U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF INSPECTOR GENERAL

Catalyst for Improving the Environment

Evaluation Report

Lack of Final Guidance on Vapor Intrusion Impedes Efforts to Address Indoor Air Risks

Report No. 10-P-0042

December 14, 2009

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Abbreviations

EPA	U.S. Environmental Protection Agency
IRIS	Integrated Risk Information System
ITRC	Interstate Technology Regulatory Council
OIG	Office of Inspector General
ORD	Office of Research and Development
OSWER	Office of Solid Waste and Emergency Response
PCE	Perchloroethylene
RCRA	Resource Conservation and Recovery Act
TCE	Trichloroethylene
UST	Underground Storage Tanks

U.S. Environmental Protection Agency
Office of Inspector General

10-P-0042
December 14, 2009

At a Glance

Catalyst for Improving the Environment

Why We Did This Review

We conducted this review to determine what actions the U.S. Environmental Protection Agency (EPA) has taken, both general and site-specific, to identify and mitigate human health risks from chemical vapor intrusion that can be associated with contaminated sites. When EPA had not taken site-specific actions, we examined the reasons why.

Background

Vapor intrusion is the migration of volatile chemicals from the subsurface into overlying buildings. EPA has acknowledged that current and former contaminated sites could have extensive vapor intrusion issues and pose a significant risk to the public. In 2002, based on its current understanding of subsurface vapor intrusion, EPA issued draft guidance. The guidance included technical and policy recommendations for determining whether vapor intrusion posed a risk at sites. The 2002 guidance remains in draft form and has not been finalized since it was issued.

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

To view the full report, click on the following link:
www.epa.gov/oig/reports/2010/20091214-10-P-0042.pdf

Lack of Final Guidance on Vapor Intrusion Impedes Efforts to Address Indoor Air Risks

What We Found

EPA's efforts to protect human health at sites where vapor intrusion risks may occur have been impeded by the lack of final Agency guidance on vapor intrusion risks. EPA's 2002 draft vapor intrusion guidance has limited purpose and scope, and the science and technology associated with evaluating and addressing risk from vapor intrusion is evolving. EPA's draft also contains outdated toxicity values for assessing risk to humans from chemical vapors in indoor air.

EPA's draft guidance does not address mitigating vapor intrusion risks or monitoring the effectiveness of mitigation efforts. The draft guidance also does not clearly recommend that multiple lines of evidence be used in evaluating and making decisions about risks from vapor intrusion. The draft guidance is not recommended for assessing vapor intrusion risks associated with petroleum releases at Underground Storage Tank sites. EPA's outdated toxicity values allow for the use of widely different, nonfederal toxicity values and have caused delays in work to address possible risks.

EPA has not finalized its guidance, according to EPA managers and staff, because the 2007 Interstate Technology Regulatory Council guidance addressed many issues that EPA would have addressed in a final guidance, and because finalizing EPA's guidance would take a long time in light of the emerging scientific issues in the field. Also, previous administrative review requirements for Agency guidance were perceived as barriers to issuing timely guidance in a rapidly changing environment. These requirements were revoked by the current Administration, but significant guidance remains subject to some administrative review.

Seven years later, EPA is developing a roadmap of technical documents that will update its draft guidance. However, technical documents may not be effective for conveying and representing Agency policy. EPA has also made some progress in updating toxicity values for some contaminants most frequently associated with vapor intrusion.

What We Recommend

We recommend that EPA issue final guidance to establish current Agency policy on the evaluation and mitigation of vapor intrusion risks. The Agency should also finalize toxicity values for trichloroethylene and perchloroethylene – common contaminants associated with vapor intrusion. The Agency agreed with our recommendations and provided milestones.

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

OFFICE OF
INSPECTOR GENERAL

December 14, 2009

MEMORANDUM

SUBJECT: Lack of Final Guidance on Vapor Intrusion Impedes Efforts to Address Indoor Air Risks
Report No. 10-P-0042

FROM: Wade T. Najjum
Assistant Inspector General
Office of Program Evaluation

TO: Mathy Stanislaus
Assistant Administrator
Office of Solid Waste and Emergency Response

Lek Kadeli
Acting Assistant Administrator
Office of Research and Development

This is our report on the subject evaluation conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established resolution procedures.

The estimated cost of this report – calculated by multiplying the project's staff days by the applicable daily full cost billing rates in effect at the time – is $454,233.

Action Required

Based on the Agency's planned actions and milestones provided, the OIG will close the recommendations in the OIG tracking system. No further action is required, except that, within 90 days of this report date, the OIG requires that the Assistant Administrator, Office of Solid Waste and Emergency Response, provide interim corrective actions and milestones for its planned actions related to Recommendation 2 because the planned completion date for

Recommendation 2 is nearly 3 years from this final report date. We have no objections to the further release of this report to the public. This report will be available at www.epa.gov/oig.

If you or your staff have any questions regarding this report, please contact Carolyn Copper at (202) 566-0829 or copper.carolyn@epa.gov, or Tina Lovingood at (202) 566-2906 or lovingood.tina@epa.gov.

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Appendices

Purpose

The purpose of our review was to determine what actions the U.S. Environmental Protection Agency (EPA) has taken to identify and mitigate human health risks from chemical vapor intrusion that can be associated with contaminated sites. We addressed the following questions:

1. What steps has EPA taken to identify the potential risks of vapor intrusion from contaminated sites?

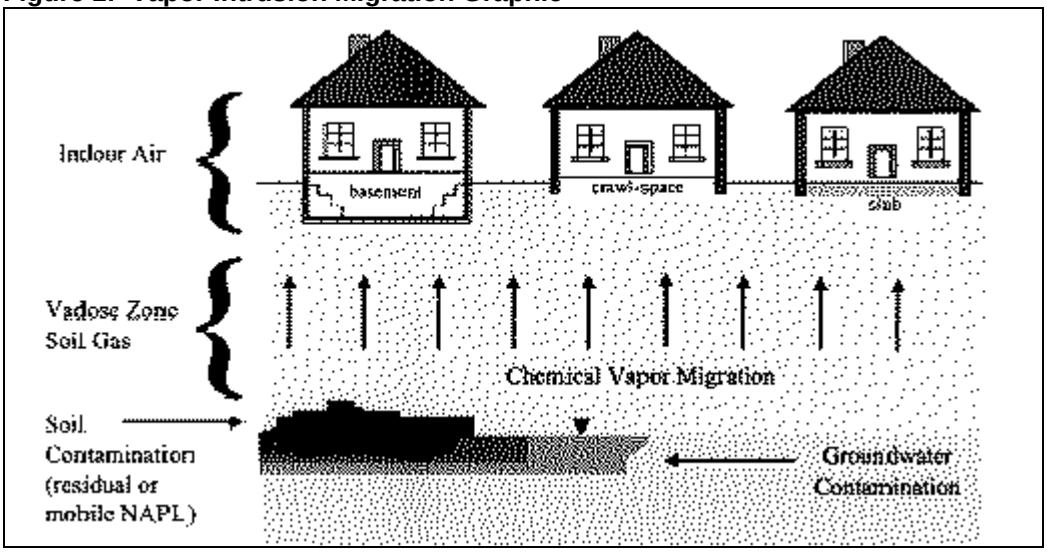
2. What actions has EPA taken to ensure that vapor intrusion is being site-specifically identified and addressed within in its various programs, including Resource Conservation and Recovery Act (RCRA), Superfund, Brownfields, and Underground Storage Tanks (UST)? Where EPA has not taken actions to site-specifically identify and address vapor intrusion, why not?

This assignment is included in the Office of Inspector General (OIG) Fiscal Year 2009 annual plan.

Background

Vapor intrusion is the migration of volatile chemicals from the subsurface into overlying buildings. Volatile chemicals in buried wastes and/or contaminated groundwater can emit vapors that may migrate through subsurface soils and into indoor air spaces of overlying buildings in ways similar to those of radon gas seeping into homes, as shown in Figure 1. According to EPA, in extreme cases, the vapors may accumulate in dwellings or occupied buildings to levels that may pose near-term safety hazards (e.g., explosion), acute health effects, or aesthetic problems (e.g., odors).

Figure 1: Vapor Intrusion Migration Graphic



Note: NAPL is non-aqueous phase liquid.
Source: *OSWER 2002 Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils (Subsurface Vapor Intrusion Guidance).*

According to an EPA scientist, the four chlorinated chemicals that pose the highest risks from vapor intrusion are the ones that are most frequently found at contaminated sites. These chemicals are perchloroethylene (PCE), trichloroethylene (TCE), dichloroethylene, and vinyl chloride.

EPA's Integrated Risk Information System (IRIS) is an electronic database containing information on human health effects that may result from exposure to various chemicals in the environment. IRIS contains toxicity values for cancer and/or noncancer effects from oral and/or inhalation exposures for more than 540 chemicals, including dichloroethylene and vinyl chloride.

In November 2002, EPA issued draft guidance titled *OSWER Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils (Subsurface Vapor Intrusion Guidance).* This guidance provides a tool for evaluating vapor intrusion at RCRA sites, some Superfund sites,[1] and Brownfields sites. Since issuing the draft guidance, EPA has neither updated nor finalized it. Separately, States, other federal agencies, and stakeholder groups have issued vapor intrusion guidance or technical documents. According to the Interstate Technology Regulatory Council (ITRC), as of 2008, 26 States have issued their own vapor intrusion guidance.[2]

Noteworthy Achievements

EPA has issued a number of guidance and technical documents to help regions and States address vapor intrusion. In 1999, EPA's Office of Solid Waste developed human health environmental indicators for the RCRA program that required regulators to consider vapor intrusion and issued draft vapor intrusion guidance for use in environmental indicators in 2001. EPA's Office of Solid Waste and Emergency Response (OSWER) issued draft vapor intrusion guidance in 2002. To help address the Agency's concern that the science and technology associated with evaluating and addressing risk from vapor intrusion is complex and evolving, it issued a fact sheet and other documents. Specifically, in 2004, OSWER developed a Brownfields fact sheet, "Design Solutions for Vapor Intrusion and Indoor Air Quality." OSWER also partly funded the 2007 ITRC vapor intrusion guidance, and in 2008, OSWER issued a Brownfields Vapor Intrusion Primer. In 2008, EPA also developed the Superfund Environmental Indicator Guidance Human Health Revision, which includes consideration of vapor intrusion into indoor air. EPA is in the process of creating a roadmap of technical documents that update the draft guidance and the ITRC guidance. EPA's Office of Research and Development (ORD) has issued a number of research papers on sampling and modeling for

[1] According to the 2002 draft guidance, the guidance applies to the Comprehensive Environmental Response, Compensation, and Liability Act (National Priorities List and Superfund Alternative Sites). The guidance does not mention non-National Priorities List sites such as removal-action-only sites.

[2] Subsequent to our field work, we learned that on September 18, 2009, the U.S. Department of Housing and Urban Development updated its 2002 Multi-Family Accelerated Processing Guide, Environmental Review (Chapter 9). The update requires a vapor intrusion screen to determine whether there is a potential for vapors to occur in the subsurface below existing and/or proposed on-site structures from those hazardous substances, petroleum, and petroleum products that consist of volatile organic compounds and semivolatile organic compounds and inorganic volatile compounds.

specific contaminants in soil and groundwater. EPA has engaged in vapor intrusion educational activities such as training events and symposiums.

The Agency has begun the process of drafting policy on vapor intrusion in nonresidential settings. It has also progressed in developing IRIS toxicity values for PCE and TCE. EPA has also evaluated the presence of vapor intrusion in some Superfund Five-Year Reviews (or "protectiveness reviews"). It is planning to issue its Five-Year Review guidance to specifically address evaluation of vapor intrusion.

EPA Region 3 has made the review of indoor air pollutants, including vapor intrusion, a regional priority. As part of the Region's work in this area, it began evaluating Superfund National Priority List sites and RCRA sites for vapor intrusion. Where appropriate, it is mitigating the risk and also educating the public about the risks from vapor intrusion.

Scope and Methodology

We conducted our review in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the evaluation to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our evaluation objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our evaluation objectives. We performed our review from December 2008 through September 2009.

To gain an understanding of vapor intrusion, we attended two vapor intrusion conferences in Philadelphia and San Diego and reviewed various online training materials. In addition, we researched prior reports by EPA, Government Accountability Office, and ITRC. We identified and interviewed EPA vapor intrusion contacts or managers.

To identify potential internal control weaknesses, we reviewed EPA's Risk/Vulnerability Assessments and Fiscal Year 2008 Agency Assurance Letters. We also reviewed EPA's Key Management Challenges for Fiscal Year 2008, and related Federal Managers Financial Integrity Act documents.

We conducted our work in OSWER, ORD, and EPA Regions 1-10.

To address our first question, we reviewed documents and information and interviewed EPA staff. To address our second question, we analyzed EPA, ITRC, selected State guidance documents, and EPA technical/policy documents. (See Appendix A for a sample of these documents.) We reviewed existing controls that would trigger review of vapor intrusion at contaminated sites, such as environmental indicators, ready-for-reuse indicators, and protectiveness reviews. We also reviewed the hazard ranking system for specific mention of evaluating vapor intrusion, but found none.

We visited Region 3 and met with representatives and managers from various programs that address vapor intrusion. We discussed the Region 3 draft framework, vapor intrusion priorities, and how the programs are managing vapor intrusion.

To assess how the remaining regions address vapor intrusion, we sent an online survey to EPA's Vapor Intrusion Forum on February 26, 2009, and analyzed the results. We also reviewed supplementary data that were provided as part of the survey.

Results of Review: EPA Lacks Final Guidance on Vapor Intrusion

EPA does not have final guidance to establish current Agency policy on the evaluation and mitigation of vapor intrusion risks. EPA has taken some steps to identify potential vapor intrusion risks, developed plans to address risks, and taken actions to mitigate site-specific risks. However, due to perceived administrative and scientific barriers, EPA has not finalized its draft 2002 vapor intrusion guidance. The draft guidance is limited in scope and purpose. It also lacks current toxicity values, or values that estimate the risk of exposure and where action may need to be taken. The lack of final EPA guidance has impeded Agency efforts to protect human health and the environment at sites where vapor intrusion risks may occur.

In the absence of final and current guidance (including up-to-date toxicity values), EPA, States, and other parties may continue to use widely different toxicity values for determining human health risks from vapor intrusion. Some enforcement staff believe draft vapor intrusion toxicity values and requirements may limit the Agency's ability to enforce compliance with those standards and may encourage compliance with toxicity values that may not be universally viewed as safe. Incomplete evaluations or actions to address vapor intrusion risks may also continue, and vapor intrusion risk assessments at petroleum-contaminated sites may not be conducted. According to some EPA enforcement staff, the uncertainties created by draft EPA vapor intrusion guidance could also limit some EPA efforts to enforce responsible party clean-up actions.

Purpose and Scope of EPA's Draft Vapor Intrusion Guidance Is Limited

EPA's draft guidance focuses on the important issue of assessing whether unacceptable risks to human health may occur from chemical vapor exposures. However, the guidance does not address actions to mitigate chemical vapor risks. More recently, some States' and ITRC guidance, as well as EPA's Brownfields Primer and the U.S. Air Force, U.S. Navy, and U.S. Army Tri-Services Guidance, include vapor intrusion risk mitigation procedures or information. EPA's draft guidance also does not strongly recommend the use of multiple lines of evidence in evaluating and making decisions about vapor intrusion. Use of multiple lines of evidence is considered the current state of the science. EPA does not recommend its draft guidance be used to assess vapor intrusion risks associated with petroleum releases at UST sites. According to EPA, applying the draft guidance to petroleum compounds may overestimate the impact of vapor intrusion. EPA's draft guidance refers the public to UST guidance from 1995,[3] but the 1995 guidance does not discuss vapor intrusion. More recent guidances address a broader scope of relevant vapor issues.

[3] U.S. Environmental Protection Agency, *Use of Risk-Based Decision Making in UST Corrective Action Programs*, 1995.

The recent EPA technical paper addresses some aspects of mitigation, but it is not guidance. In October 2008, EPA issued a technical document titled *Indoor Air Vapor Intrusion Mitigation Approaches*. It focuses on "interim remedial measures" to address vapor intrusion. Some of the strengths of this document are that it provides an overview of vapor intrusion mitigation methods, estimated mitigation costs, discussion of long-term monitoring to assess mitigation performance, and development of operations and maintenance plans. However, the document provides few details on when to terminate vapor intrusion mitigation systems. It also does not include operations and maintenance plan requirements, and it does not convey Agency policy or guidance. The document refers readers to New York and New Jersey vapor intrusion guidance for further information on operations and maintenance and termination of the systems.

The draft guidance does not clearly address the multiple lines of evidence approach. EPA's 2002 guidance begins to discuss, but does not clearly and strongly recommend, that multiple lines of evidence[4] are needed in evaluating and making decisions about vapor intrusion. In two places, the draft guidance refers to using more than one line of evidence, and where it does, the guidance discusses using evidence in a sequential order to screen out sites. The 2002 draft guidance also does not explain the many variables that can affect the evaluation of vapor intrusion as a pathway of concern.

According to the 2008 Tri-Services Guidance for assessing vapor intrusion, using multiple lines of evidence in evaluating vapor intrusion has become the "state of the science." If only one line of evidence is used, it could lead to incorrect conclusions about vapor intrusion risks. ITRC states that it is important to use multiple lines of evidence to reach decisions based on professional judgment. In a January 2009 memo for an interim TCE toxicity value, EPA strongly suggested the importance of using multiple lines of evidence and explained the many variables affecting the evaluation of vapor intrusion as a pathway of concern. However, due to other issues regarding the content of the memo, EPA withdrew the memo in April 2009.

The draft guidance does not address vapor intrusion at petroleum sites. EPA does not recommend use of the 2002 draft vapor intrusion guidance for assessing vapor intrusion risks from petroleum releases at UST sites. EPA states in its guidance that this is due to "certain conservative assumptions" (i.e., no biodegradation), and the draft guidance is unlikely to provide an appropriate mechanism for screening the vapor pathway at UST sites that involve petroleum releases. However, other EPA documents state that semivolatile chemicals, such as gasoline and petroleum, can pose a vapor intrusion problem. In addition, the draft vapor intrusion guidance does include toxicity values for petroleum chemicals that may be a component at non-UST sites. Nonetheless, EPA does not recommend the use of the draft guidance at UST sites.

The 2002 draft vapor intrusion guidance refers readers to the Agency's 1995 guidance, *Use of Risk-Based Decision Making in UST Corrective Action Programs*. However, this guidance does not address vapor intrusion, and the UST program does not have specific vapor intrusion guidance. According to a UST program manager, this is because mitigating vapor intrusion at petroleum sites is an evolving area that lacks consensus.

[4] Some examples of multiple lines of evidence ITRC suggests using include soil gas data, groundwater spatial data, indoor and outdoor air data, background sources, and building construction and current conditions.

EPA's UST program delegates vapor intrusion assessments to States. However, States do not report information to EPA about whether vapor intrusion has been evaluated, is a risk, or needs to be mitigated at UST sites. Therefore, EPA lacks the information. In January 2009, the Association of State and Territorial Solid Waste Management Officials requested assistance from the EPA Office of Underground Storage Tanks to develop vapor intrusion guidance for petroleum.

ITRC's vapor intrusion guidance acknowledges risk from petroleum vapors. It provides an example of a site where petroleum vapors have caused human health concerns. For example, " . . . at a petroleum hydrocarbon site in Colorado, vapor intrusion caused the evacuation of two schools. Indoor air samples were collected in another school located outside of the influence of the contaminated plume. Following mitigation activities, the students were allowed to return to the formerly impacted school when contaminant concentrations in indoor air were in the range of concentrations detected in the unaffected school."

Although EPA does not recommend its broad 2002 vapor intrusion guidance for UST sites, EPA's 2008 Brownfields Primer does address petroleum.

Other guidances address a broader scope of relevant vapor intrusion issues. The purpose of EPA's 2002 draft guidance is to help the user conduct a screening evaluation to determine whether subsurface chemicals are entering indoor air and, if so, whether they pose an unacceptable risk to human health. More recent guidance documents[5] are broader and go beyond evaluation of the risk posed by vapor intrusion. Some of these documents provide information regarding when or whether preemptive mitigation may be appropriate. Some discuss the selection, design, installation, and/or sustainability over the long term of a vapor intrusion mitigation system. Some documents also discuss long-term monitoring, when institutional controls and deed restrictions are appropriate, and/or when to terminate the mitigation systems. EPA also issued guidance in April 2009 on transferring fund-lead vapor intrusion systems to States.[6] However, this guidance does not detail an operations and maintenance plan or the types of operation and maintenance activities that may be required. The April 2009 directive is also not included in a comprehensive vapor intrusion guidance.

Lack of Current EPA Toxicity Values Allows for Use of Disparate Nonfederal Toxicity Values and Delays Work to Address Possible Risks

EPA survey respondents said that EPA's guidance was outdated because it did not include current toxicity values for some chemicals of concern in vapor intrusion assessments. As a result, EPA, States, and other parties use alternative toxicity values that vary widely in their definition of levels that are considered safe. Lack of some toxicity values has also delayed work at Superfund sites with potential risks from vapor intrusion.

[5]EPA's Brownfields Primer (2008), ITRC guidance (2007), Tri-Services Handbook (2008), and guidance from the States of California (2005 and draft 2008), New Jersey (2005), and New York (2006). See Appendix A for complete bibliographical information on these documents.

[6] U.S. Environmental Protection Agency, *Operational and Functional Determination and the Transfer of Fund-lead Vapor Intrusion Mitigation Systems to the State*, April 9, 2009.

Our survey results show that one reason explaining outdated toxicity values is that the values were based on oral exposure. These toxicity values assume a default inhalation rate and body weight.[7] However, according to the Agency's January 2009 risk assessment guidance,[8] "risk assessors are discouraged" from basing toxicity values on oral data, especially when default assumptions about inhalation rate and body weight are used.

The toxicity value for TCE is one of the key values that is outdated. In early 2009, EPA issued interim toxicity values to address risks due to TCE exposure. Specifically, EPA recommended the use of California's inhalation risk value for evaluating the cancer effects of TCE in site-specific risk assessments. For noncancer effects of TCE, EPA recommended two values that could be considered in evaluating systemic toxicity at sites. One value was developed by the New York State Department of Health, and the other was developed by California's EPA. However, in April 2009, EPA withdrew the interim toxicity values. It believed that the two different values for assessing noncancer risks may have led to inconsistency in the development of preliminary remediation goals for TCE and site-specific risk assessments. In November 2009, EPA released its draft toxicological review for TCE for public review and comment.

In the absence of current and final EPA toxicity values, regulators and others may use "other values" such as nonfederal or State toxicity values.[9] These toxicity values can sometimes vary widely. One example is PCE in groundwater. The standard in micrograms per liter for New Jersey is 1; for Michigan, 25,000; and for Pennsylvania, 42,000. For PCE in indoor air, the toxicity value in micrograms per cubic meter for California is 0.41; for New Jersey, 3; for Pennsylvania, 36; and for Michigan, 42.[10] Differing State toxicity values, and EPA's lack of some toxicity values and final guidance, have raised concerns for a regional enforcement manager and staff. They believe that national consistency in screening standards is necessary. However, they also stated that they have not experienced any problems yet based on existing differing toxicity values. Enforcement staff have concerns about obtaining private party commitments to clean up sites to levels that are specified in a draft EPA guidance.

EPA reports that document the protectiveness of Superfund site remedies (Five-Year Reviews) show that the regions were waiting for final guidance or toxicity values before an evaluation or a complete evaluation of vapor intrusion would be done. For example,

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[7] U.S. Environmental Protection Agency, *OSWER Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils (Subsurface Vapor Intrusion Guidance)*, November 2002, Tables 2 and 3, third column, where the draft guidance indicates the toxicity values were extrapolated from oral sources.

[8] U.S. Environmental Protection Agency, *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual* (Part F, "Supplemental Guidance for Inhalation Risk Assessment"), EPA-540-R-070-002, OSWER 9285.7-82, January 2009.

[9] In the absence of IRIS or ORD-developed toxicity values, EPA's guidance directs the evaluator to use "other toxicity values." U.S. Environmental Protection Agency, *Human Health Toxicity Values in Superfund Risk Assessments*, OSWER Directive 9285.7-53, December 5, 2003. The Directive contains a hierarchy for human health toxicity values. The first tier is EPA's IRIS, the second is EPA's Provisional Peer Reviewed Toxicity Values developed by ORD, and the third is other toxicity values. Priority is recommended for sources of information that are the most current, the basis of which is transparent and publicly available, and which have been peer reviewed.

[10] Eklund, B. et al., "An Overview of State Approaches to Vapor Intrusion," *EM*, February 2007.

- The 2005 protectiveness review for a Region 3 site stated, "Due to the proximity of residential homes to the contaminated ground water plume, the potential for vapor intrusion into basements will need to be addressed in the future, once . . . EPA policy/guidance regarding investigation of vapor intrusion is established."

- The 2006 protectiveness review for a Region 9 site stated, "Once the guidance for evaluating the vapor intrusion to indoor air pathway is finalized or EPA and [the state regulatory agency] can agree to the process for evaluating the pathway, an indoor air risk evaluation should be conducted at the Site."

- The 2007 protectiveness review for a Region 7 site stated, "Revise the vapor intrusion risk evaluation after the new TCE toxicity factor is approved by EPA."

The protectiveness statements for the three sites were either qualified or limited. The Region 3 and Region 7 protectiveness reviews stated that the remedies for those sites were protective but had qualifications regarding vapor intrusion. The Region 9 protectiveness review could not make a protectiveness statement and recommends, among other actions, a vapor intrusion risk assessment.

EPA delays in conducting vapor intrusion risk assessments result in limited assurance that site clean-up actions have addressed these potential risks to humans and the environment.

Scientific and Administrative Issues Are Perceived as Barriers to Issuing Final Vapor Intrusion Guidance

According to Headquarters managers and staff, EPA has not finalized its guidance because the 2007 ITRC guidance, partly funded and supported by EPA, addressed many issues EPA would have included in a final guidance. They also believe finalizing EPA's guidance would take a long time in light of the emerging scientific issues in the field. In addition, if EPA issued vapor intrusion guidance, it would have been considered "significant guidance" under Executive Order 13422. The administrative review process triggered by Executive Order 13422 could be more detailed and lengthy.[11] However, in January 2009, Executive Order 13422 was revoked.[12]

Conclusions

EPA's efforts to address vapor intrusion and demonstrate policy positions and environmental leadership could be strengthened by updating, finalizing, and broadening the scope of one of its primary management controls – its guidance. Final guidance and toxicity values can promote effective and transparent enforcement of clean-up standards and requirements. They can also

[11] Executive Order 13422 created the term "significant guidance." When a guidance document is determined to be significant, an administrative review process is triggered. This process includes review by the Office of Management and Budget's Office of Information and Regulatory Affairs.

[12] All significant policy and guidance documents remain subject to review by the Office of Management and Budget, Office of Information and Regulatory Affairs under Executive Order 12866. See Office of Management and Budget, *Memorandum for the Heads and Acting Heads of Executive Departments and Agencies, Guidance for Regulatory Review,* M-09-13, March 4, 2009.

promote recovery of the government's clean-up costs, where applicable. Technical papers may not be effective for conveying and representing Agency policy.

Recommendations

We recommend that the Assistant Administrator for Solid Waste and Emergency Response:

1. Identify and publicly report the portions of OSWER's November 2002 draft vapor intrusion guidance that remain valid and the portions that should be updated.

2. Issue final vapor intrusion guidance(s) that incorporates information on:

    a. Updated toxicity values.
    b. A recommendation(s) to use multiple lines of evidence in evaluating and making decisions about risks from vapor intrusion.
    c. How risks from petroleum hydrocarbon vapors should be addressed.
    d. How the guidance applies to Superfund Five-Year Reviews.
    e. When or whether preemptive mitigation is appropriate.
    f. Operations and maintenance, the termination of the systems, and when institutional controls and deed restrictions are appropriate.

3. Train EPA and State staff and managers and other parties on the newly updated, revised, and finalized guidance document(s).

We recommend that the Assistant Administrator for Research and Development:

4. Finalize toxicity values for TCE and PCE in the IRIS database.

Agency Comments and OIG Evaluation

The OIG made changes to the report based on the Agency's comments where appropriate. Appendices B and C provide the Agency comments.

OSWER agreed with Recommendations 1 through 3, but was unclear about the milestones for Recommendations 1 and 2. Based on our follow-up, OSWER provided the milestones of August 2010 for Recommendation 1 and November 2012 for Recommendation 2. The milestone for Recommendation 3 will be May 2013. The recommendations will remain open with agreed-to actions pending.

ORD agreed with Recommendation 4, but was unclear about the milestones for each of the toxicity values. Based on our follow-up, ORD provided the milestones of December 2010 for the TCE toxicity value and July 2010 for PCE. The recommendation will remain open with agreed-to actions pending.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in $000s)	
Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Claimed Amount	Agreed To Amount
1	9	Identify and publicly report the portions of OSWER's November 2002 draft vapor intrusion guidance that remain valid and the portions that should be updated.	O	Assistant Administrator, Office of Solid Waste and Emergency Response	August 2010		
2	9	Issue final vapor intrusion guidance(s) that incorporates information on: a. Updated toxicity values. b. A recommendation(s) to use multiple lines of evidence in evaluating and making decisions about risks from vapor intrusion. c. How risks from petroleum hydrocarbon vapors should be addressed. d. How the guidance applies to Superfund Five-Year Reviews. e. When or whether preemptive mitigation is appropriate. f. Operations and maintenance, the termination of the systems, and when institutional controls and deed restrictions are appropriate.	O	Assistant Administrator, Office of Solid Waste and Emergency Response	November 2012		
3	9	Train EPA and State staff and managers and other parties on the newly updated, revised, and finalized guidance document(s).	O	Assistant Administrator, Office of Solid Waste and Emergency Response	May 2013		
4	9	Finalize toxicity values for TCE and PCE in the IRIS database.	O	Assistant Administrator, Office of Research and Development	December 2010 (TCE) and July 2010 (PCE)		

[1] O = recommendation is open with agreed-to corrective actions pending
C = recommendation is closed with all agreed-to actions completed
U = recommendation is undecided with resolution efforts in progress

Appendix A

EPA and Other Regulatory Guidance on Vapor Intrusion

U.S. Environmental Protection Agency. *OSWER Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils (Subsurface Vapor Intrusion Guidance).* EPA 530-D-02-004, November 2002.

U.S. Environmental Protection Agency. Office of Solid Waste and Emergency Response. *Brownfields Technology Primer: Vapor Intrusion Considerations for Redevelopment.* EPA 542-R-08-001, March 2008.

U.S. Environmental Protection Agency. Office of Solid Waste and Emergency Response. *Design Solutions for Vapor Intrusion and Indoor Air Quality.* EPA 500-F-04-004, March 2004.

U.S. Environmental Protection Agency. Office of Solid Waste and Emergency Response. *Superfund Environmental Indicator Guidance Human Health Revisions,* March 2008. http://www.epa.gov/superfund/accomp/ei/pdfs/final_ei_guidance_march_2008.pdf.

California Environmental Protection Agency. Department of Toxic Substances Control. *Interim Final Guidance for the Evaluation and Mitigation of Subsurface Vapor Intrusion to Indoor Air*, December 15, 2004 (revised February 7, 2005).

California Environmental Protection Agency. Department of Toxic Substances Control. *Vapor Intrusion Mitigation Advisory.* Draft, December 10, 2008.

Interstate Technology Regulatory Council. *Vapor Intrusion Pathway: A Practical Guideline*. Technical and Regulatory Guidance, January 2007.

New Jersey Department of Environmental Protection. *Vapor Intrusion Guidance*, October 2005. Also see 2009 updates at: http://www.nj.gov/dep/srp/guidance/vaporintrusion/whatsnew.htm#20090821.

New York State Department of Health. Center for Environmental Health. Bureau for Environmental Exposure Investigation. *Guidance for Evaluating Soil Vapor Intrusion in the State of New York*, October 2006.

U.S. Air Force, U.S. Navy, U.S. Army. *Tri-Services Handbook for the Assessment of the Vapor Intrusion Pathway.* Rev 4.0. Draft Final, February 15, 2008.

Appendix B

OSWER Response to OIG Draft Report

10/29/09

MEMORANDUM

SUBJECT: Response to Draft Evaluation Report: Lack of Final Guidance on Vapor Intrusion Impedes Efforts to Address Indoor Air Risks (Project No. 2009-0733).

FROM: Mathy Stanislaus /s/
Assistant Administrator

TO: Wade Najjum
Assistant Inspector General
Office of Program Evaluation

Thank you for the draft evaluation report of September 29, 2009, Lack of Final Guidance on Vapor Intrusion Impedes Efforts to Address Indoor Air Risks (Project No. 2009-0733). In general, we concur with your recommendations, and we are providing schedules for completing the various activities. We will seek input from the public on our efforts, and the schedules reflect this important step.

We appreciate the important role of EPA guidance in addressing risks from vapor intrusion and understand that final guidance will be beneficial. We also recognize the important role of our State and Tribal co-regulators who have the authority to establish and enforce standards in their jurisdiction. Likewise, we believe it is important to acknowledge that the EPA regions and OSWER program offices have continually taken steps to address risk from vapor intrusion using draft guidance.

The science and technology associated with evaluating and addressing risk from vapor intrusion is complex and evolving. A considerable amount of new information has become available since the draft 2002 OSWER Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soil (Subsurface Vapor Intrusion Guidance) EPA 530-D-02-004 was prepared. We concur with the recommendation (#1) to identify the portions of OSWER's November 2002 draft vapor intrusion guidance that remain valid and the portions that may need to be updated. OSWER will release the results of this review by the summer of 2010.

We also concur with the recommendation (#2) to issue final vapor intrusion guidance(s) that incorporates information on:

- sustainable vapor intrusion mitigation, operations and maintenance, the termination of the systems, and when institutional controls and deed restrictions are appropriate,

- when, or if, preemptive mitigation is appropriate,
- a recommendation(s) to use multiple lines of evidence in evaluating and making decisions about risks from vapor intrusion,
- how risks from petroleum hydrocarbon vapors should be addressed,
- updated toxicity values, including TCE and PCE, and
- how the guidance applies to Superfund Five-Year reviews.

In addition to these recommendations, OSWER plans to address other relevant topics (e.g., monitoring effectiveness of mitigation systems). Multiple guidance documents may be needed to update parts of the 2002 draft guidance and to address the issues raised in recommendation #2. We will seek public input early in the development of each document, interagency review, and external peer review. If multiple documents are developed they will be released as soon as possible with the final document being completed by the fall of 2012.

We concur with the recommendation (#3) to train EPA and State staff and managers, and other parties, on the newly updated, revised, and finalized guidance document(s). We also intend to provide outreach information that is appropriate for individuals that are not environmental professionals, for example members of the public. We will develop training materials within six months from the release of the guidance document(s).

We have attached a marked-up version of the draft report with suggestions to improve technical accuracy. One comment that we would like to highlight is interchangeable use of the terms toxicity values and exposure levels. We would also like to note that “standards” are typically considered to be values that have been promulgated and enforceable values. In closing, we would like thank you again for the draft evaluation report.

Attachment

Appendix C

ORD Response to OIG Draft Report

10/29/09

MEMORANDUM

SUBJECT: ORD Response to Draft OIG Report, *Lack of Final Guidance on Vapor Intrusion Impedes Efforts to Address Indoor Air Risks*, Project No. 2009-0733

FROM: Lek G. Kadeli /s/ Kevin Teichman for
Acting Assistant Administrator (8101R)

TO: Wade Najjum
Assistant Inspector General
Office of Program Evaluation (2460T)

Thank you for the opportunity to comment on the Draft OIG Report, *Lack of Final Guidance on Vapor Intrusion Impedes Efforts to Address Indoor Air Risks*, dated September 29, 2009. We have reviewed the draft report and generally concur with the findings as well as the one recommendation addressed to our office. Our comments are as follows:

ORD understands the importance of being able to provide updated vapor intrusion guidance to the public and is moving ahead to complete the Agency's toxicological reviews for the two compounds identified in subject draft report under Recommendation 4 and enter them into the IRIS database. Both are high priorities for ORD and are in varying stages of completion.

Predicting schedules for the completion and final posting of the assessments for these chemicals is difficult due to the variations in duration that may be experienced at different steps in the development, review and finalization process. Below, we present a synopsis of where the chemicals are in the review cycle, offer an anticipated completion date for the next milestone in the process, and projected completion dates.

Trichloroethylene (TCE)
The Interagency Science Consultation on the Draft Toxicological Review of Trichloroethylene (TCE) was held on Tuesday, September 22, 2009. Comments from the review are being considered, and it is expected that the draft document will be released for External Peer Review and public comment in early November 2009. Projected completion date for TCE is winter 2010.

Tetrachloroethylene (PERC)
The draft Toxicological Review of Tetrachloroethylene /Perchloroethylene(PERC) is currently undergoing External Peer Review by the National Academy of Sciences (NAS), and a prepublication draft of their final report is expected in late December 2009. Publication of the final NAS peer review report is expected by the end of March 2010. Projected completion date for PERC is summer 2010.

For both chemicals, it is very difficult to predict how long subsequent revisions and editing of the Toxicological Reviews may take until we understand the nature and extent of the comments and recommendations made by the reviewers. Finalization dates provided here represent our current best projection for completing these assessments. Updated schedules for both of these chemicals and many others are always available on the IRISTrack website at: https://cfint.rtpnc.epa.gov/ncea/iristrac/index.cfm?fuseaction=listChemicals.showList

Finally, we would like to clarify the purpose of these assessments and the information they provide. A toxicity assessment for IRIS provides an "inhalation unit risk" or an "oral cancer slope factor" for cancer that allows the risk to be calculated for various exposure scenarios. For non-cancer effects, the quantitative aspect is usually represented by a value (a concentration in air or an oral dose) such that if exposure is continuously below that value it is likely there will be no appreciable risk of deleterious effects. These toxicity values are not estimates of the current risk in any particular population because they do not include analysis of current exposure patterns. These are also not regulatory standards, although they may be used by EPA and others to decide upon regulatory standards appropriate to various situations. The term "exposure level" is used in the draft OIG report in several places where the term "toxicity value" should be used:

- In the "At A Glance" summary in the last two paragraphs
- Page 2, last sentence of the first paragraph
- Page 2, second to last paragraph, second sentence
- Page 8, "Conclusions" section, second sentence
- Page 9, Recommendation #4, "exposure levels" should be either "toxicological reviews" or "toxicity values"

ORD Corrective Action plan for Recommendation 4

Recommendation	Action Official	Corrective Action	Anticipated Completion Date
4. Finalize exposure levels for TCE and PCE in the IRIS database.	Assistant Administrator, Office of Research and Development	ORD will finalize the toxicological reviews for TCE and PCE by completing the following steps for each chemical 1. Draft Development 2.Agency Review 3.Interagency Review 4. External Peer Review 5. Final Assessment	TCE-winter 2010 PCE-summer 2010 For both chemicals, it is very difficult to predict how long subsequent revisions and editing of the Toxicological Reviews may take until we understand the nature and extent of the comments and recommendations made by the reviewers. Finalization dates provided here represent our current best projection for completing these assessments.

Should you or your staff have questions or require further information, please have them contact David Bussard at (703) 347-8647.

cc: Kevin Teichman
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Appendix D

Distribution

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