried out in parallel to continued cleanup efforts.

The OIG is correct in that the interagency agreement is specifically for work to support site cleanup and remediation activities for Libby, MT and the surrounding community. However, EPA disagrees with the OIG's interpretation that only individuals physically located in Libby, MT can perform actions under this IA. There are many aspects of the work supporting cleanup activities for Libby, MT that are appropriately performed at locations outside of the physical vicinity of Libby, MT. Examples of this include sample analysis, contract management, and project management functions. Similarly, the UC scientists do not need to be physically located in Libby, MT to conduct their scientific study in support of the site-specific RfC. Thus, EPA disagrees with the OIG's finding that the Volpe IA was an inappropriate contracting mechanism based on the requirement that all work conducted under this IA must occur physically in Libby, MT.

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

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

EPA Response: Nonconcur

EPA does not concur with the recommendation to develop a new process for setting priorities across the Office of Research and Development (ORD) for pending and ongoing research. EPA believes that this draft OIG recommendation is overly broad, the criteria are vague, and the recommendation is beyond the scope of the investigation. EPA's mission is complex and encompasses working on many high-priority activities. EPA has a research planning process that sets priorities for funding and conducting research across the ORD's laboratories and centers. This ORD planning process obtains input from EPA programs and Regional Offices as well as from the scientific community and advisory groups such as the EPA's SAB and Board of Scientific Counselors for planning its research and making decisions about which research is conducted.

With respect to toxicity assessments specifically, ORD has a process of soliciting nominations for Integrated Risk Information System (IRIS) assessments. This process solicits input from EPA programs, Regional Offices, and the public regarding Agency and public need and public health impact. That process involves periodic input from EPA offices and a Federal Register notice seeking nominations and information from the public.

EPA did determine that assessing the toxicity of Libby amphibole asbestos was a high priority. EPA assembled a team with the appropriate expertise within and outside of the Agency and assigned a high priority to development of an assessment of the toxicity of Libby amphibole asbestos.

However, EPA disagrees with any implication that the declaration of a PHE made completion of the *Toxicological Review of Libby Amphibole Asbestos* the primary or highest-priority toxicity assessment for EPA. The PHE declaration accomplished its main purpose, which was to trigger provisions under CERCLA to allow the Federal government to provide health care to the population in Libby, MT. This health care was provided by ATSDR and the local community health agencies, not by EPA. More importantly, neither asbestos removal actions nor public health actions in Libby, MT have been delayed pending a final *Toxicological Review of Libby Amphibole Asbestos*.

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.

EPA does acknowledge that some portion of the delay in the Toxicological Review was due to EPA work completing other equally high-priority assessments. However, as noted, EPA believes that there are multiple high-priority assessments, and the most efficient use of EPA's expert staff and resources often entails staff with particular expertise working on more than one priority assessment at the same time. The OIG did not evaluate ORD's process for priority setting, which places this recommendation outside the scope of the OIG investigation.

EPA also disagrees with any implied finding that the delay in completing the *Toxicological Review of Libby Amphibole Asbestos* was due solely to competing demands. As EPA explained to OIG staff, there were multiple reasons the draft toxicological review took longer than initially expected. The OIG should present the other factors which impacted project timelines, as noted below.

- The time needed to complete the exposure-response modeling for the Libby amphibole asbestos IRIS assessment was initially underestimated. Modeling of epidemiology data is complex and as such it is difficult to predict the level of effort and resources needed until one evaluates the data and begins to conduct the modeling.
- The time needed to resolve legal issues regarding the protection of personal medical information in data shared between National Institute for Occupational Safety and Health (NIOSH) and EPA was longer than anticipated.
- A science-based decision to update the cancer mortality data for the Libby worker cohort was made in order to provide more information on rates of mesothelioma. This increased the amount of time needed to update the NIOSH database that EPA used for the exposure response modeling, as well as the time needed to conduct additional exposure response modeling with these new data.

- The RfC was originally begun as a site-specific toxicity value, which does not require the intra-agency, interagency, and external peer review process that accompanies an IRIS document. Thus, the original draft RfC schedule did not include time for these review steps in the IRIS process or the corresponding time needed to craft appropriate responses to comments and document revisions. The shift to an IRIS document also resulted in additional work on model evaluation and other content development.

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.

Agency Responses to Findings in the OIG Draft Report

A) Original Project Milestones Were Ambitious

A.1) OIG finding (Page 7)

"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."

EPA Comments: Nonconcur

- EPA 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.
- The draft project timelines were submitted to the OIG while EPA was still determining the scope and resources required for each project (see "*Draft Planned Completion Dates for Individual Studies*," in EPA's April 2007 follow-up response). In addition, with respect to the five National Health and Environmental Effects Research Laboratory (NHEERL) studies, EPA stated at the time "... however, this date is tentative pending the completion of the detailed workplans." Further, EPA made the OIG aware that workplans had not been developed as of the date of the April 2007 memo for all 12 proposed studies, stating that "*detailed workplans are currently being developed and will include consultation with other Agencies ...*" As project planning continued, EPA refined the initial timelines to reflect the more detailed project scoping and planning.
- EPA does acknowledge that the initial draft project milestones submitted to the OIG were ambitious. Updated milestones and project plans were developed in 2008, after detailed workplans were peer-reviewed. These updated milestones and project plans were presented in public meetings in 2008. September 2009 is when EPA initially notified the OIG of revisions to the draft initial milestones, followed by a formal request for extension dated October 20th 2009.

Proposed revised text:

"The EPA provided the OIG with *Draft Planned Completion Dates for Individual Studies* which were ambitious and specifically noted that some of the completion dates were "*tentative pending the completion of the detailed workplans.*" As project planning continued, EPA developed completion dates that reflected a better understanding of the scope, level of effort, and time

needed for each of the individual projects under the LAP. However, EPA did not provide the OIG with these updated completion dates until September 2009. At that time, EPA provided the updated completion dates as well as some of the factors which resulted in changes to the completion dates.

A.2) OIG finding (Page 7):

“These revisions have impacted the Agency’s timely execution of a comprehensive amphibole asbestos toxicity assessment to determine the effectiveness of the Libby removal actions.”

EPA Comments: Nonconcur

- The action of revising the timelines did not impact the execution of the LAP projects. The action of revising the timelines reflected – not caused – project delays.
- This sentence is inaccurate because the "effectiveness of the Libby removal actions" will be determined by the site-specific risk assessment, which utilizes the toxicity assessment. The toxicity assessment is only one part of the risk assessment. The toxicity values derived in the Toxicological Review of Libby Amphibole Asbestos (toxicity assessment) will be used in the site-specific risk assessment. Exposure measurements at the Libby Superfund site are also integral to the site-specific risk assessment.
- The site-specific risk assessment will also be used to inform the need for and nature of future cleanup actions.
- Removal actions, which have significantly reduced exposures to Libby citizens, have not been impeded by delays in the LAP projects.

Proposed revised text:

“EPA estimated the baseline risk assessment including a comprehensive toxicity assessment would be complete in September 2010 (EPA April 2007). EPA revised this completion date to September 2012 citing substantial analytical and statistical complexity associated with exposure characterization and contracting delays for the RfC as the basis for the revised completion date (EPA Memo to the OIG, 20 Oct 2009). EPA has further revised the completion date for the site-specific risk assessment, indicating it will be completed six months after the Toxicological Review of Libby Amphibole Asbestos (toxicity assessment) is finalized (expected September 2013) and the Libby amphibole asbestos toxicity values (the RfC and IUR) are available. The site-specific risk assessment will be used to establish cleanup levels at the Libby Superfund sites and will inform the effectiveness of removal actions. As noted above, the removal actions to significantly reduce exposures to the community have not been impeded by delays in either the toxicity assessment or the site-specific risk assessment

A.3) OIG finding (Page 9):

“We understand that unforeseen events are unavoidable and can delay project milestones. However, the risk that the Libby Action Plan would not be completed on time were known but not disclosed. Undisclosed risks in a corrective action plan deny stakeholders the ability to understand the problems and offer meaningful solutions.”

EPA Comments: Nonconcur

- EPA disclosed to the OIG in the April 2007 memo that the draft timelines were subject to change. Specifically, EPA provided *“Draft Planned Completion Dates for Individual Studies”*

on which the overall timeline for the LAP was based. Additionally, with respect to the five NHEERL studies, the memo stated the completion date was “*tentative pending detailed work plans.*” Further, EPA made the OIG aware that workplans had not been developed as of the date of the April 2007 memo for all 12 proposed studies, stating that “*detailed workplans are currently being developed and will include consultation with other Agencies... .*”

- EPA does not agree with the OIG’s interpretation that draft timelines provided in April 2007 should be the baseline against which the EPA’s progress on LAP projects should be evaluated. Thus disclosure of the ‘risks’ of not meeting these preliminary draft timelines to other stakeholders is not a reasonable expectation.
- EPA did provide information to both internal and external stakeholders, including the community and congressional staff as well as senior EPA managers on project status and schedules and/or dates of specific interim milestones prior to the OIG inquiry in September 2009 (See details below in the response to item F.1). In these documents, EPA provided detailed descriptions of the complex research being conducted, disclosing that the projects were expected to take years in some cases. As project delays were in many cases due to the technical difficulties and complexity of the projects that make up LAP activities, communication of the nature and scope of the experiments proposed was a meaningful disclosure of the factors that contributed to project delays.
- EPA acknowledges that we did not provide updated project timelines to the OIG prior to September 2009 as a follow-up to our April 2007 draft timelines.
- EPA first apprised the OIG of changes to the Corrective Action Plan on September 11, 2009, in an email to Dwayne Crawford from Johnsie Webster. On September 24, the OIG requested a meeting (email from Dwayne Crawford to Johnsie Webster) for the following week, which occurred on September 30, to discuss the Libby Corrective Action milestones. EPA submitted revised completion dates within one week of meeting with the OIG.

Proposed revised text:

“We understand that unforeseen events are unavoidable and can delay project milestones. We also understand that the initial milestones received by the OIG were draft. Regardless, EPA should have apprised the OIG of changes in the proposed schedule well before the draft milestones submitted to the OIG in April 2007 were revised. The LAP coordinator kept both senior management and community stakeholders advised of project schedules and status, including some of the technical issues which contributed to project delays. Thus, although the OIG was not informed on an ongoing regular basis, EPA did update both internal and external stakeholders of project schedules and progress. EPA’s communication with external stakeholders would have been improved if all factors contributing to project delays had been explicitly provided.”

B) No Charter Established

B.1) OIG finding (Page 9):

“*EPA considered developing a charter but decided against it. The project charter could have addressed areas such as 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 participation from staff from the other EPA program offices. This management approach lacks a single figure with the authority to ensure project milestones were being met, delineate responsibilities, oversee funding, and ensure proper channels of communications."

EPA Comments: Nonconcur

- EPA does not agree with the overall characterization of the LAP management portrayed in the above text. While EPA acknowledges no office had authority over staff from other EPA program offices, the LAP Coordinator did manage the overall project to ensure: that projects were adequately scoped and planned; that the needed resources were identified and obtained; and that individual program offices coordinated to resolve issues that arose in conducting this research program.
- The OIG Draft Report provides no specific examples or documentation that the lack of a project charter or the lack of a single Agency authority contributed in any way to the actual project delays of any portion of the LAP.
- EPA believes the record demonstrates cross-Agency coordination in every stage of the LAP:

Project development and planning: The LAP was scoped and developed in a cross-Agency meeting held in January 2007 where scientists, engineers, and management from the major offices were all represented, including Region 8, ORD/NHHERL, ORD/NCEA, and Office of Solid Waste and Emergency Response (OSWER)/Office of Superfund Remediation and Technology Innovation (OSRTI). A written plan was drafted and agreed upon by all offices. Additional cross-Agency scoping of projects 10 and 11 began in July 2007 in meetings which included ATSDR as the lead Agency for the epidemiological studies.

Ongoing Coordination for LAP Activities: The overall LAP effort has been overseen by three senior Agency managers: AA for OSWER, AA for ORD and the Region 8 Regional Administrator. This management structure began in early 2007 and has continued to present through Administration and appointed senior management changes. Both the former and current senior management have been briefed periodically on progress of LAP projects.

- 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. The LAP coordinator has routinely held regular conference calls (e.g. bi-weekly), organized LAP conference meetings once a year, and prepared briefing materials for senior management of LAP activities.
- The abstracts and minutes of the annual meetings serve to document project status each year and demonstrate that all members of the LAP research group and their supervisors across the Agency were advised of the status of all the individual projects. Research staff and first line supervisors were part of the annual meetings, as were research partners in other Federal Agencies (e.g. ATSDR and United States Geological Survey).
- The LAP participants across the Agency communicated directly as needed on specific projects, and there was constant communication within the group through e-mail

distribution lists where project coordination materials and research findings could be conveyed.

- The regular LAP conference calls included discussion of ongoing studies including presentation of preliminary results, coordination of LAP activities between offices, discussion of LAP progress, and in some cases additional studies to meet LAP goals. Minutes of the meetings were prepared and distributed throughout the group to include supervisors of each working group.
- Where two offices needed to coordinate more closely, meetings on specific topics between the different offices occurred as frequently as weekly (e.g., coordination between Region 8 and NCEA for RfC development and work on the combined toxicity assessment, coordination between NHHERL and Region 8 staff on generating test materials and fiber analysis of tissue samples.)

Coordination and Review of LAP Products: All products (both EPA documents and individual research reports) were shared among the members of the LAP prior to forwarding for review outside of the Agency. All LAP members are encouraged to comment on and discuss the draft documents. Additionally, the LAP was formally included in the IRIS Program Agency Review of the both the internal draft RfC and the internal draft Cancer Evaluation.

Proposed revised text:

“EPA considered developing a charter but decided against it. Alternatively, EPA chose to have the overall LAP effort overseen by three senior Agency managers: AA for OSWER, AA for ORD and the Region 8 Regional Administrator. These managers approved the original LAP projects and were briefed periodically on their progress. A LAP Coordinator, appointed from management of one of the participating offices, was responsible for cross-Agency coordination of all of the individual projects within the LAP, including: defining measurable objectives, developing project plans and milestones, identify needed resources, and coordinated LAP progress across the Agency.

Project objectives, resources, funding, and schedules were established and managed appropriately. Coordination between offices did not require a single authoritative figure. None of the documented project delays stemmed from lack of coordination between EPA offices, lack of a single authority, confusion over roles, or lack of funding.”

C) Contracting Issues Delayed Noncancer Assessment

C.1) OIG finding (Page 11):

“We found no evidence that suggests that these officials took action to expedite the contracting process to ensure established timeframes were met for issuing the sole source contract to the University of Cincinnati. Consequently, EPA did not get the better, faster, and innovative contracting through use of the Volpe Center.”

EPA Comments: Nonconcur

- EPA did take action to try and expedite contracting procedures by choosing to use an existing contract mechanism through the Volpe Center. Initially, EPA officials judged that using an

- existing contract mechanism through Volpe would be the most expeditious contracting mechanism; the use of an existing contracting mechanism is often much faster than beginning a new contracting effort.
- EPA does not agree with the OIG's characterization of the contracting processes used to obtain a contract with the UC. Utilization of an existing contracting mechanism for work that is in-scope of the Statement of Work is an appropriate exercise of contracting mechanisms.
- When there was a recognition that efforts to use the existing contract was taking longer than expected, it was the opinion of EPA that the use of the Volpe contract was still more efficient; cessation of the current contracting efforts and starting a new contracting mechanism would take additional time.
- Although we acknowledge the contracting effort took longer than predicted, the OIG does not support the case that use of the Volpe center was the cause of the delays. The requirement for sole source sub-contracting accounted for much of the time needed for awarding the UC contract.
- The OIG Draft Report indicates contracting took 19 months. However, the OIG includes development of the statement of work (six months) which is not part of the procurement process and would have been unchanged by procurement mechanism. Also, work with UC to prepare and negotiate the work plan and cost proposal took five months. This time was not a function of the contracting mechanism. The remaining eight months is not an unreasonable amount of time to issue sole source solicitation of this magnitude.

Proposed revised text:

“Although EPA used an existing contract to expedite the contracting process to ensure established timeframes were met for issuing the sole source contract to the UC, significant delays occurred. Time needed for development of the statement of work by Region 8, work plan development, and cost estimates by the UC researchers were independent of the contracting mechanism chosen by EPA. Consequently, EPA not getting the better, faster, and innovative contracting it expected through use of the Volpe Center was not a function of the contracting mechanism, but rather due to other factors.”

C.2) OIG finding (Page 13):

“The Director stated that the Volpe Center does not do, nor has the authority to do, assisted acquisitions or so called “pass through acquisitions.” The Director further stated that EPA requested the Volpe Center’s assistance for its technological expertise, and not acquisition services. However, the evidence we obtained contradicts this assertion.”

EPA Comments: Nonconcur

- 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. Region 8 has an IA to provide this type of technical assistance for the Libby Superfund cleanup.
- The Volpe Center contract scope included work essential to the development of a site-specific RfC for the Libby, MT risk assessment and in support of risk management decisions and remedy selection. As such, the work was integral to Superfund site cleanup actions.
- The IA with Volpe was for the conduct of Removal Actions and for the completion of Remedial Investigations. This IA was signed with Volpe due to the technical expertise provided through

this agency. A Superfund Remedial Investigation includes a Human Health Risk Assessment and, Volpe can provide the support necessary to complete that task. If additional assistance, outside the abilities of Volpe, were needed to conduct the Human Health Risk Assessment, the Volpe Center was to provide services necessary to complete that task. Since the UC was the only agent capable of providing the data on the Marysville, OM Scott cohort exposures, which was used to derive a noncancer RfC for Libby asbestos, Volpe provided the services required to obtain that assistance. All of those activities are entirely within the scope of the IA with Volpe.

Proposed revised text:

“The Director stated that EPA requested the Volpe Center’s assistance for its technological expertise, and not acquisition services. Development of a site-specific RfC was integral to risk assessment in support of risk management decisions and site remedy for the Libby Superfund site and is therefore within the scope of the EPA IA with the Volpe Center.”

C.3) OIG finding (Page 12):

“We believe that Region 8’s use of the Libby clean-up 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 in Ohio. ... Even allowing for a liberal interpretation of the enumerated tasks, we did not find language that would include contracting with the University of Cincinnati for a study that would assist EPA in developing an RfC.”

EPA Comments: Nonconcur

- The EPA disagrees with the OIG finding that the contract work was outside of the scope of the IA. The contract included work that was integral to Superfund site cleanup actions.
- Region 8 adheres to the FAR with regard to 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 contract included work essential to the development of a site-specific RfC for the Libby, MT risk assessment and in support of risk management decisions and remedy selection. The site-specific risk assessment includes site-specific exposure measurements and toxicity values. Where no toxicity values are available, site-specific values are needed. The RfC was initially scoped as a site-specific toxicity value. Thus, this work is equal in importance and relevance to site remedy selection and cleanup as is the exposure monitoring.
- The IA is specifically for work to support site cleanup and remediation activities for Libby, MT and the surrounding community.
- EPA disagrees with the OIG’s interpretation that actions under this IA can only be performed by individuals physically in Libby, MT. There are many aspects of the work supporting cleanup activities for Libby, MT that are appropriately done at locations outside of the physical vicinity of Libby, MT. Examples of this include project management, sample analysis, and data analysis, which Volpe and its subcontractors also conducted. Similarly, the UC scientists do not need to be physically located in Libby, MT to conduct their scientific study in support of the site-specific RfC.

Proposed revised text:

“We believe that Region 8’s use of the Libby cleanup interagency agreement to award a contract to the University of Cincinnati was within the scope of work under the agreement between Region 8 and the Volpe Center”

D) Risk and Toxicity Assessment Guidance and Science Advisory Board Review

D.1) OIG finding (Page 14):

“EPA should determine whether the SAB or another organization should review the risk assessment. That review should be an assessment of the risk involved in not completing all the required studies of the Libby Action Plan.”

EPA Comments: Nonconcur

- Site-specific risk assessments are released for public comment and do not undergo a separate expert peer review as they are not new science. They represent the application of EPA policies and guidance.
- The site-specific risk assessment will be released as a draft document for public review and comment. SAB review is not warranted and would unnecessarily delay the final remedy selection for site cleanup.
- An SAB review of the site-specific risk assessment would require the SAB to begin a new review process, including potentially selecting a new SAB review panel. This action would, therefore, add significant time to completion of a final site-specific risk assessment and thus delay final remedy selection and finalization of the Record of Decision for the Libby Superfund site.
- The intention of the statement “That review should be an assessment of the risk involved in not completing all the required studies of the Libby Action Plan” is unclear. If we consider “risk” in this context to refer to the implications of not completing all the LAP studies on the adequacy of the toxicity assessment, then this is already addressed by the ongoing SAB review. The Draft Toxicological Review of Libby amphibole asbestos will provide toxicity values for use in the development of the site specific risk assessment. The Toxicological Review (also referred to as toxicity assessment in this report) discusses uncertainties in both the derivation of the IUR and the RfC, some of which may be informed by LAP studies not yet completed. Uncertainties may be addressed quantitatively through “uncertainty factors” or addressed qualitatively. The SAB panel currently reviewing this document is charged with addressing uncertainties. The charge specifically asks the panel:
 - “Please comment on whether the document adequately describes the uncertainties and limitations in the methodology used to derive the RfC [Reference Concentration] and whether this information is presented in a transparent manner.”
 - “Please comment on whether the document adequately describes the uncertainties and limitations in the methodology used to derive the IUR [inhalation unit risk] and whether this information is presented in a transparent manner.”
- The site-specific risk assessments for the Libby Superfund sites will also have a discussion of uncertainties in the site-specific risk estimates. EPA will reflect where there are data gaps in the current knowledge and the resulting uncertainty in our understanding of the potential for health effects. The risk assessment may include uncertainties in the derived toxicity values, as well as

uncertainties in exposure measurements and other factors that contribute to estimates of lifetime risk. These uncertainties are considered by the Agency in site-specific risk management decisions as defined in CERCLA statute, implementing regulations, and policy and guidance.

Proposed revised text:

None. Recommend the text be deleted.

D.2) OIG finding (Page 14):

“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.”

EPA Comments Nonconcur

- The OIG should strike this statement as it is outside the scope of this investigation.
- The Office of the Administrator responded to this text as well. Please see their response in Attachment 4.

Proposed revised text:

None. Recommend the text be deleted.

D.3) OIG finding (Page 14):

“The SAB review should clearly state any limitations on applying the RfC or inhalation unit risk (IUR) when other than PCM methods are used.”

EPA Comment: Nonconcur

- EPA cannot direct the SAB review panel. (See Attachment 4)
- The charge to SAB reviewers included identifying the limitations and uncertainties of the toxicity assessment, thus this issue is currently being addressed in the SAB review. (See response D.1 above.)

Proposed revised text:

“EPA has requested that the SAB Panel identify the limitations and uncertainties of the toxicity assessment including the derivation of both the RfC and cancer IUR.”

D.4) OIG finding (Page 14):

“We also agree with the SAB that external reviewers should be provided with all available documentation at the start of their review. This will avoid delays and make the Agency’s work transparent.”

EPA Comments: Nonconcur

- The OIG Draft Report is incorrect regarding provision of information when it states “EPA only provides information upon request.”
- EPA provided the SAB with extensive documentation in the *Draft Toxicological Review of Libby Amphibole Asbestos* including the basis for study selection and details of exposure response modeling.
- However, the EPA cannot always anticipate what further information a peer review panel will want to review, and review panels often request additional information from the Agency. In this

case, panel members requested additional information on statistical fit of various exposure response models, the raw data for air sampling for the Marysville, OH cohort, and the original data files on health effects in the workers. EPA complied with the requests for air sampling data and additional details on statistical fit. Although EPA could not provide all of the information on individual study participants due to Privacy Act requirements, EPA staff did provide data summaries to answer the questions of the SAB Panel members without providing the individual personal data. The SAB Panel was appreciative of and satisfied with EPA's responses.

Proposed revised text:

None. Recommend the text be deleted.

E) Competing Priorities and Unplanned Work Delayed Cancer Assessment

E.1) OIG finding (Page 14):

"Although this study is now complete, it was delayed due to ORD/NCEA competing priorities and to additional unplanned work that ORD/NCEA personnel realized was needed."

EPA Comments: Nonconcur

- The toxicity assessment is not yet complete. The external peer review Draft *Toxicological Review of Libby Amphibole* was released for public comment and SAB review in August 2011. The toxicity assessment is estimated to be completed and posted in the IRIS database in September 2013.
- The OIG assessment of project delays is based on preliminary draft timelines provided in EPA's April 2007 memo. However, both the OIG and EPA acknowledge that the September 2009 completion date for an IRIS assessment initiated in 2007 was not realistic.
- EPA does acknowledge that some portion of the delay in the Toxicological Review was due to EPA also working to complete other high priority assessments. However, not all of the delay in completing the cancer evaluation portion of the *Toxicological Review of Libby Amphibole Asbestos* was due to competing demands on EPA. As EPA explained to the OIG, there were multiple reasons the draft toxicity review took longer than initially expected in addition to competing priorities. These included:
 - The time to resolve legal issues regarding the protection of personal medical information in data shared between NIOSH and EPA was longer than anticipated.
 - A science based decision was made to update the cancer mortality data for the Libby worker cohort to provide more information on rates of mesothelioma. This necessitated extra time to update the NIOSH database EPA used for the exposure response modeling as well as the time needed to conduct additional exposure response modeling with these new data.
 - Estimating the total time required for completion before starting the project was complex (e.g., level of effort needed for exposure-response modeling, time allotted for document review and revision).
 - The work needed to combine the cancer and noncancer evaluations into Draft *Toxicological Review of Libby Amphibole Asbestos* was not in the original plan.
- The OIG should recognize that the current Toxicological Review of Libby Amphibole Asbestos includes not only the cancer evaluation but also the RfC derivation. Thus when evaluating whether EPA met its deadline for the cancer evaluation, it should be acknowledged that

incorporation of the site-specific RfC into the Libby amphibole asbestos IRIS assessment resulted in additional work on document development and model evaluation.

Proposed revised text:

“The external peer review Draft *Toxicological Review of Libby Amphibole* was released for public comment and SAB review in August, 2011. The assessment is estimated to be completed and posted in the IRIS database in September 2013. There are numerous factors which contributed to extended timelines: (1) longer than anticipated time to resolve legal issues regarding the protection of personal medical information in data shared between NIOSH and EPA, (2) a science based decision to update the cancer mortality data for the Libby worker cohort to provide more information on rates of mesothelioma, {necessitating extra time to update the NIOSH database EPA used for the exposure response modeling as well as the time needed to conduct additional exposure response modeling with these new data}, (3) complexity in estimating the total time required for completion before starting the project, and (4) the decision to combine the RfC with the cancer evaluation resulting in a Toxicological Review of Libby Amphibole Asbestos. Work on other high profile toxicity assessments was also cited as a contributing factor to the overall delays.”

F) Overall Communication of Plan Execution Could Be Improved

F.1) OIG finding (Page 16):

“We found that communications with internal and external stakeholders was not timely and did not fully disclose the reasons for the delays.”

EPA Comment: Nonconcur

- We believe the EPA has kept stakeholders informed. Internal and external stakeholders have been provided with project updates in a variety of forums. Although the level of detail of the information provided varied, in general project scope, status of individual projects, milestones, and/or expected project durations were often addressed.
- We acknowledge that while factors which contributed to extended timelines were included in these materials in many cases, the EPA did not explicitly link these factors with specific project delays.
- The record shows that EPA has provided monthly status reports to Congress, attended regular meetings with interested Senate staff and responded to all requests for information on LAP projects. Additionally, status of the LAP was addressed in Agency testimony in September 2007 (see Attachment 5), where it was indicated that work on LAP projects would extend beyond the fall of 2009. Specifically:
 - The former OSWER AA indicated in September 2007 that projects were anticipated to take 3 years, while acknowledging that work plans were still under development,
- 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. Thus community stakeholders did have information available to them indicating LAP projects would not be complete by September 2009. Specifically:

- In September 2007, the LAP coordinator and NHEERL researchers went to Libby, MT and briefed community stakeholders on LAP activities (see Attachment 5). Estimated project costs and current project status were discussed as well as details of the laboratory research. The slides convey that project plans had just been developed for the NHEERL research and would be published in the Federal Register in September 2007 for public comment. Although the slides for this meeting did not have project schedules attached, press coverage (Western News, Friday, October 5, 2007) of the meetings stated “The most exciting entourage to descend on Libby in the last eight years was the group of Environmental Protection Agency scientists who presented their action plan for the toxicology studies *that will be conducted over the next three to four years.*” Thus it seems the message was communicated in these meetings that these studies would take more than two years.
- EPA briefed the LATAG on the scoping and planning for the long-term epidemiological studies conducted in collaboration with ATSDR. Although timelines had not yet been developed for this research, the meeting notes do indicate that these were long term projects, thus not expected before the site-specific risk assessment. (See presentation in Attachment 5.)
- EPA included an update of LAP activities in a May 2008 town meeting. EPA staff specifically noted that the cancer IUR would begin internal IRIS Program Agency review in the fall of 2009, that the NHEERL studies were “long term”, and that funding was still pending on two of the studies. (See presentation in Attachment 5.)
- ATSDR (the lead on projects 10 and 11 of the LAP) provided a fact sheet to the community in June 2008 indicating the epidemiological studies could take five years. (See Attachment 5.)
- The LAP Coordinator and team members briefed the community in September 2008 on the status of the NHEERL and NCEA research efforts. The scope and effort required for these tasks were disclosed to the stakeholders. Briefing slides and posters from this trip document that EPA representatives informed the community in several forums of the status, progress, and schedule for the cancer evaluation (September 2010). The status and progress of each NHEERL research project was reviewed, including dates of interim milestones indicating projects would not be complete by the end of 2009. (See presentation in Attachment 5.)
- In addition to the internal briefings for senior management summarized in the OIG Draft Report (Page 16), the LAP coordinator briefed senior management of LAP progress, including approval of the schedule and revised budget estimates, on May 19, 2008. This briefing specifically set out the “short-term priorities,” which supported the site-specific risk assessment (estimated then for 2010). Long term projects, such as the NHEERL studies, were indicated as taking an additional two years. (See presentation in Attachment 5.)

Proposed revised text:

“EPA routinely briefed internal and external stakeholders of the LAP project status. When EPA provided updated timelines and milestones to stakeholders, however, changes in the timelines and the causes for the changes were not specifically noted. Additionally, although senior managers may have been briefed on some of the project specific delays, there was not a presentation that specifically focused on project delays and the cause of these delays.”

F.2) OIG finding (Page 16):

“In this case, after it was clear that delays were inevitable, Agency officials responsible for the actions failed to update the Agency’s follow-up system or notify the OIG to disclose known delays until the due dates had passed. Further, the reasons for the delays were not explicitly disclosed.”

EPA Comment: Nonconcur

- The EPA first apprised the OIG of changes to the Corrective Action Plan on September 11, 2009, in an email to Dwayne Crawford from Johnsie Webster. On September 24, the OIG requested a meeting (email from Dwayne Crawford to Johnsie Webster) for the following week to discuss the Libby Corrective Action milestones. EPA met with the OIG on September 30th and submitted a formal memo with revised completion on October 20th 2009.
- This notification was completed by Agency officials responsible for maintaining the OSRTI Open Audit Corrective Actions Report which is the follow-up system for corrective action plan dates.
- EPA acknowledges that its formal notification occurred after the draft planned completion dates for several individual LAP projects provided to the OIG in April 2007.
- EPA does not agree that reason for project delays were not disclosed to the OIG. As described on pages 8 and 9 of the OIG Draft Report, when EPA notified the OIG of new project schedules in September and October 2009, specific reasons for the project delays were provided, including:
 - 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 asbestos.
 - Unforeseen problems in preparing the dosing material for animal studies.
 - Delays in government contracting.
 - Revisions to experimental designs.

Proposed revised text:

“Agency officials responsible for the actions did not formally update the Agency’s follow-up system or notify the OIG to disclose known delays until October 2009, at which time the due dates had passed for several of the LAP projects. At that time, the EPA provided information on project delays to the OIG including... .”

F.3) OIG finding (Page 16):

“It is not clear whether the Administrator or other Agency officials were made aware of the magnitude or the cause of the delays in the Libby Action Plan. ... We also noted that OSWER documents from a May 2009 briefing to the EPA Administrator did not address the original planned milestones under the Libby Action Plan. These documents did not discuss delays and the reasons for the delays.”

EPA Response: Nonconcur

- EPA focused on providing comprehensive status updates on the substantial progress made in the research and realistic timelines.

- EPA acknowledges that it did not specifically point out that the draft timelines were revised.
- EPA acknowledges there was not a presentation that specifically focused on project delays and the cause of these delays.
- EPA has, however, kept senior Agency officials informed of LAP project status including funding and factors that impacted scheduling.
- In addition, a LAP Coordinator was appointed from management of one of the participating offices who was responsible for cross-Agency coordination of all of the individual projects within the LAP. The LAP coordinator organized LAP conference meetings once a year and prepared briefing materials for upper management. The LAP coordinator also prepared the monthly reports to Senator Baucus, which were reviewed each month by management in the three offices.

Proposed revised text:

“While the Administrator and other Agency officials were briefed on the status and progress of the LAP studies, changes to the draft completion dates submitted to the OIG in April 2007 were not pointed out and the causes of the changes were not presented until the revised completion dates were submitted to the OIG in September and October 2009.”

F.4) OIG finding (Page 16):

“We also found that OSWER audit follow-up personnel had requested periodic updates from the Office of Superfund Remediation and Technology Innovation, but September 2009 was the first time the audit follow-up personnel learned of the delays. The OIG was not formally notified that the Agency had missed the planned milestones dates under the Agency’s Libby Action Plan until October 2009 (the first quarter of FY 2010). The 12 tasks in the Libby Action Plan were to be completed by the fourth quarter of FY 2009 (see appendix A).”

EPA Response: Nonconcur.

- EPA disagrees with the OIG’s interpretation that draft timelines provided in April of 2007 should be the baseline against which the EPA’s progress on LAP projects should be evaluated. The timelines given to the OIG were draft; it was clearly stated “... *this date is tentative pending the completion of the detailed workplans....*” It would be more accurate for the OIG to state that EPA provided draft timelines in April 2007, which were not updated until September/October 2009.
- OSWER had originally requested the extension of corrective action plan dates on September 11, 2009 in an email to Dwayne Crawford from Johnsie Webster. (see F.2 above)

Proposed revised text:

“Since April 2009, OSWER tracks corrective action plan dates in the “OSRTI Open Audit Corrective Actions Report.” This report lists corrective actions that have not been completed by the Program and are being tracked and monitored in the Agency’s Management Audit Tracking System (MATS). In September 2009, OSRTI requested an extension of the corrective action plan dates, which was transmitted by audit follow-up personnel via email to the OIG. However, the OIG was not formally notified that the Agency had missed the planned milestones dates under the Agency’s Libby Action Plan in October 2009 (the first quarter of FY 2010). The 12

tasks in the Libby Action Plan were to be completed by the fourth quarter of FY 2009 (see appendix A). ”

F.5) OIG finding (Page 17):

“We read through the progress reports from June 2007 through June 2011 and found nothing that explicitly described the change in planned milestones for the completion of the toxicity studies or the reason for the changes.”

EPA Response: Concur

F.6) OIG finding (Page 17):

“For example, the update for the noncancer study remained unchanged from December 2007 through September 2009, stating that Region 8 and NCEA continued efforts to develop the RfC. This information was misleading, considering the Agency did not award the contract to the University of Cincinnati until May of 2009.”

EPA Response: Nonconcur

- This information was not misleading. As stated on the monthly reports, work by in-house Region 8 scientists to improve exposure-response models and explore various options for estimating exposures did continue while contracting procedures were completed.

F.7) OIG finding (Page 18):

“Although OSWER and EPA Region 8 knew of the delays, it appears that they did not communicate the delays to the Senator or residents clearly or timely. Their failure to communicate is less than full disclosure.”

EPA Response: Nonconcur

- EPA did communicate the scope of and timelines for the LAP projects to community stakeholders and senior EPA management in several forums prior to September 2009 (see response to A.3 and F.1 above).

Proposed revised text:

“While EPA communicated the scope of and timelines for the LAP projects to the public, EPA did not explicitly compare revised timelines for the LAP project to the draft initial milestones. EPA provided basic information on project status in their monthly progress reports to Congress; however, project schedules and specific statements regarding project delays were not included. EPA should have been more direct and proactive, providing clear project schedules and notifying the Senator when project delays occurred. ORD, OSWER, and Region 8 did brief the community on the LAP projects, timelines, progress, and interim milestones in September 2008, with subsequent project updates provided by Region 8. However, EPA did not specifically brief the community on project delays, or note when project milestones were impacted.”

Agency Responses to CONCLUSIONS in the OIG Draft Report

G.1) OIG finding (Page 20):

“EPA personnel committed to performing a toxicity assessment of the Libby amphibole to determine the appropriate cleanup level at the Libby Superfund site.”

EPA Comment: Nonconcur

- The statement is unclear. The term “toxicity assessment” refers to a specific type of Agency document; in this case it is the IRIS Toxicological Review for Libby Amphibole Asbestos. The toxicological review inventories and interprets available health effects data, and if warranted, develops benchmarking health protective toxicity values or risk levels that can be used by others in a separate risk assessment to make risk management decisions about cleanup levels. The Libby amphibole asbestos Toxicological Review has been termed a “toxicity assessment” for purposes of the OIG Draft Report which addresses the toxicity of a specific chemical. It is important to reiterate that toxicity assessments do not provide “cleanup levels.” “Cleanup levels” are determined by the Agency on a site-specific basis and may vary from site to site for the same chemical. Many factors are considered in setting cleanup levels including exposure concentrations, pathways, and time frames of exposure, as well as potential health risk.
- Finally, if the OIG Draft Report intends its findings and conclusions to apply to the Agency’s execution of LAP projects, this statement is incorrect as only the cancer evaluation and reference concentration (projects 1 and 2 of the LAP) are part of the “toxicity assessment.”

Proposed revised text:

“EPA personnel committed to performing a toxicity assessment of the Libby amphibole asbestos to determine the appropriate cancer and noncancer toxicity values to be used in the future development of the site specific risk assessment for Libby.”

G.2) OIG finding (Page 20):

“This effort was intended to protect human health. However, EPA’s development and execution of the toxicity assessment was uncoordinated, leading to extensive delays.”

EPA Comment: Nonconcur

- The OIG Draft Report provides no evidence the Agency’s progress on the LAP was not well coordinated across the Agency nor that protection of public health was not addressed while work on the LAP studies progressed. {For the purposes of this response we understand the OIG to mean the whole of the LAP with the term “toxicity assessment.”}
- We believe the record demonstrates cross-Agency coordination in every stage of the LAP including project planning, execution, document development, and publication of scientific reports. See response B.1 above for specific details.

Proposed revised text:

None. Recommend the text be deleted.

G.3) OIG finding (Page 20):

“Specifically, the Agency: Issued its corrective action plan knowing that the milestones were not achievable; the Agency knew that the scope of work was greater than stated in the corrective action plan.”

EPA Comment: Nonconcur

- EPA did indicate to the OIG in the April 2007 memo that the draft timelines were subject to change based on determining the scope of work for each project. EPA informed the OIG in this memo that project planning was needed to determine project timelines. Specifically, EPA clearly indicated it was providing “Draft planned completion dates for individual studies” on which the overall timeline for the LAP was based. Additionally, with respect to the five NHEERL studies the memo stated the completion date was “tentative pending detailed work plans.” Further, EPA made the OIG aware that workplans had not been developed as of the date of the memo which states “detailed workplans are currently being developed and will include consultation with other Agencies... .”
- Although the Agency agrees that the “Draft Planned Completion Dates for Individual Studies” provided to the OIG in April 2007 were optimistic, and ultimately shown to be greatly underestimated, it is a mischaracterization and oversimplification for the OIG to conclude these dates were knowingly supplied as inaccurate. Project teams were still in the process of scoping and planning the individual project plans when the April 2007 response was written.

Proposed revised text:

“The Agency issued overly optimistic draft action plans in its April 2007 memo and did not notify OIG regarding updated timelines following the development of completed work plans.”

G.4) OIG finding (Page 20):

“Specifically, the Agency: Issued no charter establishing a single oversight authority and defining roles and responsibilities.” (Page 20 lines 12-34)

EPA Comment: Nonconcur

- We agree with the statement that EPA did not establish a charter, but do not agree that the lack of a charter contributed to delays in the project milestones or precluded appropriate definition of roles and responsibilities. (See above comments on project coordination responses B.1 and G.2).

Proposed revised text:

“The Agency issued no charter establishing a single oversight authority and defining roles and responsibilities, but this did not contribute to the delays in completing LAP activities.”

G.5) OIG finding (Page 20):

“Specifically, the Agency: Allowed contracting issues to consume 19 months for the noncancer assessment while inappropriately using an interagency agreement to bypass EPA contracting personnel.”

EPA Comment: Nonconcur

- Six of the 19 months were to develop the statement of work. Preparing the statement of work is independent of the contracting mechanism. Also, five of the months were due to the UC preparing and negotiating the work plan and cost proposal. The remaining eight months is not an unreasonable amount of time to issue a sole source solicitation of this magnitude.
- The EPA disagrees with the OIG finding that the contract work was outside of the scope of the IA. The contract included work essential to the development of a site-specific RfC for the Libby, MT risk assessment and in support of risk management decisions and remedy selection. As such, the work was integral to Superfund site cleanup actions. The site-specific risk assessment includes site-specific exposure measurements and toxicity values. Where no toxicity values are available, site-specific values are needed. Thus, this work is equal in importance and relevance to site remedy selection and cleanup as it is to the exposure monitoring. Region 8 adheres to the FAR with regard to 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 OIG is correct in that IA is specifically for work to support site cleanup and remediation activities for Libby, MT and the surrounding community. However, EPA disagrees with the OIG's interpretation that actions under this IA can only be performed by individuals physically located in Libby, MT. There are many aspects of the work supporting cleanup activities for Libby, MT that are appropriately done at locations outside of the physical vicinity of Libby, MT. Examples include sample analysis, contracting offices and project management functions. Similarly, the UC scientists do not need to be physically located in Libby, MT to conduct their scientific study in support of the site-specific RfC. Thus, this finding of the OIG that the Volpe IA was an inappropriate contracting mechanism based on the requirement that all work conducted under this IA must occur physically in Libby, MT is unfounded.
- The IA with the US Department of Transportation used to obtain a contract with the UC was an existing mechanism. The use of an existing mechanism (in contrast to a new contracting vehicle) in most cases provides a more expeditious avenue for products or services. In any case, the IA with the Department of Transportation is also governed by the FAR. Therefore, whether obtaining contract support through EPA or the Department of Transportation does not result in *bypassing contracting personnel*.

Proposed revised text:

None. Recommend the text be deleted.

G.6) OIG finding (Page 20):

"Specifically, the Agency: Placed other cancer assessment work before the Libby Amphibole Assessment despite urgent human health concerns in Libby, and encountered the need to perform unplanned work."

EPA Comment: Nonconcur

- EPA disagrees with any implication that the declaration of a PHE made completion of the *Toxicological Review of Libby Amphibole Asbestos* the sole priority toxicity assessment for EPA. The PHE declaration accomplished its main purpose, which is to trigger provisions under CERCLA to allow the Federal government to provide medical care to the population in Libby, MT. As noted above, asbestos removal actions in Libby, MT have continued without delay

pending a final *Toxicological Review of Libby Amphibole Asbestos*. This is not just the view of the ORD but was the view of the Assistant Administrator for OSWER who communicated this to the OIG on April 13, 2012

- EPA does acknowledge that some portion of the delay in the Toxicological Review was due to EPA also working to complete other equally high priority assessments. However, as noted, EPA believes that there are multiple high-priority assessments, and the most efficient use of EPA's expert staff and resources often entails staff with particular expertise working on more than one priority assessment at the same time.
- EPA did judge that assessing the toxicity of Libby amphibole asbestos is a high priority. EPA assembled a team with the appropriate expertise within and outside of the Agency and assigned a high priority to development of an assessment of the toxicity of Libby amphibole asbestos. EPA strongly disagrees with any OIG findings or implications that other assessments being conducted by ORD were not also of high public health consequence.
- The OIG did not evaluate ORD's process for priority setting, which places this recommendation outside the scope of the OIG investigation.
- 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.
- EPA disagrees with any implied finding that the delay in completing the *Toxicological Review of Libby Amphibole Asbestos* was due solely to competing demands on EPA. As EPA explained to OIG staff, there were multiple reasons the draft toxicological review took longer than initially expected. The OIG should accurately reflect the other factors which impacted project timelines. These included:
 - The time needed to complete the exposure-response modeling for the Libby amphibole asbestos IRIS assessment was initially underestimated. Modeling of epidemiology data is complex, and as such it is difficult to predict the level of effort and resources needed until one evaluates the data and begins to conduct the modeling.
 - The time to resolve legal issues regarding the protection of personal medical information in data shared between NIOSH and EPA was longer than anticipated.
 - A science based decision was made to update the cancer mortality data for the Libby worker cohort to provide more information on rates of mesothelioma. This necessitated extra time to update the NIOSH database EPA used for the exposure response modeling as well as the time needed to conduct additional exposure response modeling with these new data.
 - Incorporation of the site-specific RfC the Libby amphibole asbestos IRIS assessment resulted in additional work on document development and model evaluation.
 - The RfC was originally begun as a site-specific toxicity value, which does not require the intra-agency, interagency, and external peer review process that accompanies an IRIS document. Thus, the original initial draft RfC schedule did not include time for these reviews and the corresponding time needed for appropriate responses to comments and document revisions. The shift to an IRIS document also resulted in additional work on model evaluation and other content development.

Proposed revised text:

None. Recommend the text be deleted.

G.7) OIG finding (Page 20):

“Specifically, the Agency: Failed to update stakeholders or disclose in briefings that the milestones would be missed well after the due dates had passed.” (Page 20 lines 12-34)

EPA Comment: Nonconcur

- EPA did regularly update stakeholders on the status of LAP projects. When schedules were provided, the schedules were updated to reflect delays due to scientific/technical issues, administrative/contracting processes, or other factors project.
- As the OIG has indicated, the original draft project milestones provided to the OIG in April of 2007 were in most cases ambitious. Once EPA realized these schedules were not achievable, there seemed no utility in providing that information to stakeholders. Instead, each time timelines were provided to stakeholders, EPA provided the best available information.
- The record shows that EPA has provided monthly status reports to Congress, attended regular meetings with interested Senate staff, and responded to all requests for information on LAP projects. EPA has briefed community stakeholders on LAP project status and timelines throughout the course of the projects. Specifically, Agency officials briefed community stakeholders in a variety of forums on all LAP projects in September 2008, providing project descriptions, progress, dates for interim milestones, and available schedules. 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 project status and timelines well before September 2009. Thus community stakeholders did have information available to them indicating LAP projects would not be complete by September 2009. (See response F.1. above for more details.)

Proposed revised text:

None. Recommend the text be deleted.

cc: Vanessa Vu, Science Advisory Board

Attachments

Attachment 1: Specific comments and text changes to the OIG Draft Report.

Attachment 2: Summary of EPA activities at the Libby, MT Superfund site.

Attachment 3: List of peer-reviewed publications from LAP research and projects.

Attachment 4: Memo from US EPA Office of the Administrator to the OIG with respect to comments in the OIG Draft Report pertaining to the SAB external peer review of EPA documents, 10 Aug, 2012.

Attachment 5: New information relevant to the Libby OIG Draft Report Findings, Conclusions, and Recommendations.

Attachment 1

Agency comments on specific text in the body of the OIG Draft Report

Specific text changes as outlined in the Agency responses to the recommendations, findings and conclusions of the July OIG Draft Report are not repeated here.

Page and line numbers referenced given here are consistent with the report version provided within this attachment. Line numbers were added for ease of review; however as pagination and line numbers varied in electronic versions of the report a “pdf” version was printed and included for the record.

- 1) **Title page and cover:** The OIG Draft Report title references the “Libby Asbestos Toxicity Assessment.” However, The OIG’s field investigation and review seems to have addressed all projects under the Libby Action Plan (LAP). As such we recommend the title reflect this is a report on the progress of all LAP projects, not just the toxicity assessment.
- 2) **“At A Glance”:** As this text restates the main findings and recommendations of the OIG Draft Report, the Agency’s comments and responses to these points in EPA’s response memo to the OIG Draft Report apply to this text as well.
- 3) **“At A Glance” and Chapter 1; Background (pg 1):** 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 OIG’s statement should be changed to reflect the breadth of community’s concerns. The Libby Superfund site is not focused only on contaminated lawn and garden products.
- 4) **Page 2, lines 39-43:** This text should be revised to reflect that the dates provided to the OIG in Sept 2007 were draft (see response A.1 in EPA’s response memo to the OIG Draft Report).
- 5) **Page 3, lines 12-13:** The list of LAP projects provided to the OIG as shown in Appendix A of the draft OIG report are not in order of priority. Please remove this statement for accuracy.
- 6) **Page 3, Lines 13-16:** This statement is unclear. We recommend it be changed to read: “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.”
- 7) **Page 3, lines 18-22:** 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.

The first two LAP coordinators were managers in ORD/NHEERL; the current coordinator is a manager in OSWER/OSRTI. Please correct the text to describe the roles and responsibilities of the LAP coordinator (See response C.1 of EPA's response memo to the OIG Draft Report).

- 8) **Page 3, line 44:** strike "determining" replace with "conducting."
- 9) **Page 4, line 2:** Should read "... conducting inhalation toxicology **studies** in rats."
- 10) Page 4, line 7: should read "site-specific reference concentration (RfC) for the Libby amphibole asbestos..."
- 11) **Page 5 and 6, Scope and methodology:** Add the following bullet "Briefings to senior managers."
- 12) **Page 5, line 27:** 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.
- 13) **Page 7 lines 29-30:** The statement that stakeholder interest "... *may have caused the Agency to underestimate the time required to complete the plan,*" is unsupported. We recommend the OIG remove this comment or provide factual support for the statement. The original timeline was submitted while EPA was still determining the scope and resources required for each project and were provided to the OIG as "Draft Planned Completion Dates for Individual Studies" (EPA April 2007). As such, at least one contributing factor to the underestimated timelines was that the preliminary timelines did not yet reflect a developed understanding of the work required for each project.
- 14) **Page 8, lines 28-29:** The OIG's statement regarding reviewer comments on the NHEERL research plan is accurate. However, the OIG does not acknowledge that EPA was responsive to the reviewer comments and revised the project plans accordingly. The revised NHEERL project proposals "Dosimetric and Toxicologic Assessment of Amphibole Fiber-Containing Material from Libby, Montana" prepared in response to the reviews (Aug. 14, 2007) recognized the comments from reviewers that timelines needed revision and revised the study plans accordingly. The timeline figure in the revised project plan shows a final completion date in the calendar quarter of 2010.
- 15) **Page 9, Line 7:** The OIG cites "Delays in government contracting" as a cause of NHEERL project delays. This is true for inhalation and dosimetry contracts; however the delay in receiving material from the USGS rendered these delays relatively unimportant. The OIG should acknowledge that although true, these contracting delays 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.

- 16) **Page 10, lines 3-4:** The following statement is unclear “The RfC Development study was ranked number one by the Agency for its importance in completing the Libby toxicity assessment.” The RfC is part of the toxicity assessment (i.e. the Toxicological Review of Libby Amphibole Assessment). The list of LAP studies provided to the OIG (Appendix A of the Draft OIG report) is not ordered by relative priority.
- 17) **Page 11, line 40:** EPA disagrees with the OIG statement “Rather, EPA and the Volpe Center fault each other for the delays” Is unsubstantiated. This statement should be removed. The contracting process, although long, was necessary for a sole source contract of this size. Neither EPA nor Volpe fault each other.
- 18) **Page 16, lines 3-5:** “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. We recommend the reference to “listed” be removed.
- 19) **Page 19-lines 31-33:** The need for fiber separation studies only resulted in minor project delays (a few months).
- 20) **Page 19, lines 37-39:** The OIG states the contract award was late without providing context. As the stated purpose of the IG field investigation was to determine the cause of the project delays, we ask the following information be reflected: The dosimetry contract was delayed because it was initially developed as a desired sole source contract; it was eventually awarded based on open competition. Awarding of either the dosimetry contract or the inhalation contract any earlier would not have changed the overall completion date of the LAP because the LA material was not ready until after the inhalation contract was awarded, and the inhalation contract provides data to the dosimetry contract.
- 21) **Page 19, lines 41 - 44:** The OIG’s finding that NHEERL studies will be “6 years late” is based on the initial “Draft Planned Completion Dates for Individual Studies,” which the EPA acknowledges were not realistic completion dates. 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. Eighteen papers have already been published, and several more have been submitted or are in preparation. Lab work will be almost entirely done in 2012, and the remaining time is only to ensure time for writing peer-reviewed papers.

Attachment 4

**Memo from US EPA Office of the Administrator to the OIG with respect to
comments in the OIG Draft Report pertaining to the SAB external peer
review of EPA documents, 10 Aug, 2012**



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

AUG 1 6 2012

OFFICE OF THE
ADMINISTRATOR

MEMORANDUM

SUBJECT: Comments on OIG Draft Report on Libby Asbestos Toxicity Assessment

FROM: John E. Reeder
Deputy Chief of Staff

TO: Arthur A. Elkins, Jr.
Inspector General

Please find attached our comments on the Office of Inspector General (OIG) July 19, 2012 draft report entitled *Follow-Up Report: Better Planning, Execution, and Communication Could Have Reduced Delays in Completing the Libby Asbestos Toxicity Assessment*, pertaining to the Science Advisory Board (SAB) review of EPA's draft toxicity assessment on Libby Amphibole Asbestos. Please direct any questions you may have to Vanessa Vu at 202-564-2074 or at vu.vanessa@epa.gov.

Attachment

cc: Mathy Stanislaus, OSWER
Lek Kadeli, ORD
Vanessa Vu, SABSO
Eric Lewis, OIG
Dwayne Crawford, OIG

Review Comments
Office of Inspector General Draft Report (July 19, 2012)
*Follow-Up Report: Better Planning, Execution, and Communication Could Have Reduced
Delays in Completing the Libby Asbestos Toxicity Assessment*

We appreciate the opportunity to provide the following comments on the OIG draft report.

1. The OIG draft report recommends that *"the Deputy Administrator direct the SAB to determine and report whether:*
 - a. *EPA has followed guidance sufficient to support the findings in the toxicity assessment; and*
 - b. *Limitations exist in applying the cancer and non-cancer values to the determination of safe levels in Libby."*

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 of non-cancer and cancer toxicity values.

2. The OIG draft report includes certain statements made by the SAB Staff Office Director concerning some preliminary SAB review comments on the *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 page 13 of the draft OIG report.

3. The first bullet on page 14 referring to the SAB Staff Office 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 the 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 had requested additional data to verify the results of EPA analysis, and the agency was very responsive to the SAB request.

4. The OIG draft report states on page 14 (third paragraph) that *"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 the authority to direct the agency or negotiate with the agency regarding the SAB recommendations. Should the SAB make a specific recommendation on this issue in its final report, it is incumbent upon the agency to decide how to implement the recommendation.