Health Consultation

WRIGHT MEDICAL TECHNOLOGY, INC.

AIR SAMPLING RESULTS EVALUATION

ARLINGTON, SHELBY COUNTY, TENNESSEE

AUGUST 8, 2012

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Tennessee Department of Health's Environmental Epidemiology Program.

Foreword

This document summarizes an environmental public health investigation performed by the Environmental Epidemiology Program of the State of Tennessee Department of Health. Our work is conducted under a Cooperative Agreement with the federal Agency for Toxic Substances and Disease Registry. In order for the Health Department to answer an environmental public health question, several actions are performed:

Evaluate Exposure: Tennessee health assessors begin by reviewing available information about environmental conditions at a site. We interpret environmental data, review site reports, and talk with environmental officials. Usually, we do not collect our own environmental sampling data. We rely on information provided by the Tennessee Department of Environment and Conservation, U.S. Environmental Protection Agency, and other government agencies, businesses, or the general public. We work to understand how much contamination may be present, where it is located on a site, and how people might be exposed to it. We look for evidence that people may have been exposed to, are being exposed to, or in the future could be exposed to harmful substances.

Evaluate Health Effects: If people have the potential to be exposed to contamination, then health assessors take steps to determine if it could be harmful to human health. We base our health conclusions on exposure pathways, risk assessment, toxicology, cleanup actions, and the scientific literature.

Make Recommendations: Based on our conclusions, we will recommend that any potential health hazard posed by a site be reduced or eliminated. These actions will prevent possible harmful health effects. The role of the Environmental Epidemiology Program in dealing with hazardous waste sites is to be an advisor. Often, our recommendations will be action items for other agencies. However, if there is an urgent public health hazard, the Tennessee Department of Health can issue a public health advisory warning people of the danger, and will work with other agencies to resolve the problem.

If you have questions or comments about this report, we encourage you to contact us.

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Glossary of Terms and Acronyms

adverse health effect: A change in body function or cell structure that might lead to disease or health problems

ambient: Surrounding (for example, *ambient* air).

ATSDR: Agency for Toxic Substances and Disease Registry.

background level: An average or expected amount of a substance in a specific environment, or typical amounts of substances that occur naturally in an environment.

cancer: Any one of a group of diseases that occur when cells in the body become abnormal and grow or multiply out of control.

cancer risk: The theoretical excess risk for getting cancer if exposed to a substance every day for 70 years (a lifetime exposure). The true risk might be lower. The excess cancer risk is often expressed as $1x10^{-6}$ for one excess cancer in 1 million people.

carcinogen: A substance that may cause cancer.

chronic exposure: Contact with a substance that occurs over a long time (more than 1 year).

Comparison Value (CV): Calculated concentration of a substance in air, water, food, or soil that is unlikely to cause harmful (adverse) health effects in exposed people. The CV is used as a screening level for health assessment. Substances found in amounts greater than their CVs might be selected for further evaluation in the public health assessment process.

concentration: The amount of a substance present in a certain amount of soil, water, air, food, blood, hair, urine, breath, or any other media.

Cancer Risk Evaluation Guide (CREG): soil, water or air comparison values that are used to identify concentrations of cancer-causing substances that are unlikely to result in an increase of cancer rates in an exposed population.

contaminant: A substance that is either present in an environment where it does not belong.

detection limit: The lowest concentration of a chemical that can reliably be distinguished from a zero concentration.

EEP: Environmental Epidemiology Program of the Tennessee Department of Health.

Environmental Media Evaluation Guide (EMEG): Concentrations of substances in water, soil, or air to which humans may be exposed during a specified period of time (acute, intermediate, chronic) without experiencing adverse health effects.

EPA: United States Environmental Protection Agency.

epidemiology: The study of the distribution and determinants of disease or health status in a population; the study of the occurrence and causes of health effects in humans.

exposure: Contact with a substance by swallowing, breathing, or touching the skin or eyes. Exposure may be short-term [acute exposure], of intermediate duration, or long-term [chronic exposure].

exposure pathway: The route a substance takes from its source (where it began) to its end point (where it ends), and how people can come into contact with (or get exposed to) it. An exposure pathway has five parts: 1. a source of contamination (such as an abandoned business), 2. an environmental media and transport mechanism (such as movement through groundwater), 3. a point of exposure (such as a private well), 4. a route of exposure (eating, drinking, breathing, or touching), and 5. a receptor population (people potentially or actually exposed). When all five parts are present, the exposure pathway is termed a completed exposure pathway.

groundwater: Water beneath the Earth's surface in the spaces between soil particles and between rock surfaces.

hazard: A source of potential harm from past, current, or future exposures.

health consultation: A review of available information or collection of new data to respond to a specific health question or request for information about a potential environmental hazard. Health consultations are focused on a specific exposure issue. Health consultations are therefore more limited than a public health assessment, which reviews the exposure potential of each pathway and chemical.

inhalation: The act of breathing. A hazardous substance can enter the body this way.

intermediate duration exposure: Contact with a substance that occurs for more than 14 days and less than a year.

migration: Chemical movement from one location to another.

Minimal Risk Level (MRL): An ATSDR estimate of daily human exposure to a hazardous substance at or below which that substance is unlikely to pose a measurable risk of harmful (adverse), noncancerous effects. MRLs are calculated for a route of exposure (inhalation or oral) over a specified time period (acute, intermediate, or chronic). MRLs should not be used as predictors of harmful (adverse) health effects.

plume: A volume of a substance that moves from its source to places farther away from the source. Plumes can be described by the volume of air or water they occupy and the direction they move. For example, a plume can be a column of smoke from a chimney or a substance moving with groundwater.

ppb: parts per billion.

reference dose: An EPA estimate, with uncertainty or safety factors built in, of the daily lifetime dose of a substance that is unlikely to cause harm in humans.

Regional Screening Level (RSL): comparison levels prepared by the U.S. Environmental Protection Agency that are chemical-specific concentrations for individual contaminants in air, drinking water, and soil that may warrant further investigation or site cleanup.

remediation: 1. Cleanup or other methods used to remove or contain a toxic spill or hazardous materials from a site.

risk: The probability that something will cause injury or harm. For non-carcinogen health effects, it is evaluated by comparing an exposure level over a period to a reference dose derived from experiments on animals. For carcinogenic health effects, risk is estimated as the incremental probability of an individual developing cancer over a lifetime (70 years) as a result of exposure to a potential carcinogen.

route of exposure: The way people come into contact with a hazardous substance. Three routes of exposure are breathing (inhalation), eating or drinking (ingestion), or contact with the skin (dermal contact).

sample: A portion or piece of a whole. A selected subset of a population or subset of whatever is being studied. For example, in a study of people the sample is a number of people chosen from a larger population. An environmental sample, such as a small amount of soil or water, might be collected to measure contamination in the environment at a specific location.

soil-gas: Gaseous elements and compounds in the small spaces between particles of earth and soil. Such gases can be moved or driven out under pressure.

solvent: A liquid capable of dissolving or dispersing another substance (for example, acetone or mineral spirits).

source area: The location of or the zone of highest soil or groundwater concentrations, or both, of the chemical of concern. The source of contamination is the first part of an exposure pathway.

TDEC: Tennessee Department of Environment and Conservation

Trichloroethylene (TCE): A chemical that is nonflammable liquid at room temperature. It is a manufactured chemical that is widely used to remove grease from metal parts. Trichloroethylene is also an ingredient in other consumer products. It evaporates easily into the air from surface water and has a somewhat sweet odor.

toxicological profile: An ATSDR document that examines, summarizes, and interprets information about a hazardous substance to determine harmful levels of exposure and associated health effects. A toxicological profile also identifies significant gaps in knowledge on the substance and describes areas where further research is needed.

Toxicology: The study of the harmful effects of substances on humans or animals.

$\mu g/m^3$: micrograms per cubic meter. Air results are usually measured in both $\mu g/m^3$ and ppb.

vapor intrusion: The process by which volatile chemicals migrate from an underground source into the indoor air of buildings.

Volatile Organic Compounds (VOCs): Organic compounds that evaporate readily into the air. VOCs include substances such as benzene, dichloroethylene, toluene, trichloroethylene, methylene chloride, methyl chloroform, and vinyl chloride.

Introduction

The Tennessee Department of Environment and Conservation (TDEC), Division of Remediation's (DoR), State Remediation Program (SRP) asked the Tennessee Department of Health's (TDH) Environmental Epidemiology Program (EEP) to review the results of air samples collected at the Wright Medical Technology, Inc. (WMT) Site. All samples were collected as part of a vapor intrusion investigation conducted in March 2012 (EnSafe 2012a). This review is based on samples collected during one indoor air sampling event and is not intended to be an in-depth comprehensive evaluation of the site.

Through previous environmental investigations, soil and groundwater beneath the WMT Site were found to be contaminated by various chemicals. Many of the chemicals were volatile organic compounds (VOCs). Historical groundwater sampling found chlorinated solvent VOCs. Chemicals found in the groundwater included: 1,1-dichloroethane (1,1-DCA), 1,1-dichloroethylene (1,1-DCE), tetrachloroethylene (PCE), trichloroethylene (TCE), vinyl chloride (VC), 1,1,1-trichloroethane (1,1,1-TCA), 1,1,2-trichloroethane (1,1,2-TCA), and other VOCs such as xylenes and trichloroflurometháne. The primary chemicals found in groundwater samples included 1,1-DCE, 1,2-DCA, TCE, and 1,1,1-TCA. Based on groundwater sampling and analysis, the VOC groundwater plume was found to have remained on the site property (EnSafe 2011). TDEC SRP was concerned about vapors from these chemicals that are dissolved in groundwater migrating into the indoor air of the main WMT Site building. All air samples collected as part of the vapor intrusion investigation were collected by EnSafe Inc. (EnSafe) of Memphis, Tennessee, working for the responsible party.

As asked for by TDEC SRP, this review will specifically evaluate the WMT air sampling results of the WMT manufacturing building. This review and preparation of this health consultation was done to document the evaluation of the air sampling results and provide information to those who currently work in the WMT building.

Background

The WMT Site is located at 5677 Airline Road in Arlington, Shelby County, Tennessee 38002. The investigation area focused on an approximate 73,000 square foot manufacturing building at the WMT Site that is located on an approximate 12.3 acre parcel located on the west side of Airline Road (Figure 1). Roughly 8.3 acres of the 12.3 acre parcel is owned by WMT. WMT leases the remaining acreage from the City of Arlington's Industrial Development Board. Administrative offices along with research and development for WMT are in buildings located on approximately 8.5 acres leased from the City of Arlington on the east side of Airline Road (EnSafe 1999). The site is located in a mixed use residential and light- to medium-industrial area of Arlington (Figure 1). A day care facility is located approximately 0.1 miles north of the site (Google Earth 2012). The site is bounded on the west by the former Arlington municipal airport. A high school is located approximately 0.2 miles south of the site (Google Earth 2012). The children attending the day care and the high school pupils would both be considered sensitive populations located near WMT.

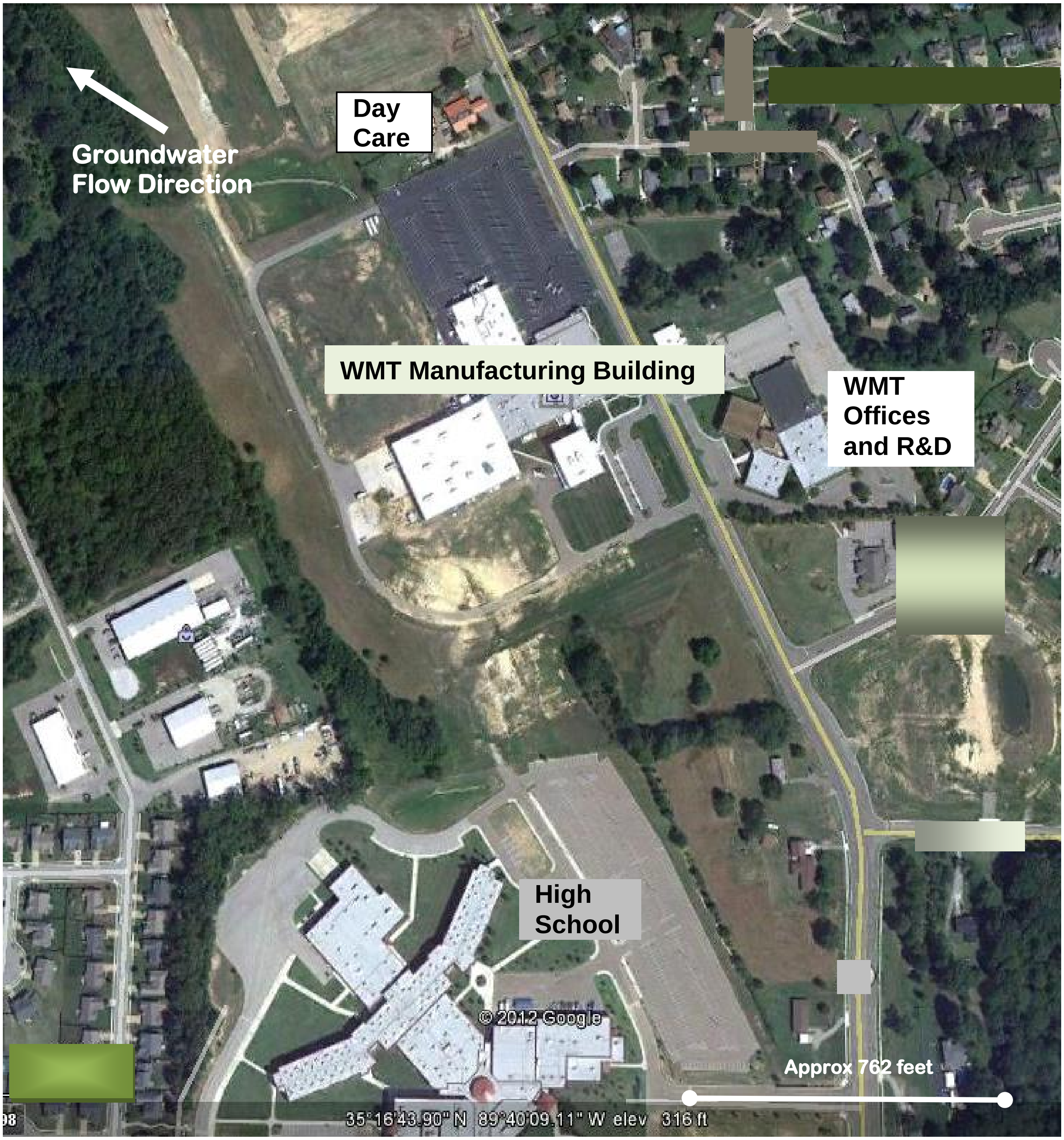


Figure 1. Wright Medical Technologies, Inc. (WMT) Site location in Arlington, Shelby County, Tennessee. Wright has two buildings at the site; a 73,000 square-foot manufacturing building (center) and a second building housing offices and a research and development center (right center). There are homes east and southwest of the site. A day care is north of the site and a high school is south of the site. The western portion of the WMT Site is a portion of the former Arlington municipal airport. Groundwater reportedly moves to the northwest. (Source: Google Earth 2012).

The site was developed in 1975 for Wright Manufacturing. Wright Manufacturing was acquired by Dow Corning Corporation in 1977. WMT acquired the site from Dow Corning in 1993 and has operated it since then. WMT produces a variety of medical devices, primarily orthopedic implants. With the exception of adding or eliminating products, the facility has reportedly not changed a great deal since it was constructed in 1975.

Dow Corning was the primary user of chlorinated solvents at the site. Solvent handling practices at Dow Corning reportedly included the use of chlorinated solvents for degreasing in a vat/dip tank process located in the former chemical finishing area of the WMT manufacturing building. A spill of 100 gallons of chlorinated solvents occurred in 1989 (EnSafe 1999). The spill was reported to site management. The solvent dip tank process was eliminated in 1990 by Dow Corning. WMT reportedly never has used chlorinated solvents in large quantities. Chlorinated solvents were used in insignificant quantities such as in spray cans for parts or equipment cleaning (EnSafe 2012b). As such, current workers are not covered under a workplace health and safety plan that would outline the hazards associated with previous solvent use (EnSafe 2012b) at the site.

Volatile and semi-volatile chemicals can evaporate from impacted subsurface soil and/or groundwater beneath a building and move toward areas of lower chemical levels such as in the atmosphere, utility conduits, or basements. This process is called vapor intrusion. Subsurface vapors can enter a building due to two main factors: environmental effects and building effects. Some examples of these factors are barometric pressure changes, wind load, temperature currents, or depressurization from building exhaust fans. Chemicals can migrate up and enter indoor air through foundation slabs, crawl spaces, or basements. The chemical migration depends on the construction of the building, unsealed joints or cracks in the foundation, the building's heating and ventilation characteristics, and other factors. The amount of movement of the vapors into the building is difficult to measure and depends on soil type, chemical properties, building design and condition, and pressure differences between the outside and inside air (ITRC 2007). Upon entry into a structure, chemical vapors mix with the existing air through the natural or mechanical ventilation of the building.

Vapors may accumulate in buildings to levels that pose safety hazards, health risks, or odor problems. Vapor intrusion has been documented in buildings with basement, crawlspace, or slab-on-grade foundation types. Vapor intrusion can be an acute health hazard. Usually, indoor vapor levels are low. Low levels of vapors, breathed over a long period of time, may or may not be a chronic health concern.

Findings of Previous Investigations

TDEC SRP has been managing the site and has designated it State Remediation Program Site SRS-0497. Soil and groundwater investigations have been performed over the last 13 years at the WMT Site. Groundwater was found at depths from 3 to 8 feet across the site (EnSafe 2011). It moves to the northwest (EnSafe 2000), away from the WMT manufacturing building. The direction of groundwater movement is away from both the day care and the high school located nearby. There is not any evidence of off-site groundwater contaminant migration.

In the site groundwater, 1,1-DCE was found at the highest levels. Detections of 1,1-DCE ranged from 49.8 micrograms per liter (µg/L) to 15,000 µg/L. The highest levels were found in the source area well. TCE, 1,1,1-TCA, 1,1-DCE, 1,2-DCA, and VC were found in the groundwater at levels above their respective U.S. Environmental Protection Agency (EPA) maximum contaminant levels (MCLs). TCE levels in groundwater ranged from 46 to 130 µg/L. 1,1,1-TCE levels ranged from 13 to 200 µg/L. Levels of 1,2-DCA ranged from 16 to 56 µg/L. Vinyl chloride was found at levels ranging from an estimated concentration of 0.97 to 60 µg/L. Other chemicals found in groundwater such as 1,1-DCA, tetrachloroethylene (PCE), xylenes, and trichlorofluoromethane were not found at levels above their respective MCLs. 1,1-DCA levels in groundwater ranged from 21 to 252 µg/L. Groundwater monitoring is on-going at the site. Levels of PCE ranged from 2.4 to 3.8 µg/L. Xylene levels were not reported in the groundwater monitoring report reviewed by EEP. Trichlorofluoromethane was found at levels ranging from 17.6 to 23.8 µg/L.

Indoor Air Investigation Work Plan

EnSafe designed the March 2012 indoor air testing with suggestions from TDEC SRP and TDH EEP. The original work plan (EnSafe 2012c) was approved by TDEC SRP on March 7, 2012. It proposed to collect samples of indoor air at two locations inside the WMT manufacturing building. The indoor air testing locations were those closest to groundwater monitoring well locations having the highest historic levels of VOCs. All groundwater monitoring wells were located on the outside of the WMT manufacturing building.

The chemicals to be tested for in the indoor air samples were those found above their respective MCLs in groundwater: 1,1-DCE, TCE, 1,2-DCA, and VC. The indoor air sampling work plan was approved by TDEC and was reviewed by EEP. After being provided groundwater monitoring data by TDEC, EEP also expressed potential concern about levels of 1,1,1-TCA and 1,1-DCA in the indoor air. EEPs concern stems from the fact that 1,1,1-TCA could also have been used as a solvent at the site based on groundwater monitoring data. EEP was concerned about 1,1-DCA because it is a breakdown chemical of 1,1,1-TCA. Both 1,1,1-TCA and 1,1-DCA were found in groundwater at levels below their MCLs and not reported in indoor or outdoor air samples.

Discussion

Introduction to Chemical Exposure

To determine whether persons have been or are likely to be exposed to chemicals, TDH EEP evaluates mechanisms that could lead to human exposure. Chemicals released into the environment have the potential to cause harmful health effects. Nevertheless, a release does not always result in exposure. People can only be exposed to a contaminant if they come into contact with it. If no one comes into contact with a contaminant, then no exposure occurs, and thus, no exposure-related health effects could occur. An exposure pathway contains five parts:

- a source of contamination,
- contaminant transport through an environmental medium,

- a point of exposure,
- a route of human exposure, and
- a receptor population.

An exposure pathway is considered complete if there is evidence that all five of these elements have been, are, or will be present at the site. An exposure pathway is considered incomplete if one of the five elements is missing.

The source is the place where the chemical was released. For this site, the source is spills from past activities performed at the site. The environmental media (such as, groundwater, soil, surface water, or air) transport the contaminants. For this site, the chemicals are transported through the groundwater and indoor air. The point of exposure is the place where persons come into contact with the contaminated media. Indoor air is the potential point of exposure for this site. The route of exposure (for example, ingestion, inhalation, or dermal contact) is the way the contaminant enters the body. For this site, the route of exposure would be breathing of indoor air if the VOCs are migrating into the indoor air.

Physical contact alone with a potentially harmful chemical in the environment by itself does not necessarily mean that a person will be harmed. A chemical's ability to affect health is controlled by a number of other factors, including:

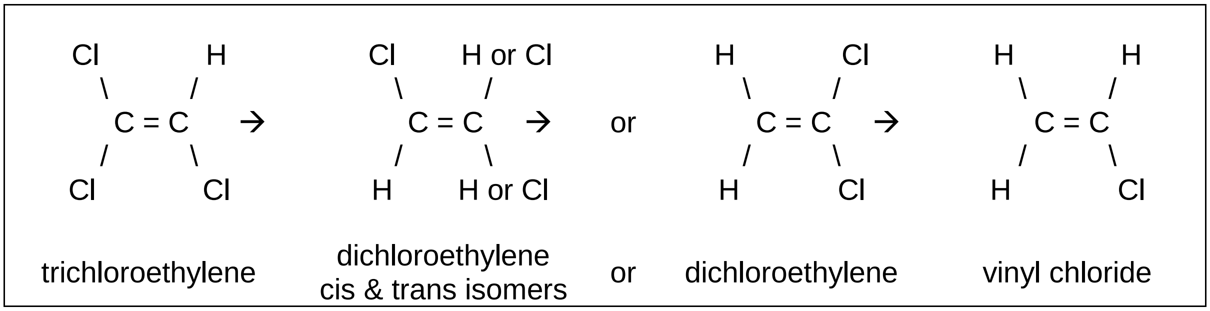
- the amount of the chemical that a person is exposed to (dose),
- the length of time that a person is exposed to the chemical (duration),
- the number of times a person is exposed to the chemical (frequency),
- the person's age and health status, and
- the person's diet and nutritional habits.

For this project, the people who would be exposed if vapor intrusion was occurring are the workers in the WMT manufacturing building.

Solvent Explanation

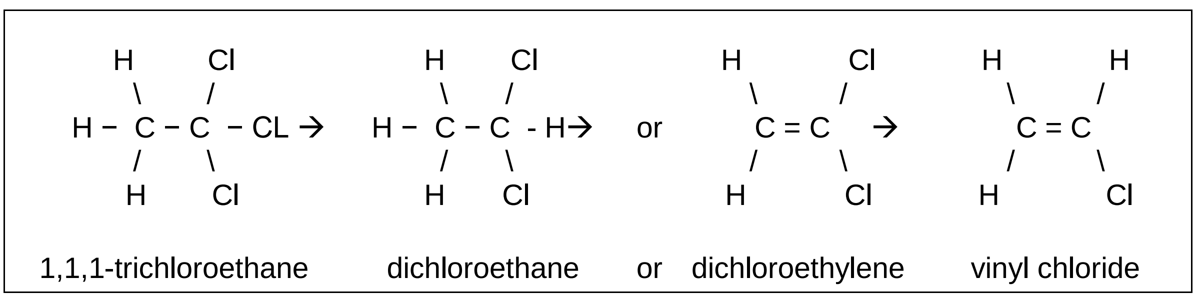
Past activities included the use of solvents for degreasing in the WMT building during the time Dow Corning owned the site. Site environmental investigations have indicated that these solvents may have included TCE and 1,1,1-TCA. These two chemicals were likely used to remove grease and other contaminants from the metal parts manufactured at WMT. Other chemicals found in groundwater at the site seem to be breakdown chemicals from these two main parent chemicals. This evaluation will focus on these two chemicals and their chemical breakdown products.

TCE is a volatile organic compound (VOC). It can quickly evaporate into a gas at room temperature. As its name implies, trichloroethylene has three chlorine anions on a two-carbon molecule. TCE can breakdown into other chlorinated volatile organics. Each of these breakdown chemicals has slightly different chemical properties and toxicities. The following diagram is an example of how one chemical can break down to form another.



In this example, TCE can break down to cis- or trans-DCE, or DCE, and then to VC. The only way to truly know the ratio of these breakdown chemicals is to collect environmental samples. The degradation products 1,1-DCE and VC have been noted in groundwater samples collected, showing that there are anaerobic conditions in the soils and groundwater beneath the site. Based on past groundwater monitoring, 1,1-DCE appears to be the chemical present in the highest levels in groundwater.

1,1,1-TCA is also a volatile organic compound that may have been used at WMT. It can also quickly evaporate into a gas at room temperature. As its name implies, 1,1,1-TCA has three chlorine anions and three hydrogen ions on a two-carbon molecule. 1,1,1-TCA can break down into other chlorinated volatile organics. Each of these breakdown chemicals has slightly different chemical properties and toxicities. The following diagram is an example of how 1,1,1-TCA can break down to form other chemicals.



In this example, 1,1,1-TCA can also break down to 1,1,-DCA, or to 1,1-DCE and then to VC. As stated above, the degradation products 1,1-DCE and VC have been noted in groundwater samples collected at the site. 1,1-DCE appeared to be the dominant chemical present in site groundwater. 1,1,-DCA has also been found in the groundwater at the site but at levels below its MCL. The presence of these breakdown products in WMT Site groundwater support the assumption that anaerobic degradation of the chemicals is happening at the WMT Site.

Comparison Values

To evaluate exposure to a hazardous substance, health assessors often use health comparison values. If the chemical concentrations are below the comparison value, then health assessors can be reasonably certain that no adverse health effects will occur in people who are exposed. If concentrations are above the comparison values (ATSDR 2012) for a particular chemical, then further evaluation is needed.

The Agency for Toxic Substances and Disease Registry's (ATSDR) develops Minimal Risk Levels (MRLs) using conservative assumptions. ATSDR uses the term 'conservative' to refer to values that are protective of public health in essentially all situations. Environmental Media Evaluation Guidelines (EMEGs) are calculated by ATSDR from their MRLs. EMEGs consider non-cancer adverse health effects (ATSDR 2012) and are used for comparison to the indoor air data that was collected. Exposure durations are defined as acute (14 days or less), intermediate (15–365 days), and chronic (365 days or more) exposures. ATSDR does not use serious health effects, such as irreparable damage to the liver or kidneys, or birth defects, as a basis for establishing EMEGs. Chronic EMEGs assume exposure for 24 hours per day, 7 days per week, 52 weeks, 365 days per year, over a 70-year lifetime exposure. Exposure to a level above the EMEG does not necessarily mean that adverse health effects will occur (ATSDR 2007).

EPA's Regional Screening Levels (RSLs) for residential air inhalation were also used in evaluating the results of the indoor air testing (EPA 2012). Exposure to workers at the WMT Site would be involuntary. Since solvents are no longer used to clean parts at the site, current site workers may not know that there could be potential exposure issues from previous solvent use in the site building. Federal Occupational Safety and Health Administration (OSHA) work place standards were not used because employees of WMT are not covered under a workplace safety plan outlining the hazards associated with the past use of these chemicals (EnSafe 2012b). Industrial health comparison values were not used for comparison of the indoor air values measured. This is because the exposure that would be experienced by those workers would be involuntary. Since the exposures would be involuntary, residential comparison values published by ATSDR and EPA were used for evaluation of exposure to workers.

The comparison values for breathing indoor air used for the evaluation of non-cancer health effects include those outlined below.

ATSDR has a chronic EMEG for TCE in indoor air of 0.37 parts per billion (ppb). The EPA non-cancer RSL for a residential exposure for TCE is 0.39 ppb.

ATSDR has not calculated a chronic EMEG for 1,1-DCE, 1,1-DCE does have an intermediate EMEG of 20 ppb. Its EPA RSL is 53 ppb. ATSDR has a chronic EMEG for 1,2-DCA of 600 ppb. EPA has a non-cancer RSL for a residential exposure for 1,2-DCA of 1.8 ppb.

VC does not have a chronic EMEG established but has an intermediate EMEG of 30 ppb. EPA's non-cancer residential exposure RSL is 39 ppb.

The indoor air samples were not analyzed for 1,1,1-TCA or 1,1-DCA because both 1,1,1-TCA and 1,1-DCA were not found in groundwater samples above their respective MCLs. For completeness, the potential for migration of vapors from these two chemicals from groundwater into indoor air will also be evaluated in this health consultation. The intermediate exposure (15 to 364 days) EMEG for 1,1,1-TCA, is 700 ppb. Its EPA non-cancer RSL is 953 ppb. There is not an EMEG established for 1,1-DCA nor is there a non-cancer RSL. Because indoor air was not sampled for 1,1,1-TCA or 1,1-DCA, the highest groundwater levels at the site for these two compounds were evaluated using EPA's simplified Johnson and Ettinger (J&E) model. The model will be discussed further in the Health Risk Evaluation section of this report.

To understand if concentrations of the solvents TCE, or TCE's breakdown chemicals, 1,1-DCE and VC, in indoor air could lead to excess cancers above the background rate, measured concentrations of these chemicals were also compared to ATSDR cancer risk evaluation guides (CREGs). Lifetime exposure to a chemical at a concentration equal to its CREG comparison value could theoretically result in a one in a million risk of developing cancer in addition to the background risk of developing cancer. The background cancer risk is the risk that all people have of developing cancer. The background cancer risk for the U.S. population is currently 1 in 2 for men and 1 in 3 for women. Both ATSDR and EPA prefer to have residential risk values for excess cancer risk in addition to the background cancer risk less than 1 excess cancer in 1 million people or a $1x10^{-6}$ risk. An excess cancer risk between 1 in 10,000 and 1 in 1 million is considered acceptable by EPA (EPA 1991). 1,1,1-TCA and 1,1-DCA were also evaluated based on their groundwater concentrations using the J&E model.

TCE is *"reasonably anticipated to be a human carcinogen"* (IARC 1995, NTP 2001). For this site, we are concerned with the inhalation of TCE from vapor intrusion into indoor air.

ATSDR has generated a CREG for TCE (ATSDR 2012) of 0.045 ppb. EPA has a residential setting TCE inhalation RSL for one excess cancer in 1 million people of 0.08 ppb.

1,1-DCE has not been classified with regard to carcinogenicity and is treated as a non-cancer causing chemical.

1,2-DCA has an ATSDR CREG of 0.01 ppb. EPAs cancer RSL for residential exposures is 0.02 ppb.

VC has been determined to be a *"known human carcinogen"* (NTP 2005). ATSDR has a published CREG of 0.04 ppb. EPA's RSL for one excess cancer in 1 million people for VC is 0.06 ppb.

1,1,1-TCA is not classified as to its carcinogenicity. Therefore, ATSDR does not have a published CREG for this chemical. EPA also does not have a cancer effects RSL for 1,1,1-TCA.

EPA has a cancer effects RSL for one excess cancer in 1 million people for 1,1-DCA of 0.37 ppb. ATSDR does not have any cancer risk comparison value for 1,1-DCA.

Environmental Sampling

For this air investigation, 1 outside and 2 indoor air samples were collected on March 18, 2012. The outside air sample was collected from the parking area southeast of the WMT manufacturing building (Figure 2). The indoor air samples were taken at two separate locations inside the WMT manufacturing building (Figure 2). The samples were collected in locations in the building that were closest to groundwater monitoring wells that have been found to historically have the highest levels of VOCs at the site.

The indoor air testing inside the WMT manufacturing building was carried out over an approximate 7½-hour period on a Sunday. No employees were working in the building.

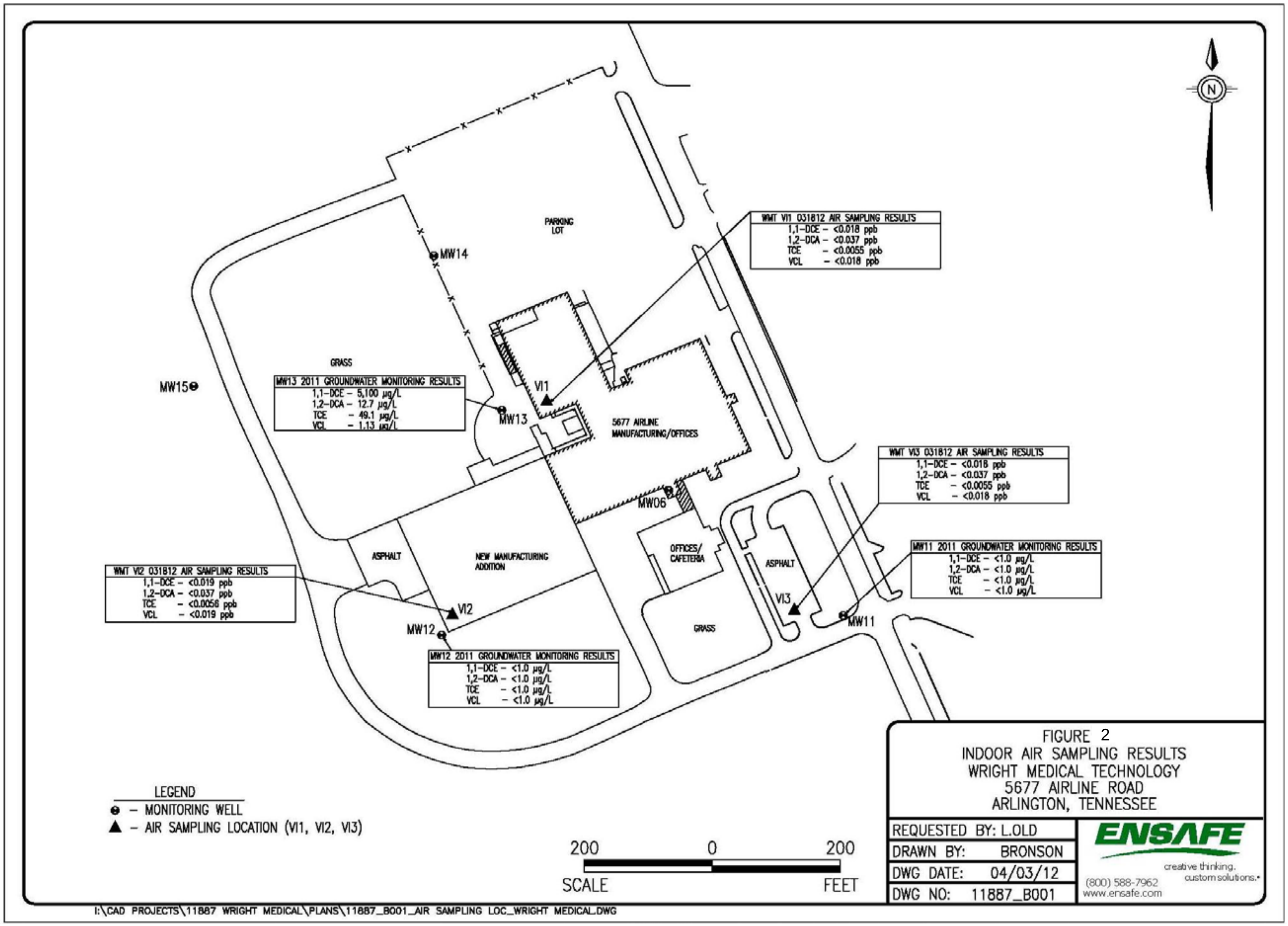


Figure 2. WMT Site building details. Shown are locations of groundwater monitoring wells, indoor air samples, and air sample results (EnSafe 2012).

Heating, ventilation, and air conditioning systems were operating during the testing to simulate normal working conditions. Sampling locations are shown in Figure 2. One sample was collected inside the building near monitoring well MW-13, in the northern portion of the manufacturing building. The second indoor air sample was collected near monitoring well MW-12, in the far western portion of the building. The outdoor air sample was collected adjacent to monitoring well MW-11, which is located southeast of the building.

All air samples were shipped in their appropriate containers under chain-of-custody procedures to Eurofins Air Toxics, Inc., located in Folsom, CA (EnSafe 2012b). The samples collected were tested for the following TO-15 list chemicals: TCE, 1,1-DCE, 1,2-DCA, and VC. The testing included these chemicals because of their presence in on-site groundwater and the potential health implications their presence in indoor air may have. Selective ion mode (SIM) methodology was used to analyze the air samples. The SIM method allows the recommended lower detection levels to be met.

1,1,1-TCA and 1,1-DCA were not analyzed. As mentioned previously, for completeness, 1,1,1-TCA and 1,1-DCA will be evaluated based on their levels in site groundwater.

Results

Air testing results showed that none of the chemicals tested for were found in the 1 outdoor air sample or in the 2 indoor air samples from within the WMT manufacturing building.

Outdoor Air

See Table 1 below for results of the outdoor air sampling. TCE, 1,1-DCE, 1,2-DCA, and VC were not found in the outdoor air sample. The results from the outdoor air sample were not compared to any regulatory level or comparison values. They were compared to measured background levels in the United States.

Indoor Air — WMT Building

Table 2 shows the results of the indoor air sampling in the WMT building. TCE, 1,1-DCE, 1,2-DCA, and VC were not found in either indoor air sample. Sample detection limits were very low.

Health Risk Evaluation

For this health consultation, the evaluation of the health risk at the site will only consider the chemicals that have been confirmed to be present in groundwater and have potential health risks. These chemicals included TCE and the TCE breakdown chemicals 1,1-DCE, 1,2-DCA, and VC. For completeness 1,1,1-TCA and 1,1-DCA will also be evaluated. The evaluation is organized by locations of samples: the outdoor air sample and the two indoor air samples collected inside the WMT manufacturing building.

TABLE 1. Outdoor air sampling results for the WMT Site, Arlington, Shelby County, TN. Site-related chemicals are shown. Samples were collected on March 18, 2012, over 7-½ hours with Summa canisters (EnSafe 2012a). The location of outdoor air sample is shown on Figure 2. Values reported in parts per billion (ppb). Background chemical measurements are from various sources and are also reported in ppb.

Chemical / Sampling Data and Location Name	Acronym	March 18, 2012 Outdoor Air Measurements	Measured United States Background Levels
trichloroethylene	TCE	<0.0055	0.15[1]
1,1-dichloroethylene	1,1-DCE	<0.018	4.6[2]
1,2-dichloroethane	1,2-DCA	<0.037	0.012 – 0.26[3]
vinyl chloride	VC	<0.018	<0.008[4]

Notes:

< = Not detected in the air sample. Concentration represents the analytical reporting limit.

1 = Some emission and exposure data for trichloroethylene and related chemicals EPA National Center for Environmental Assessment, Office of Research and Development, Washington, D.C. March 2001.

2 = Toxicological profile for 1,1-Dichloroethylene, ATSDR, Atlanta, GA, May 1994.

3 = Toxicological profile for 1,2-Dichloroethane, ATSDR, Atlanta, GA, September 2001.

4 = Background concentrations of 18 air toxics for North America, Journal of Air and Waste Mgmt. Assoc. 2006. 56: 3-11

Preliminary Johnson & Ettinger Model Evaluation

Chemicals found in groundwater at the site were first evaluated by inputting the highest groundwater concentrations measured for each chemical into EPA's simplified J&E vapor intrusion model (EPA 2012). The model is a one-dimensional analytical solution, which incorporates both advection and diffusion transport mechanisms to produce a unit-less "attenuation factor." This attenuation factor is a measure of how soil and building properties limit the intrusion of organic vapors into overlying buildings and is defined as the concentration of the compound in indoor air divided by the concentration of the compound in soil-gas or groundwater. Chemical concentrations in groundwater will attenuate more than chemicals in soil-gas because of certain limitations in the transfer of mass across the area immediately above the water table. Site-specific characteristics and properties can be put into the model if they are available. In this case, they were not. The J&E model also uses conservative assumptions about the fate and transport of the chemicals in the subsurface.

The 2011 groundwater concentrations of 1,1-DCE, 1,2-DCA, TCE, 1,1,1-TCA, 1,1-DCA, cis-1,2-DCE, and vinyl chloride were put into the J&E model to understand if they could be a vapor intrusion concern. J&E model output showed that the potential for non-cancer health effects would only be related to 1,1-DCE. Other chemicals such as 1,1,1-TCA or cis-1,2-DCE were not likely to cause non-cancer health effects. Model output also suggested that levels of TCE, 1,1-DCA, 1,2-DCA, and vinyl chloride in groundwater would equate to an excess cancer risk between 1 in 100,000 to 1 in 1,000,000. This risk is slightly higher than the standard assumed excess cancer risk for a residential setting of 1 excess cancer in 1,000,000.

Further evaluation using the measured indoor air levels was the next step in the risk evaluation process. The indoor air evaluation is discussed in the sections that follow.

TABLE 2. WMT manufacturing building, Arlington, Shelby County, TN indoor air sampling results. Two samples were collected on March 18, 2012, over 7½ hours with Summa canisters (EnSafe 2012a). Locations of samples are shown on Figure 2. Values reported in parts per billion (ppb). Where the chemical was not detected, the result is reported as being less than (<) the reporting limit. Health comparison values shown are non-cancer chronic environmental media evaluation guides (ATSDR 2012), ATSDR cancer risk evaluation guides (ATSDR 2012), and EPA residential indoor air Regional Screening Levels (EPA 2012).

Chemical / Sampling Data and Location Name	Acronym	Sample 1 Northern portion of Building 03/18/12	Sample 2 Western portion of Building 03/18/12	ATSDR EMEG (non-cancer) (ppb)	ATSDR CREG (10^{-6} excess cancer risk) (ppb)	EPA RSL	
						(10^{-6} excess cancer risk) (ppb)	(10^{-4} excess cancer risk) (ppb)
trichloroethylene	TCE	<0.0055	<0.0056	0.37	0.045	0.08	8
1,1-dichloroethylene	1,1-DCE	<0.018	<0.019	20i	nc	ngv	ngv
1,2-dichloroethane	1,2-DCA	<0.037	<0.037	600	0.01	0.02	2
vinyl chloride	VC	<0.018	<0.019	30i	0.04	0.06	6

Notes:

Reporting Limit = Limits that can be greater than or equal to the method detection limit for the analysis.

ATSDR EMEG = Agency for Toxic Substances and Disease Registry Environmental Media Evaluation Guide (ATSDR 2012). Chronic non-cancer exposure comparison values (exposure greater than 365 days) used to determine if chemical concentrations warrant further health-based screening.

ATSDR CREG = Agency for Toxic Substances and Disease Registry Cancer Risk Evaluation Guide (ATSDR 2012). Cancer risk comparison values for cancer risk of 1 excess cancer in 1,000,000 people.

EPA RSL = Environmental Protection Agency Regional Screening Level (EPA 2012). The screening levels were developed using risk assessment guidance from the EPA Superfund Program. They are risk-based concentrations derived from standardized equations combining exposure information assumptions with EPA toxicity data. RSLs are considered by EPA to be protective for humans (including sensitive groups) over a lifetime.

Modifiers:

< = Not detected in the air sample. Numerical values represent the analytical reporting limit.

i = ATSDR comparison value for intermediate exposures (15-365 days); typically higher than a chronic value.

nc = Not classified as to carcinogenicity and no guidance value is available.

ngv = No guidance value available.

Outdoor Air

Results are shown in Table 1. No chemicals were found in outdoor air. As a conservative evaluation, detection limits for each chemical tested were compared to average United States background outdoor air chemical levels. All detection limits were below the background air levels.

Building Indoor Air Non-Cancer Evaluation

No chemicals were found in the indoor air. This includes TCE which was thought to be the main contaminant present at this site. Chemical detection limits were very low. As a worst-case evaluation, the reported detection limits for each chemical as shown in Table 2 were compared to their respective non-cancer indoor air health comparison values published by the ATSDR (2012) and EPA (2012). All detection limit levels for TCE, 1,1-DCE, 1,2-DCA, and VC were below their respective non-cancer health comparison values.

As mentioned earlier, both 1,1,1-TCA and 1,1-DCA were evaluated by inputting the highest groundwater concentrations of each chemical measured at the site into EPA's simplified J&E vapor intrusion model (EPA 2012). The estimated indoor air levels calculated using the J&E model for 1,1,1-TCA was a low prediction of 0.05 ppb, a best estimate prediction of 0.48 ppb, and a high prediction of 0.49 ppb. These levels are negligible and the associated hazard index of these levels averaged 0.0012. A hazard index less than 1 is acceptable for non-cancer causing chemicals (EPA 2012). The predicted levels are also very low when compared to ATSDR's EMEG for 1,1,1-TCA of 700 for an intermediate exposure of 15 days to 364 days in duration.

For 1,1-DCA, the estimated indoor air levels calculated using the J&E model were a low prediction of 1.4 ppb, a best estimate prediction of 1.5 ppb, and a high prediction of 1.5 ppb. There is not a non-cancer health effects value for 1,1-DCA. These levels are very low and the associated hazard index of these levels average 0.0012.

Based on the results of this one time sampling of indoor air, the workers in the WMT manufacturing building should not experience non-cancer health effects from breathing the indoor air in the building. Vapor intrusion does not appear to be occurring at the site. The inhalation exposure pathway is not complete for the workers at the site.

Building Indoor Air Cancer Evaluation

As discussed above, there were no detections of TCE, 1,1-DCE, 1,2-DCA, or VC in the one indoor air sampling (Table 2) of the WMT manufacturing building. As part of a worst case evaluation, detection limit values of these chemicals were compared to their respective health comparison values published by the ATSDR (ATSDR 2012) or EPA (2012).

The test detection limits were low; all were less than 0.02 ppb. TCE had a detection limit of 0.0055 or 0.0056 ppb. These values are much less than both ATSDR's CREG of 0.045 ppb and EPA's RSL of 0.08 ppb for TCE, at a 1 in 1 million additional risk. 1,1-DCE has not been shown to cause cancer and therefore, there are no cancer health affects comparison values for this chemical.

For 1,2-DCA, the detection limit of 0.037 ppb is slightly higher than both ATSDR's CREG of 0.01 and EPA's RSL of 0.02 ppb. Using the detection limit value of 0.037 ppb (0.15 $\mu g/m^3$) and multiplying by the inhalation unit risk value of $2.6x10^{-5}$ $(\mu g/m^3)^{-1}$ produced a cancer risk of $3.9x10^{-6}$ or about 4 excess cancers in 1 million people. This is a very low additional cancer risk considering the background cancer risk of the U.S. population is 1 in 2 for men and 1 in 3 for women (NTP 2011).

The detection limits for VC were 0.018 and 0.019 ppb. ATSDR's CREG for VC was 0.04 ppb. EPA's RSL was 0.06 ppb. These detection limits were lower than VC's health comparison value indicating there should not be any concern for VC.

1,1,1-TCA is not classifiable with respect to carcinogenicity; meaning that there is no evidence that it causes cancer. There are no cancer health effects comparison values from ATSDR or EPA for this chemical.

For 1,1-DCA, the calculated J&E indoor air values suggest an additional very low additional risk of between $1x10^{-5}$ and $1x10^{-6}$. This excess risk is acceptable (EPA 1991) and is a risk of between one excess cancer in 100,000 people and 1 excess cancer in 1 million people. The possibility of a person developing cancer in a lifetime is 1 in 2 for men and 1 in 3 for women (NTP 2011).

Even though the chemicals tested for in the indoor air of the WMT Building were reported as non-detect, it may not mean that there are none present in the indoor air. The above evaluation was completed to identify if there could be any health impact from breathing chemicals at the very low detection limit values. Using the detection limit values as a worst case scenario, as was mentioned earlier, is a conservative evaluation. This conservative evaluation still found no problems. The J&E modeling also suggested that there would not be a problem from levels of chemicals found in groundwater that were not tested for in the indoor air. Since none of the chemicals were found in the indoor air, and the calculated groundwater to indoor air values were very low, vapor intrusion does not appear to be happening at the WMT Site. There should not be any concern about chemicals found in site groundwater and the potential to breathe these chemicals in the indoor air of the WMT manufacturing building.

Chemical Mixture

When you have more than one chemical found at a sampling location, there are potential additive health effects from a mixture of chemicals to an exposed population (ATSDR 2004). There is no evidence to indicate that greater-than-additive interactions among TCE or 1,1-DCE happen. TCE, 1,1-DCE, 1,2-DCA, or VC were not measured in indoor air samples collected from the WMT manufacturing building. This also holds true for 1,1,1-TCA, and 1,1-DCA. There should not be greater-than-additive interactions with these chemicals either.

Child Health Considerations

The health of children was considered as part of this health consultation. The many physical differences between children and adults demand special emphasis. Children could be at greater risk than adults from certain kinds of exposure to hazardous substances (ATSDR 1997, 1998). Children have lower body weights than adults. Although children's lungs are usually smaller than adults, children breathe a greater relative volume of air compared to adults. If toxic exposure levels are high enough during critical growth stages, the developing body systems of children can sustain permanent damage.

There is no indication that trichloroethylene (TCE) or its breakdown chemicals affect children's bodies differently than adults (ATSDR 1997). Children may be more sensitive to the carcinogenic effects of TCE than adults (IRIS 2011). ATSDR considered this increased sensitivity when they developed their CREG value.

The workers inside the WMT manufacturing building are adults. Children should not have any exposure to the indoor air in the building since they are not part of the population that works inside the building nor would children spend any significant time in the building.

There are children that spend time in nearby buildings. These include a day care and a high school. Groundwater movement is to the northwest and away from the day care and the high school. Based on the testing and modeling of groundwater data, there is no indication vapors from the groundwater are migrating off-site to or anywhere near these buildings. The indoor air of the WMT building above the groundwater contamination was tested and nothing was found. Vapor intrusion does not appear to be happening and no additional testing is needed.

Limitations and Uncertainties in Vapor Intrusion

Having and following an accepted protocol for conducting indoor air investigations is important. A general protocol was developed for this investigation and approved by TDEC DoR and was reviewed by TDH EEP. Even a good protocol cannot remove all limitations and uncertainties.

There were several characteristics of buildings that may have influenced the indoor air testing. Some examples of limitations and uncertainties include the detail of the design of the building not being readily available. The large size of the WMT building also can influence testing results. The numbers of breaks in floor slabs or utility perforations entering the buildings were also variables that could have influenced the test results. Also, the exact amount of the chemicals in the groundwater beneath the building is unknown. Hence, the amount and frequency of vapor off-gassing from the groundwater is likely not constant. The presence of background chemicals in the indoor air could also be a limitation. The use of cleaning products that sometimes contain many chemicals could influence the results of the testing. This can be the case especially if cleaning products were recently used inside the building.

Conclusion

TDH EEP concludes that it does not appear that vapors from contaminated site groundwater are reaching the indoor air of the Wright Medical Technologies manufacturing building.

No chemicals found in site groundwater were found in the 2 indoor air samples collected. Groundwater concentrations of chemicals did not appear to elevate indoor air levels. All analytical detection limits were reported to be either lower than or about a 1 in 1,000,000 excess cancer risk. Modeling of two other chemicals found in groundwater at the site were not part of the indoor air testing showed that there should not be any indoor air levels above health concerns. Breathing air inside the WMT building would not result in adverse health effects. The inhalation exposure pathway does not appear to be complete at the site. Based on the analytical testing results and the modeled results, vapor intrusion does not appear to be occurring.

Recommendations

TDH EEP does not have any recommendations.

Public Health Action Plan

The public health action plan for the WMT Site contains a list of actions that have been or will be taken by TDH EEP and other agencies. The purpose of the public health action plan is to ensure that this health consultation identifies public health concerns and offers a plan of action designed to mitigate and prevent harmful health effects that result from breathing, eating, drinking, or touching hazardous substances in the environment. Included is a commitment on the part of EEP to follow up on this plan to ensure that it is implemented.

Public health actions that have been taken by TDH's EEP include:

- Reviewing indoor air data from the WMT manufacturing building.
- Preparing this Health Consultation.

Public health actions that will be taken include:

- TDH EEP will provide copies of this health consultation to state and federal government agencies interested in the WMT Site.
- TDH EEP will provide copies of this health consultation to the environmental contractor for WMT.
- TDH EEP will maintain dialogue with ATSDR, TDEC, EPA, and other interested stakeholders to safeguard public health.

- TDH EEP staff are available to answer questions regarding the interpretation of the indoor air results.

- TDH EEP will be available to review additional environmental data, and provide interpretation of the data, as requested.

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Certification

This Public Health Consultation: *Evaluation of Air Sampling Results for Wright Medical Technology, Inc., Arlington, Shelby County, Tennessee*, was prepared by the Tennessee Department of Health's Environmental Epidemiology Program. It was prepared in accordance with the approved methodology and procedures that existed at the time the health consultation was begun.

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