

**Public Health Response Plan
Midlothian, Texas**

Public Comment Release

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Prepared by:

The Agency for Toxic Substances and Disease Registry and the Texas
Department of State Health Services

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Introduction

The Agency for Toxic Substances and Disease Registry (ATSDR) and the Texas Department of State Health Services (DSHS) are evaluating environmental public health issues for the Midlothian, Texas area. To guide the agency in its evaluation, ATSDR and DSHS have created a plan to inform our partners of the agencies intentions and activities. This plan has been developed based on the review of environmental data and community concerns. The intent of the plan is (1) to describe the public health issues that ATSDR and DSHS are aware of; (2) to respond if the agencies can or will address these issues; and, (3) to state what reports and public health actions ATSDR and DSHS will generate or undertake. This plan is a living document, meaning that as ATSDR and DSHS evaluate public health issues for the Midlothian area, the plan can be added to or revised and the status of on-going activities can be updated.

The area of investigation is identified in Appendix A. The area which will be referred to as the Midlothian area, located southwest of the city of Dallas, has a population of around 15,000 and is located 26 miles south of Dallas and 27 miles southeast of Fort Worth. The Ash Grove, Gerda Ameristeel, Holcim, and TXI facilities are included in this area. Emissions from these facilities and general air quality for the designated area will be examined in the following projects.

ATSDR and DSHS's evaluation will be carried out by a team of ATSDR and DSHS staff members. Staff members are listed in Appendix B. The documents produced in this evaluation will be peer reviewed as agreed upon by the community and the agencies. Peer review is a process where independent scientists review and comment on the scientific documents produced by ATSDR. The ATSDR peer review policy is provided in Appendix C.

The Role of the Community in the Site Evaluation

The community is very important to our process. On several occasions, we have already sought community input, primarily by gathering community concerns. As draft documents are prepared, ATSDR and DSHS will conduct community meetings that are open for all interested community members. Meetings will be held at conveniently accessible locations, based on availability of local facilities. ATSDR and DSHS scientists will provide an overview of all documents, as they are released, and answer any questions that community members may have. ATSDR and DSHS expect the community to review the documents and provide comments.

ATSDR and DSHS will rely on various mechanisms to keep the community informed. These include: direct mailings; paid advertisements in the Dallas Morning News, the Star-Telegram and the Midlothian News-Mirror; notices on the ATSDR and DSHS websites, notices on the city and school district websites, email notices for those that we have email addresses; as well as other types of communication. We encourage the community to take an active part in sharing information with each other about our activities and meetings.

Contractual Support

The Eastern Research Group (ERG), a contractor to ATSDR, will be assisting in gathering site specific data and in developing and conducting air models. A work plan and time table will be developed for this work. ATSDR and DSHS will make all final decisions related to how the data interpreted from the contractors work.

Background

In July 2005, ATSDR was petitioned by Midlothian residents to evaluate health concerns, including respiratory illnesses and birth defects, that residents believed were associated with air quality from industrial emissions.

In October 2005, the ATSDR and DSHS met with several residents to listen to their concerns and discuss a plan of action. Because ATSDR has a cooperative agreement with DSHS (meaning that DSHS carries out the site work with oversight by ATSDR), DSHS took the lead in gathering and evaluating available environmental data from the Texas Commission on Environmental Quality (TCEQ) and speaking with residents to better understand their health concerns.

In December 2007, the DSHS issued a draft Public Health Consultation for Public Comment. The draft health consultation addressed the various air contaminants identified from ambient air samples collected by the TCEQ in the Midlothian area from May 1981-March 2005. This included 119 volatile organic compounds (VOCs) and 108 metals and other inorganic substances present in particulate matter. The draft health consultation concluded that there was an Indeterminate Public Health Hazard, because further information was needed to fully characterize the extent of the public health hazard posed by air contaminants, specifically chromium. Because of the large amount of data, DSHS had planned to develop a second health consultation to address other contaminants, including National Ambient Air Quality Standards (NAAQS) compounds.

Many comments were received on the draft Public Health Consultation. During the process of evaluating these comments, the ATSDR/NCEH Director requested that the ATSDR and DSHS team take a more comprehensive look at the site. Specifically, review the initial petitioner's concerns which questioned whether or not the data generated by the air monitors was being collected in a manner that could provide the pertinent answers to the community health concerns. ATSDR and DSHS are working collectively to look at all available data and determine is a relationship between air emissions and health concerns in the community. The community will be engaged throughout this review. As ATSDR staff members work with the community and stakeholders, this plan could be revised to add new activities to the list or to show the final outcome of listed activities. Changes in the plan will be indicated by revised text along with a change in the date. Technical reports will be peer reviewed by external scientists to ensure that they are of the highest scientific quality.

Community Concerns and Public Health Issues

Community concerns have been collected during the initial petition request, during a door-to-door survey 2005, and during the July 2009 community survey. The concerns are listed below.

Petition Concerns:

- Emitted chemicals not fully characterized – all emissions not identified (petition request)
- Persistence of emissions, the effects of continuous low level exposure, and the synergistic effects of emitted chemicals (petition request)
- Impact on pregnant women, infants, children, the elderly, the immuno-suppressed (petition request)
- Protectiveness of the regulatory health-based screening guidelines (petition request)
- Effectiveness of air monitoring from TCEQs monitoring stations (only run periodically) (petition request)
- DSHS reliance on data collected by other agencies (petition request)
- Rates of health problems, including leukemia, birth defects and childhood total cancer, are higher in Ellis Co. when compared to state-wide values (petition request)
- Rates for birth defects, including hypospadias/epispadias and others, are higher in Ellis Co. when compared to state-wide values (petition request)
- A study by TDSHS of a Down syndrome cluster in Ellis Co. was conducted but not designed to consider environmental factors (petition request)
- A higher incidence of respiratory problems has been identified in Midlothian, as stated in a symptom survey conducted by Legator, et al. (1998) (petition request)
- Current PHA be peer-reviewed by a panel of internal and external experts with experience in evaluating hazardous waste incineration sites (3/16/09 email to Dr. Frumkin)
- Peer review should incorporate comments from 6 scientists (3/16/09 email to Dr. Frumkin)
- Spatial and temporal coverage of this network, meteorology, dispersion modeling, identification of hot spots and resulting data be scientifically evaluated for its reliability for assessing public health (3/16/09 email to Dr. Frumkin)
- Empirical evidence such as higher birth defect rates, animal health problems, evidence of higher incidence of respiratory illness, etc, not be disregarded (3/16/09 email to Dr. Frumkin)
- Ms Markwardt's records be reviewed to determine incidence of her animal health issues (3/16/09 email to Dr. Frumkin)
- Confounding circumstances be considered (i.e. Ellis Co. is an ozone non-attainment area.) (3/16/09 email to Dr. Frumkin)
- ATSDR reclaim the responsibility for making the final public health determination inherent to this PHC (3/16/09 email to Dr. Frumkin)
- TXI continues to obtain permit approval without public input (recent news)

Community Concerns voiced during door-to-door surveys in Dec 2005:

- Cars are dusty all the time – thick/white dust
- Respiratory infections
- Allergies
- Asthma – improves when leave area
- Smell of rotten eggs around sunset

- Sinus problems
- Cancer
- Auto-Immune diseases (sarcoidosis involving lungs and eye lids)
- Dogs with tumors and birth defects
- Air quality problems
- Graves Disease

Concerns voiced during interviews in July 2009:

Monitoring quality faulty; testing of emissions; lack of accurate testing (most frequently mentioned)

- Air or water quality in Midlothian, TX (cleaner air, better tasting water)
- Health effects of air quality
- Common cause for diseases (no one disease or condition was mentioned more frequently than others and were general e.g. categories of respiratory, cancer, Down Syndrome, Autism, etc.)
- What the cement plant is burning and discharging?
- Are disease rates higher in Midlothian than other cities?
- Are there air or water quality issues in Midlothian?
- Whether air quality can be corrected?
- Are emission levels of chemical safe (e.g. mercury, lead, HCL acid, etc)?
- Strong smell of air
- Potential contamination of lake/fish
- How to protect air/water quality in Midlothian
- Transportation contribution to air quality problem
- Everyone does not have access to same information; not enough information
- Burning hazardous waste and long term effects
- Air and water quality issues will give wrong idea of Midlothian (great place to live, good jobs, etc.)

The majority of the concerns fall under 10 themes as described in the summarized community concerns below.

Summarized Community Concerns

1. Effectiveness of air monitoring from TCEQs monitoring stations (only run periodically);
2. Emitted chemicals not fully characterized – all emissions not identified;
3. Protectiveness of the regulatory health-based screening guidelines;
4. Persistence of emissions, the effects of continuous low level exposure to individual chemicals and/or mixtures.
5. Impact on pregnant women, infants, children, the elderly, the immuno-suppressed;
6. Rates of health problems, including leukemia, birth defects and childhood total cancer, are higher in Ellis Co. when compared to state-wide values;
7. Rates for birth defects, including hypospadias/epispadias and others, are higher in Ellis Co. when compared to state-wide values; and,
8. Lack of inclusion of environmental factors in a study by TDSHS of a Down syndrome cluster in Ellis County.
9. A higher incidence of respiratory problems has been identified in Midlothian, as stated in a symptom survey conducted by Legator, et al. (1998).
10. Many concerns have been expressed about animals and the illnesses that they are experiencing. Concern that animals may be acting as sentinels for humans.

Based on these concerns, six projects have been developed to each concern as designated in Table 1. The description of each project follows.

Concern	Project 1	Project 2	Project 3	Project 4	Project 5	Project 6
Community Involvement	X	X	X	X	X	X
Complete Pathway and Chemical evaluation	X	X	X	X	X	X
Effectiveness of air monitoring from monitoring stations	X					
Emitted chemicals not fully characterized	X	X				
Protectiveness of regulatory screening guidelines	X					
Persistence of emissions and the effects of continuous low level emissions		X	X	X		
Impact on sensitive populations	X	X	X	X	X	
Rates of birth defects are higher in Ellis County					X	
Rates of health problems are higher in Ellis County					X	
Lack of inclusion of environmental factors in Down Syndrome evaluation					X	
Higher incidence of respiratory problems (Legator, et al survey)					X	
Animal concerns						X

Project 1: Review and Analysis of TCEQ Air Monitoring and Its Applicability for Drawing Health Conclusions for the Surrounding Populations

Purpose: Are the air monitors in the right place to capture good information about air exposures?
Are the air monitors monitoring for the right chemicals?
Does monitoring every 6th day for 24 hours give adequate information for the emitted chemicals?
Are there “hot spots” in the community?

Actions:

- This project will be discussed in detail as we initiate and progress through the project.
- ATSDR and DSHS and ERG will review the TCEQ quality assurance/quality control plan for the previously conducted and current sampling efforts in the Midlothian community.
- ATSDR and DSHS will use meteorological data to determine typical downwind wind vectors and identify whether or not for various sampling locations adequately represent downwind conditions.
- ATSDR, DSHS and ERG will complete a Public Health Consultation that will evaluate literature, permits and available data to characterize site emissions. This information will be compared to similar operations to ensure that all chemicals of concern are evaluated. The need for additional air data and/or modeling will be assessed by the team and a recommendation will be made, if warranted.
- The document will go through a public comment and then a formal peer review process prior to being finalized.

Timeline:

Project 2: Review and Analysis of Volatile Organic Compounds (VOC) and Metal Exposures in Air

Purpose: What are the public health implications of exposure to VOCs and metals in ambient air? (Persistence of emissions and the effects of continuous low level exposure to individual chemicals and/or mixtures)

Actions:

- This project will be discussed in detail as we initiate and progress through the project.
- ATSDR and DSHS will organize and evaluate VOC and metal data and describe the data statistically to assess trends of chemical contaminants over time (peaks vs. average concentrations).
- ATSDR and DSHS will review available current toxicity screening values and ensure that the most current screening values are used. In the event no screening value is available, recent published peer review studies will be researched. In the event that no screening data are available and no recent epidemiologic studies are available, toxicity screening values for surrogate, chemically – similar compounds will be used.
- ATSDR and DSHS will use health protective screening values to determine contaminants of concern and if the contaminants are at levels that could cause health effects. The potential health effects, particularly risks to sensitive populations such as pregnant women, infants, children, and the elderly will be considered. This will include an analysis of short term or intermittent exposures and chronic term exposures.
- ATSDR and DSHS will complete a Public Health Consultation, which will include toxicological analysis, conclusions, recommendations and appropriate health actions based on the VOC and metal contaminant data.
- The document will go through a public comment and then a formal peer review process prior to being finalized.

Timeline:

Project 3: Review and Analysis of Volatile Organic Compounds and Metal Exposures From Air Emissions in Media Other than Air (eg, vegetation, soil, slag, wheat, fish (Joe Pool Lake), and water samples)

Purpose: What are the public health implications of exposure to VOCs and metals in other contaminant data?

Actions:

- This project will be discussed in detail as we initiate and progress through the project.
- ATSDR and DSHS will collect available data on VOC and metal contaminants in vegetation, soil, slag, wheat, fish and water.
- ATSDR and DSHS will use health protective screening values to determine contaminants of concern and if the contaminants are at levels that could cause health effects. ATSDR/DSHS and ERG will review available current toxicity screening values, and ensure that the most current screening values are used from various entities (DSHS, ATSDR, USEPA, etc.). In the event that no recent screening values are available, recent published peer review studies will be researched. In the event that no screening data are available and no recent epidemiologic studies are available, toxicity screening values for surrogate, chemically-similar compounds will be used.
- ATSDR and DSHS will complete an evaluation, which will include toxicological analysis, conclusions and recommendations. This evaluation will include an evaluation of health impacts to adults and children.
- The document will go through a public comment and then a formal peer review process prior to being finalized.

Timeline:

Project 4: Evaluation of the public health implications of NAAQS and Hydrogen Sulfide ambient air pollutants in Midlothian.

Purpose: Do facility emissions and Midlothian air quality (eg, ozone, hydrogen sulfide [H₂S], nitrogen dioxide [NO₂], and sulfur dioxide [SO₂]) impact the health of residents?

Actions:

- This project will be discussed in detail as we initiate and progress through the project.
- ATSDR and DSHS will obtain available data on ozone, hydrogen sulfide, nitrogen dioxide, sulfur dioxide, and particulate matter levels in the Midlothian area.
- ATSDR and DSHS will compare community exposure levels to health protective screening values, obtained from USEPA, WHO and ATSDR, for these ambient air pollutants
- ATSDR and DSHS will determine if individual air pollutants are at levels that could cause harmful health effects. To the extent possible, we will determine if the levels of any combination of the air pollutants exposure levels may cause harmful effects. This evaluation will include an evaluation of health impacts to adults and sensitive populations, like children and others.
- ATSDR and DSHS will complete a Public Health Consultation, which will include toxicological evaluation, conclusions, recommendations and applicable health actions.
- The document will go through a public comment and then a formal peer review process prior to being finalized.

Timeline:

Project 5: Evaluation of Health Outcome Data for the Midlothian Area

Purpose: Is there a relationship between acute or chronic health outcomes of interest and short-term and long-term exposures to emissions from the facilities and ambient air in the impacted area?

Actions:

- This project will be discussed in detail as we initiate and progress through the project.
- Obtain the most up-to-date health outcome data available and analyze the health statistics in areas that receive emissions from the facilities, as defined by the air modeling.
- Address health concerns that Midlothian residents feel are associated with air quality that result in respiratory diseases (including asthma, respiratory infections, symptoms reported in the Legator study, sinus problems, etc.) by evaluating available asthma data for the area and reviewing literature on respiratory impacts in light of the environmental air sampling data.
- Use the cancer registry data available for the impacted area to address concerns that Midlothian residents feel are associated with air quality and cancer incidence and mortality (including leukemia, adult and childhood cancers).
- Evaluate the birth defect registry data for the impacted area to address health concerns that Midlothian residents feel are associated with air quality for birth defects (including hypospadias, epispadias, and Down syndrome).
- Investigate the feasibility of obtaining and using alternate health outcome or indicator data (such as school attendance data or pharmaceutical purchases) to be used in the assessment of health outcomes of concern for the Midlothian area.
- For the community-reported health concerns on other diseases including immune diseases (immune system deficiencies, sarcoidosis, Grave's disease, allergies) and acute effects (odor complaints, headaches) for which no registry data exists, review the plausibility of any relationship with short-term or long-term air emissions from the facilities by evaluating the medical and toxicological literature.
- Provide appropriate community health education which may include a public meeting, fact sheets, or other outreach tools.
- ATSDR and DSHS will complete a Public Health Consultation, which will include the health outcome data evaluation and review, literature review, conclusions, recommendations and applicable health actions.
- The document will go through a public comment and then a formal peer review process prior to being finalized.

Timeline:

Project 6: Evaluation of Reported Health Issues in Animals in the Midlothian Area

Purpose: Is there an association between animal-related health issues and air emissions reported in the Midlothian area?

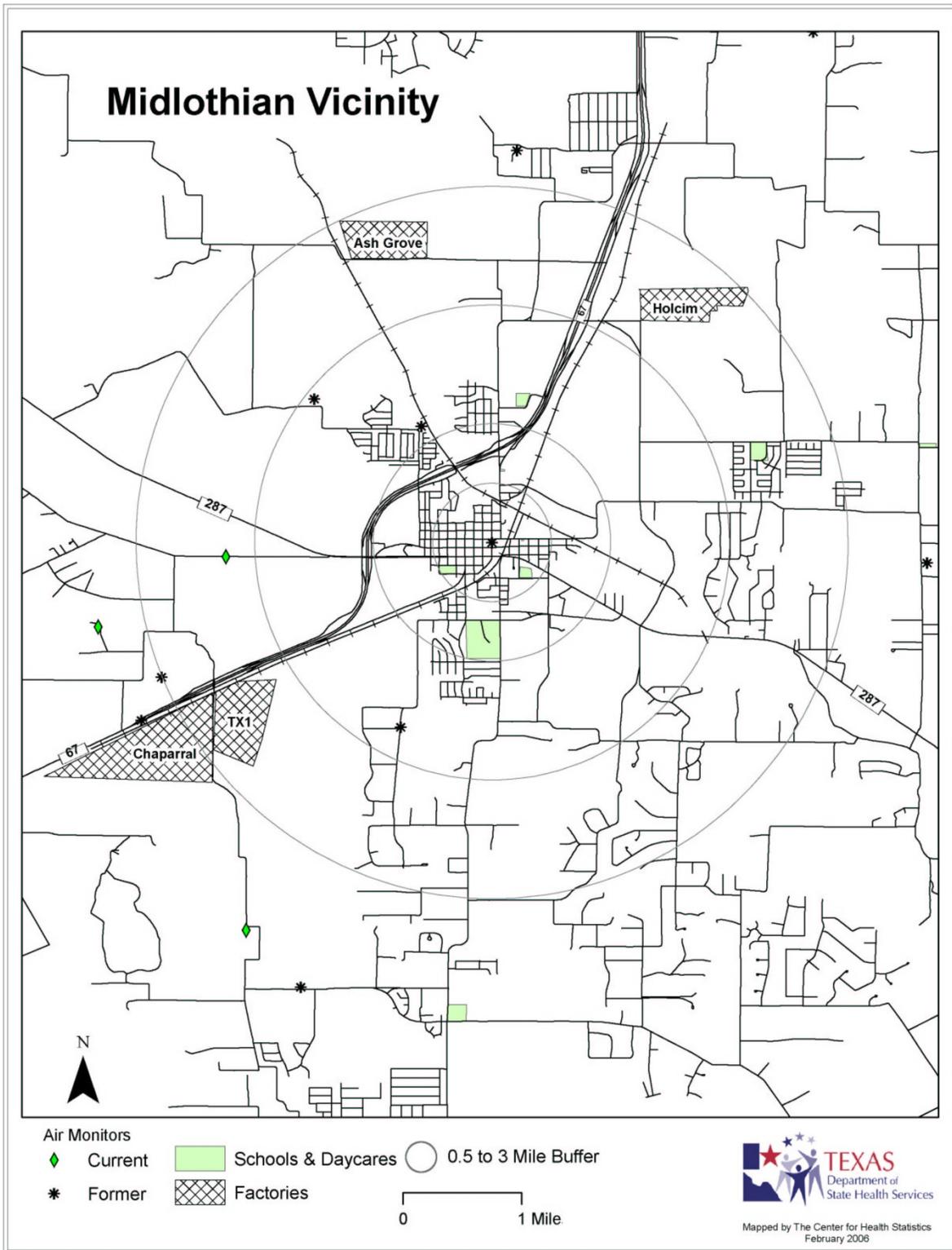
Actions:

- This project will be discussed in detail as we initiate and progress through the project.
- Identify veterinary issues by review of the site petition, site visit, and community survey results.
- Identify and contact local practicing veterinarians and state veterinarians to request information on animal related health issues reported and/or investigated in the Midlothian area.
- Conduct a site visit to discuss animal health issues with the Midlothian community.
- Develop a list of symptoms of concern for various organ systems.
- Assess the findings of the TCEQ Report to determine the extent to which data can be used to estimate exposures of companion animals and livestock in Midlothian area.
- Conduct a literature review for toxicological information on contaminants of concern and potential health effects.
- Develop route specific Provisional Animal Health Guidance Values (PAHGVs) for use in screening environmental contaminants identified in evaluation of the TCEQ data.
- Utilize screening values (PAHGVs) to identify contaminants of concern and whether contaminants are at levels that could produce adverse outcomes in the animals (past and present).
- ATSDR and DSHS will complete a Public Health Consultation, which will include toxicological evaluation, conclusions, recommendations and applicable health actions.
- The document will go through a public comment and then a formal peer review process prior to being finalized.

Timeline:

Completed Activities

Appendix A



Appendix B

January 2010

Midlothian Team
ATSDR/DSHS

Team Lead:

Jennifer Lyke

Environmental:

Michelle Colledge, PhD
Karl Markiewicz, PhD
Greg Ulirsch, PhD
Richard Beauchamp, MD, MPH
John Villanacci, PhD

Health Outcome:

Michelle Watters, MD, PhD, MPH
Charles Weir, MPH, MS EnvE, PE
John Villanacci, PhD
Susan Prosperie, MS, RS
Richard Beauchamp, MD, MPH

Animal Issues:

Tina Walker
Dennis Jones, DVM
Stephanie Ostrowski, DVM, MPVM, DAVCPM, CAPT, USPHS
Nancy Ingram

Health Education:

Tina Walker
Nancy Ingram
Michelle Watters, MD, PhD, MPH
Januett George-Smith, MSW, CDR, USPHS

Community Involvement:

Tina Walker
Nancy Ingram
Jennifer Lyke
Januett George-Smith, MSW, CDR, USPHS

Table 1. Team Assignments

Project #	Description	Lead Staff Assigned	Outcome	Status
1	Review and Analysis of TCEQ Air Monitoring and it's Applicability for Drawing Health Conclusions for the Surrounding Populations	Colledge/ Markiewicz		
2	Review and Analysis of Volatile Organic Compounds (VOC) and Metal Exposures in Air	Colledge/ Markiewicz		
3	Review and Analysis of Volatile Organic Compounds (VOC) and Metal Exposures in Media Other Than Air	Markiewicz		
4	Evaluation of the Public Health Implications of Total Air Quality in Midlothian	Ulirsch		
5	Evaluation of Health Outcome Data for the Midlothian Area	Watters		
6	Evaluation of Reported Health Issues in Animals in the Midlothian Area.	Jones/ Ostrowski		First visit to community – Dec 2009

Appendix C

ATSDR Peer Review Policy

Effective Date: May 1, 1990

Revised Date: March 1, 1996

All protocols, studies, and results of research that ATSDR carries out or funds in whole or in part; and studies that have not previously been peer reviewed that are intended to be used in the Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profiles must be peer reviewed according to this policy.

I. Legislation

Studies and results of research used in ATSDR's Toxicological Profiles will be peer reviewed by the Agency for Toxic Substances and Disease Registry (ATSDR) if they have not been peer reviewed elsewhere as required by the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) section 104(i)(3), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA).1

All studies and results of research (other than health assessments) that ATSDR carries out or funds in whole or in part will be peer reviewed to meet the requirements of CERCLA section 104(i)(13), as amended by SARA.2 ATSDR funded or conducted studies must:

Be reported or adopted only after appropriate peer review.

Be peer reviewed within a period of 60 days to the maximum extent practical.

Be reviewed by no fewer than three or more than seven reviewers who a) are selected by the Administrator, ATSDR; b) are disinterested scientific experts; c) have a reputation for scientific objectivity; and d) who lack institutional ties with any person involved in the conduct of the study or research under review.

II. Proposed Research

The ATSDR policy is to assure that all proposed research (whether proposed by ATSDR investigators or non-ATSDR investigators) receives proper consideration based on the principles of excellence expressed in the following criteria.*

A. Principles of Excellence

Research performance competence

Capability of the investigator(s), technical soundness of the proposed approach, institutional resources available, and recent research performance of the investigator.

Intrinsic merit of the research

The likelihood that the research will lead to new discoveries or fundamental advances within its field of science or will have substantial scientific impact.

Utility or relevance of the research

The likelihood that the research can contribute to achieving goals extrinsic to those of the research field itself, and can thereby serve as the basis for new or improved technology or assist in solving societal problems.

Effect of the research on the science infrastructure

The potential of the proposed research to contribute to a better understanding or improvement of the quality, distribution, or effectiveness of the nation's base of scientific research, education, and human resources.

B. Epidemiologic Research

For epidemiologic research, ATSDR considers that associations between risk factors and adverse health effects are more likely to be valid if they have been obtained from studies with the following characteristics:^{3,4,5,6}

Are derived from well-designed and well-executed case-control or cohort studies without significant bias.

Display a strong association unlikely to be due to chance variation.

Follow a logical, temporal sequence of exposure and response.

Have been replicated in a variety of settings.

Exhibit a dose-response relationship.

Are toxicologically plausible.

Include examinations of causality, where possible (strength of association, consistency, specificity, temporality, biological gradient, plausibility, coherence, experimental evidence, analogy).

Include chain of custody procedures for biological and environmental samples.

Include quality assurance and quality control procedures for laboratory analyses.

C. Toxicologic Research

For toxicologic research, ATSDR considers that National Research Council Guidelines should be followed to the greatest extent possible.⁷ These include:

All elements of exposure are clearly described.

Results in test subjects are predictive of human responses and test subjects are sensitive to the substance's effects.

Controls are comparable to test subjects in all respects except the treatment variable.

End points answer the specific question addressed in the study and observed effects are sufficient in number or degree to establish a dose-response relationship that can be used in estimating the hazard to the target species.

Due consideration in both study design and interpretation must be given for appropriate statistical analysis of the data.

Subjective elements in scoring should be minimized.

Peer review of scientific papers and reports is desirable.

Reported results have increased credibility if they are supported by findings in other investigations.

Results should be similar to those of tests conducted on structurally related compounds.

Study protocols should evidence adherence to good laboratory practices including quality assurance and quality control procedures for laboratory analyses.

III. Applicability and Scope

A. General

The peer review policy applies to all research protocols, studies, and results of research carried out or funded in whole or in part by ATSDR; reports with substantive interpretation of data derived from exposure and disease registries and health surveillance programs; and studies used in ATSDR's Toxicological Profiles that have not been previously peer reviewed. Questions concerning whether a project is research should be submitted in writing to the Associate Administrator for Science, ATSDR.

ATSDR will peer review a) protocols prior to carrying out or funding research projects, b) reports of studies and results of research (including reports of preliminary findings) after projects are completed, but before final reports are submitted to ATSDR, c) reports with substantive interpretation of data derived from exposure and disease registries and health surveillance programs, and d) studies and results of research not previously peer reviewed that are used in ATSDR's Toxicological Profiles.

Peer review is conducted by ATSDR through ad hoc mail reviews, reviews by a panel of experts (either by telephone or assembled), or a combination of both. Peer review may be supplemented with additional reviews, site visits, etc., as appropriate for specific protocols, studies, or results of research.

Reviewers will be selected by ATSDR for a given peer review because they meet the CERCLA requirements for peer reviewers and they have an appropriate mix of knowledge areas for the research being considered.²

When possible, all protocols or reports of studies or results of research submitted for a specific research program of an ATSDR Division or for a specific Toxicological Profile will be sent to the same peer reviewers. However, ATSDR recognizes that, at times, the number of protocols or reports received may be so large that individual reviewers would be overwhelmed. When necessary, ATSDR will submit protocols, reports of studies, or results of research for a specific ATSDR research program or a specific Toxicological Profile to different peer reviewers.

Individual peer review comments will be provided to the principal investigator and ATSDR Division submitting the protocol, study, or results of research.

B. Protocols

Exceptional circumstances (e.g., chemical emergencies) may mitigate against peer review of a study protocol. These instances will be handled on a case-by-case basis by the ATSDR Associate Administrator for Science.

C. Studies and Results of Research

All studies and results of research carried out or supported by ATSDR must have a final report submitted to the appropriate Division of ATSDR at the completion of the project.

Reports of studies and results of research must be peer reviewed before the final report is submitted to the appropriate Division of ATSDR. The final report submitted to ATSDR must consider all peer review comments. The reasons for not adopting any peer reviewer's comment should be documented in a separate letter to the appropriate ATSDR Division.

Manuscripts that substantially alter the conclusions of a study report or present new, previously unreported data from studies and results of research conducted with CERCLA funds require a peer review before being submitted for publication or being released to the public.

ATSDR encourages the presentation of work in progress at local, regional, national, and international workshops, seminars, and meetings, providing that an appropriate disclaimer be given at the beginning of the presentation that findings being reported have not yet undergone peer review and are therefore, provisional; and further that (a) for ATSDR presenters, presentation materials are reviewed and approved in advance at the Division/Office level, or (b) for grantee presenters, presentation materials are discussed in advance with the relevant ATSDR project officer to insure that premature and/or misleading inferences are not likely to be drawn from the presentation and that results of biomedical tests on study participants are not being divulged before they have been formally transmitted to study communities and participants.

D. Studies That Have Not Previously Been Peer Reviewed That Are Intended To Be Used in the ATSDR Toxicological Profiles

Studies and results of research not previously peer reviewed that are used in ATSDR's Toxicological Profiles will be peer reviewed.

E. Exceptions

Research conducted by the National Toxicology Program (NTP) under ATSDR funding will be peer reviewed by the NTP Board of Scientific Counselors, as mandated in CERCLA, section 104(i)(13), as amended by SARA.2

Health Assessments, Toxicological Profiles, and ATSDR's Case Studies in Environmental Medicine, are not considered to be studies or research. Therefore, peer review under this statute [(104(i)(13) as amended by SARA], is not required by ATSDR.

Work in progress may be presented at local, regional, national, and international workshops, seminars, and meetings, providing that an appropriate disclaimer be given at the beginning of the presentation that findings being reported have not yet undergone peer review and are therefore, provisional; and further that (1) for ATSDR presenters, presentation materials are reviewed and approved in advance at the Division/Office level, or (b) for grantee presenters, presentation materials are discussed in advance with the relevant ATSDR project officer to insure that premature and/or misleading inferences are not likely to be drawn from the presentation and that results of biomedical tests on study participants are not being divulged before they have been formally transmitted to study communities and participants.

Documents consisting only of statistical information (i.e., tabular data without substantive interpretation of those data) are not considered studies or results of research under CERCLA, section 104(i)(3) and 104(i)(13), as amended by SARA. Peer review of such documents, under this statute, is not required by ATSDR.

Manuscripts based on previously peer reviewed studies and results of research do not need to undergo additional peer review if they are restatements of a study report or results of research a) already peer reviewed under the "ATSDR Peer Review Procedures" and b) already accepted by ATSDR as a final report.

IV. Glossary of Terms Peer Review -- A critical review by outside (not ATSDR) expert scientists of a study protocol or studies or results of research performed in conformity with the description of peer review given in CERCLA as amended by SARA, section 104(i)(13).2

Disinterested Scientific Experts -- Persons with a reputation for scientific objectivity who lack institutional ties with any person involved in the study or research under review and who conform with the requirements in CERCLA as amended by SARA, section 104(i)(13).2

Study -- A systematic investigation conducted to answer a question of scientific interest, leading to new or updated knowledge. A study may be designed to investigate and plan control measures for a specific problem occurring in a specific population or community (non-research) or to contribute to generalizable knowledge (research). If the main purpose of the study is to determine both the cause and or extent of a community health problem and to develop control plans, it is considered to be non-research. If the main purpose of the study is to contribute to generalizable knowledge, the

study is considered to be research. However, both research and non-research studies must be preceded by the preparation of a study protocol and followed by a study report.

Study Protocol -- An exact plan for a study or investigation containing specific information and descriptions of the elements listed in the study proposal problem, hypothesis, and methods, including chain of custody procedures for biologic and environmental samples, and quality assurance and quality control procedures for laboratory analyses.

Study Report -- A detailed description of the problem, hypothesis, methods, results, conclusions, and recommendations that collectively constitute a performance record of the study or investigation.

Preliminary Findings -- Data collected up to a certain point in a study or results of incomplete data analysis.

V. References

Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA, section 104(i)(3), 42 U.S.C.

Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA, section 104(i)(3), 42 U.S.C.

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*Many of the ideas and some of the specific wording used in the "ATSDR Peer Review Policy" are taken from the "Proposal and Award Manual" published by the National Science Foundation (NSF Manual No. 10, Washington, D.C.: National Science Foundation, 1989.)