

Public Health Assessment for

RAM LEATHER CARE SITE CHARLOTTE, MECKLENBURG COUNTY, NORTH CAROLINA EPA FACILITY ID: NCD982096653 JANUARY 31, 2006

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE Agency for Toxic Substances and Disease Registry

THE ATSDR PUBLIC HEALTH ASSESSMENT: A NOTE OF EXPLANATION

This Public Health Assessment was prepared by ATSDR pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) section 104 (i)(6) (42 U.S.C. 9604 (i)(6)), and in accordance with our implementing regulations (42 C.F.R. Part 90). In preparing this document, ATSDR has collected relevant health data, environmental data, and community health concerns from the Environmental Protection Agency (EPA), state and local health and environmental agencies, the community, and potentially responsible parties, where appropriate.

In addition, this document has previously been provided to EPA and the affected states in an initial release, as required by CERCLA section 104 (i)(6)(H) for their information and review. The revised document was released for a 30-day public comment period. Subsequent to the public comment period, ATSDR addressed all public comments and revised or appended the document as appropriate. The public health assessment has now been reissued. This concludes the public health assessment process for this site, unless additional information is obtained by ATSDR which, in the agency's opinion, indicates a need to revise or append the conclusions previously issued.

Agency for Toxic Substances & Disease Registry	Julie L. Gerberding, M.D., M.P.H., Administrator Howard Frumkin, M.D., Dr.P.H., Director
Division of Health Assessment and Consultation	
Health Promotion and Community Involvement Branch	Lisa Calhoun Hayes, P.E., DEE, Acting Chief
Exposure Investigations and Consultation Branch	Susan M. Moore, Ph.D., Chief
Federal Facilities Assessment Branch	Sandra G. Isaacs, B.S., Chief
Superfund and Program Assessment Branch	Richard E. Gillig, M.C.P., Chief

Use of trade names is for identification only and does not constitute endorsement by the Public Health Service or the U.S. Department of Health and Human Services.

Additional copies of this report are available from: National Technical Information Service, Springfield, Virginia (703) 605-6000

You May Contact ATSDR TOLL FREE at 1-888-42ATSDR or Visit our Home Page at: http://www.atsdr.cdc.gov Ram Leather Care Site

Final Release

PUBLIC HEALTH ASSESSMENT

RAM LEATHER CARE SITE

CHARLOTTE, MECKLENBURG COUNTY, NORTH CAROLINA

EPA FACILITY ID: NCD982096653

Prepared by:

Superfund and Program Assessment Branch Division of Health Assessment and Consultation Agency for Toxic Substances and Disease Registry

Table of Contents

SUMMARY	3
I. PURPOSE AND HEALTH ISSUES	5
II. BACKGROUND	5
A. Site Description	5
B. Site History	5
D. Site Visit	7
E. Site Demographics	
III. ENVIRONMENTAL CONTAMINATION	
A. Groundwater	9
1. Monitoring Wells (Not used for drinking)	9
2. On-site Well and Off-site Residential Private Wells (Used for Drinking	
B. Soil	
IV. PATHWAYS OF HUMAN EXPOSURE	12
A. Completed Exposure Pathways	
1. Potable Wells	
2. Actions Taken to Reduce Exposures to Chlorinated Solvents in Private	e
Wells	
B. Potential Exposure Pathways	
1. Indoor Air	
2. Groundwater	
C. Eliminated Exposure Pathway	15
1. On-Site Soils	
V. PUBLIC HEALTH IMPLICATIONS	
A. Considerations for Estimating Exposure	16
B. Evaluating Health Effects from Exposure to Single Chemicals	
1. Private Residential Wells	
a. TCE	18
i) Noncancer Health Effects	18
ii) Cancer Health Effects	19
b. PCE	
i.) Noncancer Health Effects	20
ii) Cancer Health Effects	21
2. On-Site Well	22
a. Noncancer Health Effects	22
b. Cancer Health Effects	23
C. Evaluating Health Effects from Exposure to Multiple Chemicals	24
1. Private Wells (Multiple Chemical Exposure)	24
2. On-site Well (Multiple Chemical Exposure)	
VI. EVALUATION OF HEALTH OUTCOME DATA	27
VII. COMMUNITY HEALTH CONCERNS	27
VIII. CHILD HEALTH CONCERNS	28
IX. CONCLUSIONS	29
X. RECOMMENDATIONS	
XI. PUBLIC HEALTH ACTION PLAN	31
A. Public Health Actions Completed:	31

1
2
3
5
9
2
1
2

SUMMARY

The Ram Leather Care site is a former dry cleaning and leather restoration facility in Charlotte, North Carolina. The facility, which operated from 1977 to 1993, is situated in a rural area of eastern Mecklenburg County, North Carolina. Because of improper wastedisposal practices at Ram Leather Care, chlorinated solvents have contaminated the onsite drinking water well and nearby off-site private wells. Chlorinated solvents have been detected in drinking water wells at concentrations exceeding drinking water standards. The main contaminants of concern are tetrachloroethylene (PCE), trichloroethylene (TCE), *cis*-1,2-dichloroethylene (*cis*-1,2-DCE), and vinyl chloride. Groundwater is the only source of drinking water within at least 4 miles of the facility.

For an indeterminate period, residents were exposed to chlorinated solvents when they used their well water for drinking, showering, bathing, cooking, and other household purposes. For purposes of this assessment, residents were divided into two groups according to the length of time their wells may have been contaminated and/or the concentration of contaminants in their wells: 1) highly exposed persons who are assumed to have been exposed to the maximum level of contaminants for up 25 years and 2) moderately exposed persons who are assumed to have been exposed to the average concentration of contaminants in their wells for 9 years. Beginning in 1996, water treatment systems were installed on residential wells identified as containing contaminants at concentrations above drinking water standards. Because replacement of filters and maintenance of water treatment systems has been the responsibility of individual residents since April 2000, it is unknown whether treatment systems are maintained as required.

The facility's on-site drinking water well consistently has contained levels of contaminants above drinking water standards. ATSDR assumes that past employees of Ram Leather Care were exposed to contaminated drinking water but that exposure is not current because the facility is unoccupied. Exposures could occur to the occasional trespasser who drinks water from the outdoor spigot on the Ram Leather Care property.

On the basis of the evaluation in this public health assessment (PHA), ATSDR concludes that the Ram Leather Care site posed a past public health hazard. For many years, residents might have been exposed to chlorinated solvents in private drinking water wells at concentrations exceeding drinking water standards. Children exposed to the maximum concentration of TCE detected in residential wells are at increased risk for noncancer health effects such as liver and kidney damage, although the likelihood of these effects is low. Residents have a moderate theoretical increased risk for cancer from exposure to the maximum concentration of PCE in their water every day for 25 years. The residential wells with contaminant levels above drinking water standards have been fitted with water treatment systems, although the effectiveness of the treatment systems has not been confirmed.

Former employees of the Ram Leather Care facility who drank contaminated water (employees were assumed to drink 1 liter of water per day [or approximately 1 quart])

from the on-site well may be at increased risk for noncancer health effects if exposed to the maximum concentration of TCE for 7 years and may have a moderate to high increased risk for cancer if exposed to the maximum concentration of PCE for 7 or more years. Given the conservative assumptions used to estimate the employee doses, this conclusion probably overestimates the actual level and duration of exposure to former employees. Possible inhalation and dermal exposures to former employees could not be quantified in this analysis.

Trespassers who occasionally drink water (trespassers are assume to drink ½ liter of water per day for 30 days) from the outdoor spigot are not expected to experience adverse health effects from exposures, although this practice should be prohibited, if possible.

Whether the water treatment systems are operating properly (e.g., because filters may not be replaced as advised) is unknown; therefore, the site currently poses an indeterminate public health hazard. If it can be confirmed that water treatment systems are reducing contaminants to below regulatory levels, then the site would be considered to pose no public health hazard under current conditions.

In 2004, the U.S. Environmental Protection Agency began installing a public water supply line to residences with wells contaminated above drinking water standards. At the time of release of this document, the public water supply line had not yet been completed.

The public comment version of this document was released on August 15, 2005. The public comment period ended on November 15, 2005. No comments were received during the public comment period. Therefore, except for minor factual corrections or grammatical changes, the content of this final document is unrevised from the public comment version.

I. PURPOSE AND HEALTH ISSUES

The Ram Leather Care site was proposed for inclusion to the National Priorities List (NPL) on April 30, 2003, and was subsequently added on September 29, 2003. The NPL was established by U.S. Environmental Protection Agency (EPA) and is a list of the hazardous waste sites across the nation where cleanup is warranted. Congress requires the Agency for Toxic Substances and Disease Registry (ATSDR) to conduct public health actions on all sites proposed to the NPL. In this public health assessment (PHA), ATSDR evaluates the public health significance of the Ram Leather Care site. ATSDR has reviewed environmental data, potential exposure scenarios, and community health concerns to determine whether adverse health effects are possible. The document also recommends actions to prevent, reduce, or further identify the possibility of site-related exposures that could result in adverse health effects.

II. BACKGROUND

Note: Unless otherwise specified, information in the Background (Sections A - C) and Environmental Contamination sections of this document was obtained or excerpted from the reports listed as items 1 through 6in the reference section.

A. Site Description

The Ram Leather Care site is located at 15100 Albemarle Road (Rt. 24/27) in Charlotte, eastern Mecklenburg County, North Carolina (Figure 1, Appendix A). The on-site building was constructed in 1967 and housed a construction business until 1977. Ram Leather Care, Inc. operated at the site as a dry cleaning and leather restoration facility from 1977 through 1993.

Residential property surrounds the 10-acre site. Privately owned parcels bound the site in each direction. A small fishing pond is located on the parcel to the south. A gravel road running southeast from the driveway of the site provides access to two residences to the south. The site features are illustrated in Figure 2, Appendix A.

Most of the area within a 4-mile radius of the site relies on private or community groundwater wells for drinking water. Public water from a source outside the site vicinity serves a small area 2–4 miles east of the site. Approximately 7,900 people obtain their drinking water from wells within 4 miles of the site.

B. Site History

Ram Leather Care operated as a dry cleaning and leather restoration business from 1977 through 1993. Chlorinated hydrocarbon chemicals (primarily tetrachloroethylene (PCE)), and petroleum hydrocarbons (mineral spirits) were used in the cleaning and restoration processes. Concentrations of these chemicals and their breakdown products were detected in private wells on-site and in nearby off-site wells, and in on-site soils.

In the past, Ram Leather Care generated, stored and disposed of hazardous substances and waste. Wastes generated at the site were placed in metal dumpsters from 1977 until 1984. After 1984, 55-gallon drums were used to store the waste generated at the site. During 1984–1988, wastes from the mineral spirits were stored in an above-ground waste tank, supported by a concrete pad, for later off-site recycling. In 1988, the company began storing hazardous waste on-site instead of shipping it off-site for disposal or recycling.

On April 6, 1991, the Mecklenburg County Department of Environmental Protection (MCDEP) discovered illegal open burning of filters containing PCE at the Ram Leather Care site. The facility was instructed to stop the burning and complied. On April 29, 1991, a state inspector discovered a 250-gallon above-ground storage tank of mineral spirit waste and 49 drums of liquid waste in an outside waste storage area. (On the site map, the storage pad is designated as the former drum storage area.) The bungs were open, allowing rainwater to enter the drum and waste to overflow. The drums were standing in liquid, indicating that some of the waste had been released onto the ground. A composite sample of the drum contents and a surface soil sample were taken on May 2, 1991. Stored on-site hazardous wastes were shipped off-site on June 14, 1991.

On April 30, 1991, the North Carolina Division of Environmental Management, Water Quality Section, was notified of a boiler blow-off in the storage area of Ram Leather Care. A permit had not been issued for the site, making this an illegal discharge. The area recently had been graded to allow surface water runoff to flow toward Albemarle Road (Figure 2, Appendix A). On May 6, 1991, MDCEP sampled one on-site drinking water well located within 50 feet of the storage area. Because of contamination found in the well, the Ram Leather Care proprietor was advised to discontinue use of the well for drinking purposes. On May 13, 1991, MCDEP sampled all off-site drinking water wells within ½ mile of the site. Sampling data identified two private residential wells contaminated with chlorinated solvents.

A series of investigations followed the May 1991 sampling event. Drums, surface soil, surface water, the septic tank drain field, on-site wells, and additional off-site wells were sampled over time.

The Ram Leather Care dry cleaning and leather restoration facility is no longer in operation. The owner filed for bankruptcy on March 18, 1993. Most recently, the site was used as a weekend flea market. According to local officials, use of the site as a flea market has been discontinued until further notice.

On February 16, 1994, the North Carolina Department of Environment and Natural Resources (NCDENR) referred the site to EPA for a possible removal action. On March 16, 1994, EPA sampled on-site soil and wells and determined that the contaminant levels were below removal action levels and assigned the site a low priority for removal action. In the meantime, a nearby resident installed a new deep well for potable purposes. NCDENR sampled the new well on September 26, 1995, and found levels of PCE that

exceeded EPA's removal action level for the contaminant. In November 1995, NCDENR requested EPA to reevaluate the site for possible removal action. On May 4, 1996, EPA determined the site qualified for a high priority removal action.

C. Site Geology and Hydrogeology

The Ram Leather Care site surface soil is silty and silty clay loam and is situated in an area of Georgeville silty clay loam. The surface layer is a yellowish red silty clay loam, approximately 5 inches thick. Below this is about 4 feet of strongly acidic subsoil. The upper part of the subsoil is a red silty clay; the lower part is a red silty clay loam. Under the subsoil is silt loam to approximately 9 feet below land surface.

The site is underlain by a saprolite (weathered bedrock) reservoir overlying bedrock. Depth to bedrock is about 42 feet. The saprolite contains water in the pore spaces between rock particles that act as a reservoir. The underlying bedrock contains water in sheet-like openings formed along fractures that act as interconnected pipes that convey water from the saprolite reservoir to wells in the bedrock. Groundwater is recharged in the area by precipitation. Average annual precipitation at the site is about 46 inches per year.

In the site area, the groundwater typically is found in the saprolite zone and the groundwater movement generally mimics the overlying ground surface. The depth to groundwater ranges from 23 to 26 feet. Groundwater movement probably is controlled by fractures in the saprolite, fractures in the partially weathered and competent bedrock, and the steep dip of the bedrock units to the northwest. Given the complexity of the bedrock at the site, the direction of groundwater movement depends primarily on such features as fractures, faults, and bedding planes.

D. Site Visit

On May 25, 2004, ATSDR staff visited the Ram Leather Care site. Mr. Mike Profit, a representative from CDM (EPA's contractor at the site), led the site tour. The ATSDR staff; along with Mr. Profit, noted the location of the on-site water supply wells, the on-site storage area, on-site and off-site monitoring wells, off-site private wells, and other notable features. We did not enter the on-site building. We observed the following during our visit:

- Access to the site was unrestricted. Graffiti on the side of the building and tossed bottles on the premises suggested trespassing.
- The on-site well was on-line and functional. A faucet turned the flow of the water on and off. Trespassers would have access to the contaminated water from the water pump.

- The on-site building appeared abandoned. A (storage) trailer was located next to the building. Trespassers might gain access to these structures through unsecured windows or other points of entry.
- Various debris (e.g., copper piping, machine parts, scrap metal components) were scattered on-site.
- An approximately 10-inch-wide hole in the ground was located on the western side of the building near the former floor drain. The bottom of the hole appeared to contain water or some other liquid. The hole was covered by a metal drum pad; however, the drum pad could be removed easily.
- One nearby resident had a swimming pool; although the source of the water in the pool was not established.

Also on May 25, 2004, ATSDR held two public availability sessions at the Mint Hill Town Hall. Mr. Mike Profit of CDM attended the sessions on behalf of EPA. Also in attendance were Ms. Sylvia Daniel and Mr. Joshua Sellers of the Mecklenburg County Health Department, and Mr. Jack Stutts of MCDEP. The purpose of the public availability sessions was to gather health-related concerns from residents. Representatives from the Mecklenburg County Health Department, MCDEP, and CDM responded to inquiries regarding well water testing, usage, and geology in the area. Approximately 14 residents attended the sessions. The health concerns gathered during these sessions are addressed in the Community Health Concerns section of this document.

E. Site Demographics

According to 2000 U.S. Census data, 928 people live within 1 mile of the Ram Leather Care site (Figure 3, Appendix A). Ethnic groups within the 1-mile radius include 851 whites, 42 blacks, 17 Hispanics, 15 Asians, and eight American Indians/Alaska Natives. Included in these numbers are 103 children aged 6 and younger, 61 adults aged 65 and older, and 216 females aged 15–44. A total of 319 housing units exist within the 1-mile area.

III. ENVIRONMENTAL CONTAMINATION

A review of environmental contamination at the site is an integral element of a PHA. In the following sections, the results of environmental sampling at the site are discussed for each media (i.e., groundwater and soil) of concern.

The following sections compare concentrations of chemicals in each media with appropriate comparison values (CVs) (see Appendix C for a full description of CVs). A **comparison value** is an estimated amount of a contaminant in the environment that is not expected to harm anyone, no matter how people contact the contaminant. CVs are used only to screen for chemicals that require further evaluation. A contaminant detected at levels lower than the CV are dropped from further analysis. A contaminant that exceeds a CV indicates a more detailed analysis is necessary for that chemical.

Levels of contamination greater than comparison values do not necessarily mean that adverse health effects will occur. The amount of the chemical, the duration of exposure, the route of exposure, and the health status of exposed people also are important factors in determining the potential for adverse health effects. At this site, all CVs for drinking water are expressed as Maximum Contaminant Levels (MCLs). An MCL is the regulatory limit set by EPA that establishes the maximum permissible level of a contaminant in water that is deliverable to the user of a public water system. MCLs are oftentimes referred to as the drinking water standard for a given chemical.

The major site-related contaminants identified at this site are PCE, TCE, *cis*-1,2-DCE, and vinyl chloride.

A. Groundwater

1. Monitoring Wells (Not used for drinking)

Note: For purposes of this PHA, groundwater sampling results are discussed separately from private well results because whether people have actually been exposed to the level of contaminants in monitoring wells is unknown. Point source samples from individual private wells provide a better indication of human exposures.

In May 1991, Bold Research Labs conducted a groundwater investigation on behalf of the site owner to identify a possible source of the contamination and to define the extent of soil and groundwater contamination. Monitoring wells were installed in three of the 17 soil borings completed at the site. The approximate depth to each of the three on-site monitoring wells was 30 feet. Groundwater samples were taken from the three monitoring wells and from two other boreholes. The samples were analyzed for volatile organic compounds (VOCs) and mineral spirits.

The maximum concentration of PCE detected in groundwater was 50,060 parts per billion (ppb) in the borehole near the drum storage area. This concentration exceeds the MCL of 5 ppb for PCE. Other contaminants detected at concentrations exceeding their CVs were 1,1,1-trichlorethane (TCA) at 6,697 ppb (the MCL for TCA is 200 ppb), TCE at 830 ppb (the MCL for TCE is 5 ppb), and 1,1,2-trichloroethane at 112 ppb (the MCL for 1,1,2-trichloroethane is 0.6 ppb).. PCE was detected at 1,201 ppb in another borehole near the dumpster area.

In March 1994, EPA conducted a site investigation to further assess the extent of groundwater contamination. EPA collected groundwater samples from the three existing monitoring wells, the on-site well, and eight off-site private residential wells. The samples were analyzed for VOCs. None of the three monitoring wells had detectable levels of VOCs. The on-site well and private residential well results are discussed below.

2. On-site Well and Off-site Residential Private Wells (Used for Drinking)

In May 1991, NCDENR sampled the on-site drinking water well that served approximately 8–10 employees of Ram Leather Care. The well-contained chlorinated solvents at levels exceeding applicable drinking water standards (MCLs). PCE was detected at 4,500 ppb, which exceeds the MCL of 5 ppb for PCE; TCE was detected at 259 ppb, which exceeds the MCL of 5 ppb for TCE; and *cis*-1,2-DCE was detected at 805 ppb, which exceeds the MCL of 70 ppb for *cis*-1,2-DCE. The Ram Leather Care proprietor was advised to discontinue use of the well for drinking water.

In May 1991, MCDEP sampled three off-site drinking wells within ½ mile of the site. Two of the three private residential wells were contaminated with the chlorinated solvents PCE and *cis*-1,2-DCE. The maximum concentration of PCE in one well was 19 ppb, which exceeds its MCL of 5 ppb. The maximum concentration of *cis*-1,2-DCE was 1.8 ppb, which did not exceed its MCL of 70 ppb. In July 1991, the Ram Leather Care proprietor was required to provide an alternate water supply to residents with contaminated wells.

MCDEP re-sampled the same three previous wells and sampled other nearby wells on January 30 and August 26, 1992. The August sampling identified an additional residential well contaminated with chlorinated solvents. The well contained PCE at 6.5 ppb, which slightly exceeded the MCL of 5 ppb for PCE.

The on-site well and surrounding private residential wells were sampled many times between 1991–2002 by NCDENR, EPA, MCDEP, or the proprietor. Table A below lists the maximum concentration of each contaminant detected at each sampling event.

	Maximum	Maximum	Maximum
Date	concentration	concentration	concentration
Sampled	of PCE (ppb)	of TCE (ppb)	of <i>cis</i> -1,2-
-			DCE (ppb)
5/91	19	_	1.8
8/91	8	_	-
1/92	45	_	5.8
2/92	66	1.7	_
7/92	26	_	_
8/92	6.5	_	_
6/93	_	_	_
3/94	24	2.8	24
9/95	204	8	6
12/95	100	26	42
4/99	110	4.1	4.5
8/02	54	2.2	40

Table A. Maximum Concentration of the Major Site-Related ContaminantsDetected In Private Residential Wells, 1991–2002

"-" chemical not detected or not sampled for.

ppb = parts per billion.

bolded numbers exceed the MCL for the chemical.

Between the March 1994 and September 1995 sampling events, a resident located across the street and north of the site installed a new, deeper well and resumed using groundwater for potable purposes. The new well contained contaminants at much higher concentrations than the previous sampling results from that residence. In September 1995, the new well was sampled, and PCE was detected at 204 ppb. This concentration exceeds EPA's MCL of 5 ppb and EPA's removal action level of 70 ppb for PCE. The exceedance of the removal action level for PCE in this residential well qualified the site for a high priority removal action by EPA.

B. Soil

The Ram Leather Care owner conducted on-site surface and subsurface soil sampling in July 1991. Soil samples were collected near the former tank pad, the dumpster area, the septic tank drain box, the drum area, along surface water runoff pathways, and in culverts near the railroad tracks. All samples were analyzed for VOCs, methyl-t-butylether (MTBE); mineral spirits; and benzene, toluene, ethylbenzene, and xylene. PCE; mineral spirits; and 1,1,1-TCA were detected in the samples at levels below applicable CVs.

In May 1991, NCDENR took a composite surface soil sample under the drum storage area. The soil sample was analyzed for total VOCs and semivolatile organic compounds (SVOCs). The sample contained detectable levels of PCE; TCE; vinyl chloride; 1,1-dichloroethene; and 1,2-dichloroethene. However, the levels were below applicable CVs.

In March 1994, EPA conducted on-site surface soil sampling. EPA collected four surface soil samples from the drum area, an area of stressed vegetation near the drum area, under a drain pipe, and along a surface water runoff pathway. Soil samples were analyzed for VOCs, SVOCs, and metals. Surface soil samples showed trace quantities of PCE and bis(2-ethylhexyl)phthalate. The levels of contamination in surface soil were below applicable CVs.

In April 1999, EPA collected additional surface and subsurface soil samples from the site. Surface soil samples were collected from the septic tank drain field, the north drainage ditch, the former dumpster area, and the former drum storage area. Subsurface samples (10- to 45-foot depth) were collected from the septic tank drain field, the north drainage ditch, and the former drum storage area. Surface soil samples were analyzed for VOCs, base neutral acids, pesticides, and metals. Subsurface samples were analyzed for VOCs only. A soil sample also was collected from the bottom of a 10-foot deep borehole lin the former drum storage area. The borehole sample was analyzed for VOCs, metals, and pesticides.

Maximum concentrations of contaminants in surface soil were 0.1 ppm for PCE and 2.4 ppm bis(2-ethylhexyl)phthalate. The maximum concentration of contaminants in subsurface soil was 20 ppm for PCE, 0.5 ppm for *cis*-1,2-DCE, 0.1 for TCE, and 0.04 for vinyl chloride. Concentrations of PCE and bis(2-ethylhexyl)phthalate were detected at 78 ppm and 7.1 ppm, respectively, in the borehole sample. This borehole sample contained the highest level of PCE and bis(2-ethylhexyl)phthalate contamination of any sample collected thus far. None of the samples, including the borehole sample, exceeded applicable soil CVs.

IV. PATHWAYS OF HUMAN EXPOSURE

ATSDR's pathways analysis determines whether people have contacted contaminants from a site and whether those contacts were substantial enough to cause harm. To determine this, ATSDR identifies exposure pathways or ways in which a chemical can enter a person's body (i.e., ingestion, inhalation, or dermal [skin] contact). An exposure pathway contains five major elements:

- 1. a source of contamination,
- 2. transport through an environmental medium,
- 3. a point of exposure,
- 4. a route of exposure, and
- 5. an exposed population.

What is exposure?

Exposure can occur by breathing, eating, or drinking the substance or by skin (dermal) contact with the substance. If no one contacts a contaminant, then no exposure occurs, and thus no adverse health effects could occur.

If an exposure pathway contains all five elements and exists now or existed in the past, the pathway is considered complete. Only completed exposure pathways are evaluated to determine whether health effects could occur. If one or more of the five elements is not

defined clearly but could exist, the exposure pathway is classified as potential. Tables 2 and 3 in Appendix B list the completed and potential exposure pathways for the site.

A. Completed Exposure Pathways

1. Potable Wells

The most significant completed exposure pathway related to the site is the use of contaminated water in wells for potable purposes. In the past, employees at Ram Leather Care probably were exposed through ingestion when they used contaminated water to make coffee or other beverages or when they drank water from the faucet at work. They probably also were exposed through dermal contact when they used the water from the faucet to wash their hands. Most recently, the site was used as a weekend flea market. Although flea market employees and patrons were supposed to be advised against using the water for potable purposes, ATSDR cannot confirm that all avoided using the water. The maximum concentrations of PCE, TCE, and *cis*-1,2-DCE in the on-site well exceeded applicable drinking water standards (MCLs) in samples taken between 1991–2002. In addition to these compounds, vinyl chloride was detected in the on-site well at levels which exceeded the applicable MCL of 2 ppb for vinyl chloride.

Nearby residents were exposed when they use water from their private wells for household purposes, such as drinking, cooking, bathing, showering, washing clothes, and filling toilets. Residents also may use their private wells to water lawns and gardens and to fill swimming pools. The maximum concentrations of PCE (204 ppb) and TCE (26 ppb) detected in private wells exceed the drinking water standards (MCLs) of 5 ppb for both compounds. The maximum concentration of *cis*-1,2-DCE (42 ppb) detected in a private well did not exceed the MCL of 70 ppb for the compound. Contamination of *cis*-1,2-DCE was never detected at levels above the MCL in any residential wells, although it will still be considered a major site-related contaminant due to its frequency of detection. The primary exposure routes for residents are ingestion and dermal contact. Because PCE and TCE readily evaporate from water, inhalation also is considered a primary route of exposure.

As reported earlier, the on-site well appeared to be on-line during our site visit. Site trespassers occasionally could drink contaminated water from the on-site well. The amount of water consumed, however, is expected to be minimal because of the assumed sporadic nature of trespassing.

Contamination above drinking water standards was first discovered in both on-site and off-site wells in 1991. Ram Leather Care operated its dry cleaning and leather restoration business from 1977 to 1993. Because monitoring data are not available before 1991, information about the duration and extent of exposure is based on reasonable assumptions. The actual length of time to which people may have been exposed depends on when the contaminants were first released into the environment, how long the contaminants took to reach the groundwater/private wells, and how long employees worked at the facility or how long residents have resided at their current home. For

example, employees at Ram Leather Care are assumed to have been exposed to contaminated water for as many as 7 years based on population studies; however, the actual number of years may be more or less than 7 years due of the mobility of employees. Considering that owners of contaminated private wells were provided with verified effective treatment systems only from 1996 until 2000 (see discussion below), residents may have been exposed for as many as 20–25 years, depending on how long they had lived in the area and when the contamination first reached their well. Also, contaminant levels in private wells might have been higher or lower during the past 20–25 years.

2. Actions Taken to Reduce Exposures to Chlorinated Solvents in Private Wells

The levels of PCE detected at three residences exceeded the MCL of 5.0 ppb for PCE. The level of TCE detected at one of the same three residences exceeded the MCL of 5.0 ppb for TCE. Detectable levels of *cis*-1,2-DCE were found at these same three residences, although the levels did not exceed the MCL of 70 ppb for *cis*-1,2-DCE. PCE (1.0 ppb) and *cis*-1,2-dichlorobenzene (3.3 ppb) were detected in the well of a fourth residence, although the levels did not exceed the MCL for either compound.

In May 1996, EPA's Emergency Response and Removal Branch (ERRB) began a removal action at the site. The ERRB removal action consisted of installing drinking water treatment systems at the three residences with wells contaminated above applicable drinking water standards, and the one residence with detectable levels of contaminants, and maintaining the change out of the filters for the first year. Pre- and post-filtration sampling confirmed that the water treatment systems were effective at removing chlorinated solvents to levels below drinking water standards.

Beginning in 1997, NCDENR assumed responsibility for filter change outs for the next 3 years. However, because of limited funds, NCDENR was unable to fund the filter change outs beyond April 2000. NCDENR advised residents that the residents would be financially responsible for future filter replacements beginning in spring 2001. According to officials, residents may not change their filters as advised (6).

In 2004, EPA began installing a public water supply line to residences identified as having contaminated wells above drinking water standards (MCLs). These residences are scheduled to be connected to the public water supply, and exposure to contaminated well water will cease once these homes are connected. At the time of the release of this document, the installation of the public water supply line has not been completed.

Although the contaminant levels in the on-site well consistently have been above drinking water standards, the property is abandoned and the well no longer is used for potable purposes. Therefore, no exposures to employees or patrons are occurring from use of the on-site well. Minimal exposures might occur for the site trespasser who occasionally drinks water from the outdoor spigot.

B. Potential Exposure Pathways

1. Indoor Air

Concentrations of PCE up to 50,060 ppb have been detected in groundwater. The highest concentration of groundwater contamination was detected near the former drum storage area, which is near the on-site building. Groundwater in the area is approximately 23–26 feet below ground surface. The possibility exists that contamination from the groundwater plume (or on-site soils) could be migrating into the indoor air of the on-site building through the soil-gas pathway. Because the building is unoccupied, this potential pathway is incomplete. However, the soil-gas pathway should be evaluated if the building is to be occupied for any reason before remediation of groundwater or soil.

2. Groundwater

Because an underlying fractured bedrock zone controls groundwater movement in the area, the direction of groundwater flow in the area is difficult to predict. As the groundwater plume migrates, site-related contaminants could migrate beyond the known area of contamination. Additional wells could be impacted if this occurs.

C. Eliminated Exposure Pathway

1. On-Site Soils

The soil sampling conducted from 1991 to 1999 confirmed the presence of chlorinated solvents in on-site soils at low levels. The sample collected from the borehole contained the highest level of contamination of any sample, but people are not likely to contact 10-foot-deep soil. Contaminant concentrations in surface soil did not exceed applicable CVs. Therefore, adverse human health effects will not occur from direct contact with this soil. The soil exposure pathway will be eliminated from further analysis. Contaminated soil thus far has not been removed from the site.

V. PUBLIC HEALTH IMPLICATIONS

In this section, ATSDR discusses the health effects that could plausibly result from exposures to contaminants at the Ram Leather Care site. For a public health hazard to exist, people must contact contamination at levels high enough and for long enough time to affect their health. The environmental data and conditions at the site revealed one completed exposure pathway—use of private wells for potable purposes. The following section discusses the public health implications of this exposure pathway.

A. Considerations for Estimating Exposure

ATSDR prefers to use site-specific conditions whenever possible to evaluate whether people are being exposed to contaminants at levels of health concern. However, two important site-specific determinants are not known for this site: 1) when the contaminants from the site reached private drinking wells and 2) what levels of contamination residents might have been exposed to over time (the levels could have been higher or lower than currently available levels). Because of these unknowns, ATSDR must rely on reasonable assumptions instead of on site-specific information.

To evaluate residents' exposures at the site, ATSDR defined two categories of residents (Table B below): 1) the highly exposed person and 2) the average exposed person. Exposure assumptions for the highly exposed person are conservative and represent a worst-case exposure scenario. Exposure assumptions for the average exposed person generally are considered "reasonable" and represent an average person's exposure level on the basis of professional judgment and/or population studies.

	Exposure Group:	Exposure Group:	
Exposure Factor	High	Average	
	(Conservative)	(Reasonable)	
Exposure Duration	20–25 years	9 years	
Exposure Frequency	365 days/year	350 days/year	
Contaminant Level	Highest level	Average/Mean level	
	detected	detected	

Table B. Site Assumptions Based on Exposure Group

For this evaluation, the highly exposed person is assumed to have been exposed to contaminants in his or her well water every day for 20–25 years. The average exposed person is assumed to have been exposed for 350 days per year for 9 years, the average length of time a person spends at one residence, according to population studies (EPA *Exposure Factors Handbook*, August 1997).

Contaminants first were discovered in residential wells in 1991. People could have been exposed before 1991 depending on when the contamination was first released into the environment, how long the chemicals took to reach a person's private well, and how long the person had resided at his or her current home. Using the worst-case scenario (that wastes were improperly discharged as soon as Ram Leather Care began operating in 1977 and that wells were contaminated soon after the discharges), ATSDR estimates the maximum duration of exposure to be 20–25 years for the highly exposed person. Using an average case scenario based on population studies from EPA's *Exposure Factors Handbook*, ATSDR estimates the exposure duration to be 9 years for the reasonably exposed person.

With regard to contaminant exposure level, a highly exposed person is assumed to be exposed to the highest level of contaminants ever detected in private wells. A reasonably exposed person is exposed to an average contaminant concentration.

From 1991 to 2002, sampling results indicate that contaminant levels in wells varied over time. The mean levels of PCE and TCE are 37.4 ppb and 2.4 ppb, respectively, which is much lower than the maximum levels used for the highly exposed persons. Therefore, use of the highest level detected may overestimate exposures to residents, although levels of contaminants in wells in the past may have been higher.

As is true with most sites, assuming long-term contact with the maximum concentration is not reasonable; therefore, any conclusions based on the highly exposed person should be viewed as an overestimation of the true risk.

ATSDR also conservatively assumed that exposure doses for dermal contact and for inhalation equal those from ingestion of contaminants in water.

B. Evaluating Health Effects from Exposure to Single Chemicals

When evaluating the possibility of harmful effects after exposure of people to multiple contaminants in potable water, ATSDR first evaluates the health effects of the individual chemicals in the mixture. The evaluation of individual chemicals is a building block for evaluating the mixture of chemicals. (Appendix C presents a detailed discussion of the public health evaluation process.)

To evaluate potential health effects from exposure to individual chemicals, ATSDR has developed MRLs for contaminants commonly found at hazardous waste sites. The MRL, similar to EPA's reference dose (RfD), is an estimate of daily human exposure to a contaminant below which noncancer, adverse health effects are unlikely. In this PHA, we estimated the dose of a contaminant to individual persons and compared the dose at this site with ATSDR's MRL or EPA's RfD. Any exposure dose below the appropriate MRL or RfD is unlikely to cause a noncancer health effect in humans. ATSDR presents the MRLs in toxicological profiles. These chemical-specific profiles provide information about health effects, environmental transport, human exposure, and regulatory status. To address the health impacts of contaminants at this site, we used the information in ATSDR's toxicological profiles for PCE (10), TCE (11), *cis*-1,2-DCE (12) and vinyl chloride (13).

1. Private Residential Wells

The only two contaminants of concern detected in private wells at the Ram Leather Care site were PCE and TCE. Levels of other chemicals are below applicable drinking water standards and are, therefore, not of public health concern. Three or four residences identified as having wells containing contaminants above applicable drinking water standards have been provided with water treatment systems. The water treatment systems effectively remove chlorinated solvents to levels below drinking water standards if

properly maintained; however, officials were notified that some residents are not changing their filters as advised. Therefore, filter breakthrough may have occurred, and some residents still may be exposed to contaminants.

Ingestion of contaminated well water is assumed to be one of the primary routes of contaminant exposure for residents. When residents drank the water or drank beverages made using water from contaminated wells, they were orally exposed to contaminants. Because PCE and TCE readily evaporate from water, residents also were exposed by inhaling vapors released into air during showering, bathing, hand washing, and cooking. Reports in the scientific literature indicate that, while showering, people generally inhale an amount of VOCs slightly less than or equal to drinking water exposures (8). Residents also were exposed to PCE and TCE from skin (dermal) contact during household use of water, such as when bathing, showering or washing their hands.

Using the above assumptions and others discussed in Appendix C, ATSDR calculated exposure doses for highly and averagely exposed children and adults resulting from ingestion, inhalation, and dermal contact with PCE and TCE in private wells. (Appendix C contains the equations, the results, and a technical description of how exposure doses were derived.) An exposure dose is the amount of a contaminant that gets into a person's body. Exposure doses for ingestion, inhalation, and dermal contact were combined to determine the possibility of harmful effects. The combined exposure levels were compared with health guidelines to determine whether further toxicological evaluation is needed.

a. TCE

i) Noncancer Health Effects

TCE at high doses has been linked with a variety of noncancer conditions, including anemia and other blood disorders, stroke, nervous system disorders, urinary tract disorders, liver problems, kidney dysfunction, diabetes, eczema, and skin allergies. A study on the reproductive effects of TCE suggests that more miscarriages might occur when mothers drink water containing TCE. Other studies have linked prenatal TCE exposure with congenital heart disease, eye malformations, neural tube defects, and oral cleft palates. The combined results of these studies are unclear, however, and further study is needed to understand the risk for reproductive and developmental effects associated with TCE exposure.

The site-specific child and adult exposure doses calculated using the highest (26 ppb) concentration of TCE measured in drinking water are 0.005 and 0.001 milligrams per kilogram per day (mg/kg/day), respectively. The child and adult exposure doses using the average concentration of TCE are 0.0004 and 0.0001 mg/kg/day, respectively. No chronic MRL exists for TCE. However, EPA's draft proposed oral RfD for TCE is 0.0003 mg/kg/day¹.

¹ Based on EPA Region 9 Preliminary Remedial Goal (PRG) Table, October 2004.

Because the estimated exposure doses for children and highly exposed adults exceed the health guideline for TCE, the possibility of health consequences for children and highly exposed adults was evaluated further. EPA's **Reference Dose** (RfD) is an estimate of the amount of chemical that a person would have to be exposed to over a lifetime before any observable health effects (excluding cancer) would be expected.

To further evaluate the possibility of adverse health effects, ATSDR divides the lowest observed adverse effect level (LOAEL) and/or the no observed adverse effect level (NOAEL) by the site-specific exposure doses. Interpretation of the resulting value is subjective and depends on a host of toxicological factors. Further evaluation consists of a careful comparison of site-specific exposure doses and circumstances with the epidemiologic and experimental data on the chemical. The purpose of the comparison is to evaluate how close the estimated exposure doses are to doses that cause health effects in humans or animals.

The estimated high exposure dose for adults of 0.001 mg/kg/day is 1,000 lower than the NOAEL of 1 mg/kg/day for TCE; therefore, adverse health effects are unlikely. The estimated high (0.005 mg/kg/day) and average (0.0004 mg/kg/day) doses for children are 200 and 2,500 times, respectively, lower than the NOAEL. The estimated average child dose is not expected to result in adverse health effects. However, because the high child dose is only 200 times lower than the NOAEL, ATSDR will further evaluate the possibility of TCE to cause harmful effects in these children.

The TCE health guideline is based on the results of oral studies in animals. Adverse effects were observed in the liver, kidney, and developing fetuses of test animals at the lowest doses tested (approximately 1–10 mg/kg/day); 1 mg/kg/day appeared to be the boundary at which effects began to be observed. Therefore, adverse health effects in children exposed daily to the highest level of TCE detected in residential well water (26 ppb) cannot be ruled out. Given the conservative assumptions used to estimate the high dose for a child, this conclusion most likely overestimates the true likelihood of harm to a child at the site.

All doses for adults and the average dose for children are small in comparison with the NOAEL and therefore are unlikely to cause noncancer health effects in adults or the average exposed child.

ii) Cancer Health Effects

The International Agency for Research on Cancer has determined that TCE is a probable human carcinogen (14). TCE causes liver and kidney cancer in experimental animals. Studies on the epidemiology of cancer among people exposed to TCE have found increases in kidney cancer, liver cancer, non-Hodgkin lymphoma, cervical cancer, Hodgkin disease, multiple myeloma, and pancreatic cancer. However, the association between exposure to TCE and cancer has been inconsistent across studies. The estimated theoretical risk for cancer from exposure to the contaminants usually is calculated by multiplying the exposure dose by EPA's corresponding cancer slope factor for TCE. EPA is reviewing the slope factor for TCE; therefore, no cancer slope factor for TCE is available at the time of the writing of this document. EPA Region 9 preliminary remedial goal (PRG) values were used instead.

Assuming an adult drinks 2 liters of water containing TCE at the maximum detected concentration every day for the maximum estimated exposure time of 25 years, and assuming a cancer slope factor of $0.4 \text{ (mg/kg/day)}^{-1}$, the predicted theoretical increased risk for cancer for this highly exposed person would be low (1 cancer case per 10,000 people exposed, or 1×10^{-4}). Assuming adult drank the same amount of water (2 liters) containing TCE at the average concentration for a maximum of 9 years, there would be no apparent increased theoretical increased cancer risk (5 cancers per one million people exposed, or 5×10^{-6}). Cancer risks less than 1 in 10,000 usually are not considered a health concern.

<u>Conclusions about health risks posed by exposure to TCE in residential wells</u>: The above worst-case scenario for adults (long-term exposure up to 25 years to the maximum contaminant concentration) and the average case scenario for children and adults (exposure to the mean contaminant concentration for a maximum of 9 years) showed no significant adverse health effects from exposure to TCE in drinking water. Children exposed to the maximum detected concentration of TCE in their drinking water every day might be at increased risk for noncancer health effects. Residents exposed to the maximum concentration of TCE for up to 25 years have a low theoretical increased risk for cancer. The average resident would have no apparent increased cancer risk from exposure to TCE. Most residential wells had TCE contaminant levels much lower than the maximum level used to calculate the high doses. The residential wells with TCE levels above drinking water standards have been fitted with water treatment systems; however, the effectiveness of the treatment systems has not been confirmed.

b. PCE

i.) Noncancer Health Effects

Results from animal and human health studies indicate that exposure to high doses of PCE can adversely affect the nervous system and reproductive system. Findings from human studies suggest a causal relation between exposure to PCE in utero and reproductive and developmental effects, including reduced birthweight and infants born small for gestational age. Studies in animals and humans suggest the developing fetus may be susceptible to PCE exposure from maternal exposure.

The estimated exposure doses of PCE for a highly exposed adult are 0.01 mg/kg/day and 0.002 mg/kg/day for an average adult. The average adult dose is less than EPA's oral RfD of 0.01 mg/kg/day for PCE; however, the dose for highly exposed adults equals the oral RfD and will be evaluated further. The estimated exposure dose of PCE for a highly

exposed child is 0.04 mg/kg/day, which is greater than the oral RfD of 0.01 mg/kg/day for PCE. The estimated dose for an average child is 0.006 mg/kg/day, which is less than the oral RfD of 0.01 mg/kg/day for PCE. Because the estimated exposure dose for a highly exposed adult equals the long-term health guideline and because the dose for a highly exposed child exceeds the health guideline for PCE, the possibility of health consequences from these exposures was evaluated further.

The next step in the evaluation is comparison of site-specific doses for PCE to known toxicological values, starting with the NOAEL and/or LOAEL used to derive the RfD. These toxicological values are doses derived from human and animal studies, which are summarized in EPA's Integrated Risk Information System.

As indicated above, ATSDR divides the LOAEL and/or NOAEL by the site-specific exposure dose. Interpretation of the resulting value is subjective and depends on a host of toxicological factors. Further evaluation consists of a careful comparison of the site-specific exposure doses and circumstances to the epidemiologic and experimental data on the chemical. The purpose of this comparison is to evaluate how close the estimated exposure doses are to doses that cause health effects in humans or animals.

The estimated dose of 0.01 mg/kg/day for the highly exposed adult is 1,400 times less than the NOAEL of 14 mg/kg/day for PCE and therefore is unlikely to result in adverse health effects. The estimated exposure dose of 0.04 mg/kg/day for the highly exposed child is 350 times less than the NOAEL of 14 mg/kg/day for PCE (15, 16). Because the child's exposure dose is only 350 times less than the NOAEL, ATSDR decided to evaluate children's exposures more closely. We looked at the study used to derive EPA's RfD for PCE. In the study (15), rats were administered PCE in drinking water for 90 days. Adverse health effects, such as decreased body weights and increased liver and kidney to body weight ratios, were observed in animals treated with 400 mg/kg/day of PCE. In another study (16), mice were exposed to PCE in corn oil by mouth for 5 days/week for 6 weeks. Harmful effects were observed in animals treated with PCE at 100 mg/kg/day. The community's past exposure to PCE at even the highest level is several orders of magnitude less than the doses which caused adverse effects in animal studies. Additionally, conservative estimates (which probably overestimate the true exposures) were used to define exposures for the high exposure group. For these reasons, noncancer health effects are not likely in children or adults exposed to even the highest level of PCE in their drinking water.

ii) Cancer Health Effects

The International Agency for Research on Cancer classifies PCE as a probable carcinogen in humans (14). The findings from animal and human studies provide some evidence of PCE carcinogenicity in animals and limited evidence for carcinogenicity in humans. Cancer effects of PCE have been studied in laundry and dry-cleaning workers, who also may have been exposed to other petroleum solvents. Among these workers, excess incidence was reported of the following cancers: lymphosarcomas; leukemia; and cancers of skin, larynx, colon, lung, urogenital tract, and urinary bladder. Although these

studies suggested a possible association between occupational exposure to PCE and TCE and increased lymphatic malignancies, the evidence was inconclusive because the workers also were exposed to petroleum solvents.

The cancer slope factor for PCE from EPA's Region 9 PRGs is $0.54 \text{ (mg/kg/day)}^{-1}$. Assuming a person drank 2 liters of water containing PCE at the maximum concentration every day for the maximum estimated exposure time of 25 years, the predicted theoretical increased risk for cancer would be moderate (2 cancer cases per 1,000 people exposed [2 x 10^{-3}]). Assuming the same, except the person drank 2 liters of contaminated water at the mean concentration of PCE for 350 days per year for 9 years, the predicted theoretical increased risk for cancer would be low (or 1 cancer case per 10,000 people exposed [1 x 10^{-4}]). Cancer risks less than 1 in 10,000 are usually not considered a health concern. Because the cancer risks for the highly exposed person exceeds accepted guidelines, residents exposed to the maximum concentration of PCE for 25 years may have an increased risk for cancer from exposure to PCE in their drinking water.

<u>Conclusions about health risks posed by exposure to PCE in residential wells:</u> Residents are not at increased risk for noncancer health effects and have a moderate theoretical increased risk for cancer.

2. On-Site Well

a. Noncancer Health Effects

The on-site well contained high levels of VOCs. Maximum levels of PCE (4,500 ppb), TCE (259 ppb), *cis*-1,2-DCE (1,200 ppb) and vinyl chloride (8.5 ppb) exceeded applicable MCLs for the compounds. In the past, employees may have drunk water from this well or used the water to make other beverages while at work. The building is currently unoccupied, and the proprietor has been advised not to use the well for potable purposes; therefore, employees currently are not being exposed. However, during our site visit, the on-site well was functioning, including access to an open spigot from which trespassers may drink.

ATSDR wanted to know whether former employees or the occasional trespasser may have experienced or may experience health effects from drinking water from the contaminated on-site well. We assumed the average worker ingested 1 liter of water per day for 260 days per year and that the average trespasser ingests 0.5 liters of water per day for 30 days per year. We did not account for dermal and inhalation exposures because employees and trespassers were unlikely to shower or bathe in the water.

All of the calculated exposure doses for trespassers are below applicable health guidelines; therefore, the chemicals do not pose a health concern for trespassers. (See Table 6 in Appendix C.) Therefore, adverse health effects are not expected for the trespasser who occasionally drinks water from the on-site well.

The calculated exposure doses for former employees exceed applicable health guidelines for PCE and TCE. The calculated dose for former employees exposed to PCE is 0.05 mg/kg/day, which is five times greater than the oral RfD of 0.01 mg/kg/day for PCE. The calculated dose for former employees exposed to TCE is 0.003 mg/kg/day, which is 10 times greater than the oral RfD of 0.0003 mg/kg/day for TCE. Because the estimated exposure doses for former employees exceed the long-term health guidelines for PCE and TCE, the possibility of health consequences from these exposures was evaluated further.

In this comparison of toxicological values, ATSDR divides the LOAEL and/or NOAEL by the site-specific exposure dose. The estimated former employee exposure dose (0.05 mg/kg/day) is 280 times lower than the NOAEL for PCE (14 mg/kg/day). The estimated former employee exposure dose for TCE (0.003 mg/kg/day) is over 330 times lower than the LOAEL for TCE (1 mg/kg/day). As previously stated, harmful effects from exposure to PCE were observed in animals at dose levels between 100 and 400 mg/kg/day. The estimated doses for former employees are several orders of magnitude less than the doses that caused adverse effects in animals. Therefore, former employees are unlikely to experience health effects from past exposure to PCE. Additionally, given that conservative assumptions were used to calculate doses, the predicted doses probably overestimate the actual risk to former employees from drinking contaminated water. However, quantification in this document of the cumulative risks to employees who also may have inhaled or had dermal contact with PCE while performing job-related duties is impractical.

Harmful effects were observed in animals exposed to TCE at doses between 1 to 10 mg/kg/day. Although the estimated exposure dose for former employees (0.003 mg/kg/day) is several orders of magnitude lower than the doses that caused adverse effects in animals, the possibility of adverse effects in former employees cannot be ruled out. Given the conservative assumptions used to estimate the employee dose, this conclusion probably overestimates the true likelihood of adverse health effects to any former employee of the facility.

b. Cancer Health Effects

Excess theoretical cancer risks for former employees and trespassers were calculated assuming that a former employee and trespasser would be exposed to the highest concentration of each contaminant for 7 and 5 years, respectively. The resulting calculations are presented in Table 7 in Appendix C. Assuming that a former employee drank 1 liter of water at the maximum concentration every day for the maximum estimated exposure time of 7 years, the predicted increased risk for cancer would be moderate for PCE (3×10^{-3}) and low for TCE (1×10^{-4}). *cis*-1,2-DCE is not a carcinogen and thus would not contribute to the overall carcinogenic potential. The excess theoretical risk cancer from exposure to vinyl chloride is 6×10^{-6} — too low to be considered a health concern. Cancer risks greater than 1 in 10,000 (1×10^{-4}) are considered a potential health concern.

The excess theoretical cancer risks for trespassers range from insignificant (3×10^{-7}) to low (1×10^{-4}) . Therefore, trespassers are unlikely to have excess cancer risks from exposures to contaminants in the on-site well.

C. Evaluating Health Effects from Exposure to Multiple Chemicals

The health impact of exposure to chemical mixtures can be of particular concern at hazardous waste sites because most such sites contain multiple chemical contaminants. Evaluation of chemical mixtures especially must consider potential toxic interactions at environmentally relevant doses of chemicals. However, relatively few studies have assessed toxic interactions in these low dose ranges. A series of important studies on the toxicity of low-dose chemical mixtures was conducted by the TNO Nutritional and Food Research Institute in the Netherlands. These studies found no discernable toxic response until the dose levels of the individual chemicals approached or exceeded their individual thresholds. However, when the chemicals were administered at their individual LOAEL doses, additive toxic effects clearly were evident. Furthermore, additive toxicity was observed even though the chemicals had different mechanisms of toxicity (18).

Other studies have provided evidence that exposure to chemical mixtures, in which the chemicals were administered at doses near their individual thresholds, can product additive toxic effects. However, no evidence exists of additive toxicity from exposure to chemical mixtures when the individual chemicals are administered at doses well below their individual thresholds. Nevertheless, the threshold doses for many toxic endpoints in animals are not well defined. Therefore, considering the potential for toxic effects from exposure to chemical mixtures at all sites is prudent (17).

ATSDR's *Guidance Manual for the Assessment of Joint Action of Chemical Mixtures* (18) provides additional information about the evaluation process for mixtures. Appendix C summarizes the applicable portions of this manual.

1. Private Wells (Multiple Chemical Exposure)

This section evaluates whether exposure to a mixture of the highest concentrations of PCE and TCE found in well water is likely to result in adverse health effects. (In this evaluation, exposure doses for dermal contact and inhalation are assumed to equal those from ingestion.) The first step is to calculate a hazard index (HI). To calculate HIs for the potentially exposed population, hazard quotients (HQs) should be calculated first for each chemical. The HQ is the ratio of the exposure dose to the appropriate MRL or RfD. The HQs are summed to derive the HI. If the HI is less than 1.0, significant additive or toxic interactions are highly unlikely, so no further evaluation is necessary. If the HI is greater than 1, then further evaluation is necessary. Table C below presents the HQs for the contaminants of concern (PCE and TCE) detected in private drinking wells.

Table C. Multiple Chemical Exposures: Residential Wells Calculation of Noncancer Risk (Hazard Quotient)						
$ \begin{array}{c c} Exposed \\ Population \\ Population \\ Media \\ Media \\ Media \\ Route \\ Route \\ Contaminant \\ Contaminant \\ Contaminant \\ Media \\ MRL or \\ RfD \\ (mg/kg/day) \\ (mg/kg/day) \\ (mg/kg/day) \\ Hazard \\ Quotient^1 \\ (mg/kg/day) \\ (mg/kg/day)$						
	Potable	Ingestion	PCE	0.04	0.01	4
Child	water	Inhalation Dermal	TCE	0.005	0.0003	17
	Potable	Ingestion	PCE	0.01	0.01	1
Adult	water	Inhalation Dermal	TCE	0.001	0.0003	3

¹ The hazard quotient is the estimated dose divided by the MRL or RfD.

The HQs for children simultaneously exposed to PCE and TCE are 4 and 17, respectively, yielding an HI of 21. The HQs for adults simultaneously exposed to PCE and TCE are 1 and 3, respectively, yielding an HI of 21.

The next step is to compare the estimated doses of the individual chemicals with their NOAELs or comparison values. If the dose of one or more of the chemicals is within one order of magnitude of its NOAEL, then the potential exists for additive or interactive effects. If the estimated doses of the individual chemicals are less than 1/10 (<0.1) of their respective NOAELs, then significant additive or interactive effects are unlikely, and no further evaluation is necessary. Table D below compares results (dose \div NOAEL) for PCE and TCE in private wells using the high doses for both children and adults.

Table D. Multiple Chemical Exposures Analysis: Residential Wells Comparison Values Divided by Doses						
Exposed PopulationMediaContaminantEstimated Dose (mg/kg/day)NOAEL (mg/kg/day)Dose/NOAEL						
	Potable	PCE	0.04	14	0.002	
Child	water	TCE	0.005	1	0.005	
	Potable	PCE	0.01	14	0.0007	
Adult	water	TCE	0.001	1	0.001	

The high doses for both children and adults are less than 1/10 (<0.1) of their respective NOAELs for PCE and TCE; therefore, significant additive or interactive effects are not likely.

2. On-site Well (Multiple Chemical Exposure)

This section evaluates whether exposure (through ingestion) to the mixture of chemicals in the on-site well is likely to result in adverse health effects to former employees and the occasional trespasser who drank/drinks water from the contaminated on-site well. Using the same approach as above, ATSDR calculated HQs for potentially exposed people for each contaminant of concern. (See Table E below.)

Table E. Multiple Chemical Exposures:On-site Well (Former Employees)Calculation of Non-Cancer Risk (Hazard Quotient)							
Exposed Population	Media	Exposure Route	-				
			PCE	0.05	0.01	5	
Former	Former Potable Employee water from	Ingestion	TCE	0.003	0.0003	10	
Employee			cis-1,2-DCE	0.01	0.01	1	
	on-site well		VC	0.00009	0.003	0.03	
			PCE	0.003	0.01	0.3	
Trespasser	Potable		TCE	0.0001	0.0003	0.3	
	water from	Ingestion	cis-1,2-DCE	0.0007	0.01	0.07	
	on-site well		VC	0.000005	0.003	0.002	

¹ The hazard quotient is the estimated dose divided by the MRL or RfD.

The HI for former employees simultaneously exposed to PCE, TCE, *cis*-1,2-DCE, and vinyl chloride is 16. The HI for trespassers is less than 1; therefore, no further evaluation of interactions for trespassers is needed. Table F below compares results (dose \div NOAEL) for former employees.

Table F. Multiple Chemical Exposures Analysis: On-site Well (Former Employees) Comparison Values Divided by Doses								
Exposed Population								
	Potable	PCE	0.04	14	0.003			
Former	water	TCE	0.005	1	0.005			
Employee from on-site	cis-1,2-DCE	0.01	None	N/A				
	well	VC	0.00009	0.13	0.0007			

The doses for former employees are less than 1/10 (<0.1) of their respective NOAELs; therefore, significant additive or interactive effects are not likely.

VI. EVALUATION OF HEALTH OUTCOME DATA

The Superfund law states that health assessments shall include a comparison of existing morbidity and mortality data on diseases that may be associated with the observed levels of exposure. Health outcome data may include mortality information (the number of people dying from a certain disease) or morbidity information (the number of people becoming sick from a certain disease). A thorough evaluation of health outcome data as they relate to a hazardous waste site requires the following elements: 1) a completed human exposure pathway, 2) sufficiently high contaminant levels to result in measurable health effects, 3) a sufficient number of people in the completed pathway for the health effect to be measured, and 4) a health outcome database in which disease rates for populations of concern can be identified.

The site does not meet the requirements for evaluating health outcome data in a PHA. Although completed human exposure pathways existed at this site, the potentially exposed population is not large enough (approximately three to four households) to result in a meaningful measurement of health outcome data.

VII. COMMUNITY HEALTH CONCERNS

On May 25, 2004, ATSDR staff held two public availability sessions at the Mint Hill Town Hall to gather community concerns about the Ram Leather Care site. Approximately 14 people attended the sessions. Most of the residents were interested in getting their wells tested. Some residents wanted to know whether their wells were safe or whether they might be impacted by contaminants from the site. Residents also expressed their desire for more information about activities at the site. The Mecklenburg County Health Department and MCDEP staff assisted residents who wanted to know about well testing that had been done or to determine whether their wells could be tested. Residents who asked about the status of EPA's plans and activities for the site were referred to the CDM representative, who was present to answer questions on EPA's behalf.

Specific concerns and ATSDR's responses are presented below.

1. How often should I get my well water tested?

RESPONSE: Federal regulations set the standards for testing for public water suppliers; however, these standards do not apply to private wells. If you have your own private well, you must decide the frequency and type of testing done on it. Commercial laboratories will test drinking water for chemicals and microbes, although the tests for chemicals (such as the VOCs found at this site) are more expensive and often difficult to understand. Once your well has been tested, you can discuss the results with your local health department.

ATSDR also has compiled a fact sheet for citizens entitled, *VOCs: Your Water and Your Health*. This fact sheet was distributed to some residents during summer 2005. The fact sheet contains information about VOCs and home water filtration systems for people who use private wells. You can contact ATSDR toll-free at 888-422-8737 or your local health department to request a copy.

2. I am uncertain if my well is being impacted by site-related contaminants. Who do I contact to get my well tested?

RESPONSE: Residents can contact Angela Miller, EPA Region 4, at 1-800-241-1754, ext. 28561, for more information about testing of private wells in your area.

3. Should I be concerned about any adverse health effects from being exposed to contaminants in my well?

RESPONSE: The average child or adult is unlikely to experience adverse health effects from exposure to any of the site-related contaminants in their well. A child who is exposed every day to the maximum concentration of TCE ever detected in a well might be at increased risk for noncancer health effects. A person exposed to the maximum concentration of PCE for 25 years would have an increased risk of developing cancer. See the "Public Health Implications" section above for more specific information about this subject.

VIII. CHILD HEALTH CONCERNS

ATSDR recognizes that the unique vulnerabilities of infants and children demand special emphasis in communities faced with contamination of their water, soil, air, or food. Children may be at greater risk than adults from certain kinds of exposures to hazardous substances from waste sites and emergency events. Children may be more likely to be exposed because they play outdoors and often bring food into contaminated areas. They may be more likely to contact dust, soil, and heavy vapors close to the ground. Also, they receive higher doses of chemical exposure because of lower body weights. The developing body systems of children can sustain permanent damage if toxic exposures occur during critical growth stages.

The fetus may be particularly susceptible to the toxic effects of chemicals if the chemicals cross the placental barrier. Before birth, the fetus is forming the body organs that need to last a lifetime. This is the time when chemical injury may lead to the greatest effects. Laboratory animal and epidemiologic studies indicate that VOC exposures to the fetus and children may result in adverse health effects. Some epidemiologic studies have found that exposure to PCE and TCE during pregnancy increase the risk of the fetus developing central nervous system defects, neural tube defects, and oral cleft defects. However, other studies have not associated PCE and TCE exposure with birth defects. A

childhood cancer study identified a statistically significant increase of childhood leukemia and associated the increase to fetal exposure because the mothers drank PCEand TCE-contaminated water. The study did not find any association between development of childhood leukemia and drinking contaminated water by children. The conclusions were based on imprecise estimates of leukemia risk because of the small number of study participants. The time of exposure was not clearly evident, which may not accurately predict the amount or strength of any effect that TCE and PCE may have on the fetus.

IX. CONCLUSIONS

1. ATSDR considers the Ram Leather Care a **past public health hazard**. For many years, residents may have been exposed to chlorinated solvents (VOCs) in their well water that exceeded drinking water standards (MCLs).

For this assessment, residents were divided into two groups according to the length of time their wells may have been contaminated and/or the concentration of contaminants in their wells: 1) highly exposed persons who are assumed to have been exposed to the maximum level of contaminants for up 25 years and 2) average exposed persons who are assumed to have been exposed to the average level of contaminants in their wells for 9 years. Most residents do not fall into the highly exposed group; yet this group was examined to represent a worst-case scenario. Assuming long-term contact with the maximum concentration ever detected in a well is not always realistic; therefore, any conclusions based on the highly exposed person should be viewed as an overestimation of the true risk. The conclusions are summarized below:

- A. Children exposed to the maximum concentration of TCE detected in residential well water are at increased risk for noncancer health effects such as liver and kidney damage, although the likelihood of these effects is low. Children exposed to an average concentration of TCE in their water are not at increased risk for noncancer health effects. Adults are not at risk for noncancer effects from exposure to TCE.
- B. Exposure to PCE at the maximum or average concentration does not pose a noncancer health hazard to children or adults.
- C. Residents have a low increased risk for cancer if they were exposed to the maximum concentration of TCE in their water every day for 25 years (assumed to be 25 years). Residents exposed to the average concentration of TCE in water for fewer years (assumed to be 9 years) have no apparent increased risk for cancer.
- D. Residents have a moderate increased risk for cancer from exposure to the maximum concentration of PCE in their water every day for 25 years. Residents who might have been exposed for a shorter period (assumed to be 9 years) to the average concentration of PCE have a low increased risk for cancer.

- E. Residents simultaneously exposed to both PCE and TCE (mixture) are not at increased risk from toxic interactions caused by additive or synergistic effects of the two chemicals. In other words, the health effects caused by exposure to both chemicals are no greater than exposure to either chemical independently.
- 2. Because the wells identified as having chemicals above drinking standards have been fitted with water treatment systems, exposure to contaminants in water should be minimal. However, because proper operation of treatment systems cannot be confirmed (filter replacement is now the responsibility of the homeowner), ATSDR considers the site to currently pose an **indeterminate public health hazard.** The site would be considered to pose no public health hazard if any of the following conditions were confirmed: 1) proper operation and maintenance of water treatment systems, 2) removal of contaminants to below regulatory levels, or 3) connection of all homes with contaminated wells to the public water supply.
- 3. Former employees of the Ram Leather Care facility who drank contaminated water from the on-site well may be at increased risk for noncancer health effects if they were exposed to the maximum concentration of TCE and may have a moderate to high increased risk for cancer from being exposed to the maximum concentration of PCE for 7 years or more. Given the conservative assumptions used to estimate the employee doses, this conclusion probably overestimates the actual risk to former employees. This analysis could not quantify possible inhalation and dermal exposures to former employees.
- 4. Trespassers who occasionally drink water from the on-site well are unlikely to experience adverse health effects, although this practice should be prevented, if possible.

X. RECOMMENDATIONS

- 1. Continue actions to reduce exposures to potable water with contaminant levels exceeding drinking water standards.
- 2. Monitoring of potentially affected private wells in the area should continue, with alternative water supplies provided to additional homes identified as having contaminant levels that exceed drinking water standards.
- 3. To remove contaminants to levels below applicable drinking water standards, installed treatment systems should be maintained and the quality of the treated water should be monitored until contamination stops or an alternative water supply is provided.
- 4. Measures should be taken to ensure that the on-site well (i.e., on Ram Leather Care property) is not used for potable purposes.

- 5. Potential sources of contamination, if any, should continue to be identified and remediated as necessary. Potential exposures from these areas also should be evaluated.
- 6. A permanent, long-term remedy should be sought for groundwater users.

XI. PUBLIC HEALTH ACTION PLAN

The Public Health Action Plan (PHAP) for this site describes actions that have been taken or will be taken by ATSDR or other government agencies at the site. The purpose of the PHAP is to ensure that this PHA identifies public health hazards and provides a plan of action designed to mitigate or prevent the potential for adverse human health effects from exposure to site-related contaminants.

A. Public Health Actions Completed:

- 1. In May 1996, ERRB/EPA installed drinking water treatment systems on wells with contaminant levels above applicable drinking water standards. ERRB replaced the filters for the water treatment systems for 1 year.
- 2. The NCDENR replaced the filters for the water treatment systems for 3 years until April 2000.
- 3. ATSDR held a public availability session on May 25, 2004, to gather health concerns from the community.
- 4. In fall 2004, EPA began testing additional private wells at residents' request to determine whether wells are contaminated beyond the known areas of contamination.
- 5. In July 2005, ATSDR mailed a Fact Sheet to residents entitled, *VOCs: Your Water and Your Health.* The Fact Sheet contained information about VOCs in groundwater, home water filtration systems and private well testing. This information was requested by residents during our public availability sessions in the community.
- 6. In October 2005, ATSDR mailed a Fact Sheet to residents which summarized the findings of the Public Health Assessment and contained information on how to comment on the document.

B. Public Health Actions Planned:

- 1. In 2004, EPA began to install public water supply lines at residences with identified contaminated wells.
- 2. ATSDR will work with the Mecklenburg County Health Department, NCDENR, and EPA to identify all contaminated private wells in the area to determine whether contaminants have spread beyond the known areas of contamination.
- 3. ATSDR will coordinate with the agencies above to develop a plan to implement the recommendations contained in this PHA.

ATSDR will reevaluate and expand the PHAP as needed. New environmental, toxicological, or health outcome data may determine the need for additional actions at this site.

XII. ATSDR TEAM

Author of Report:

Teresa Foster, MPH Environmental Health Scientist ATSDR Superfund and Program Assessment Branch

ATSDR Community Involvement Coordinator:

Januett Smith-George, MSW Health Communications Specialist Community Involvement Branch

ATSDR Health Educator:

Sarah Stuart Cox, MPH Health Education Specialist Division of Health Education and Promotion

ATSDR Regional Representative:

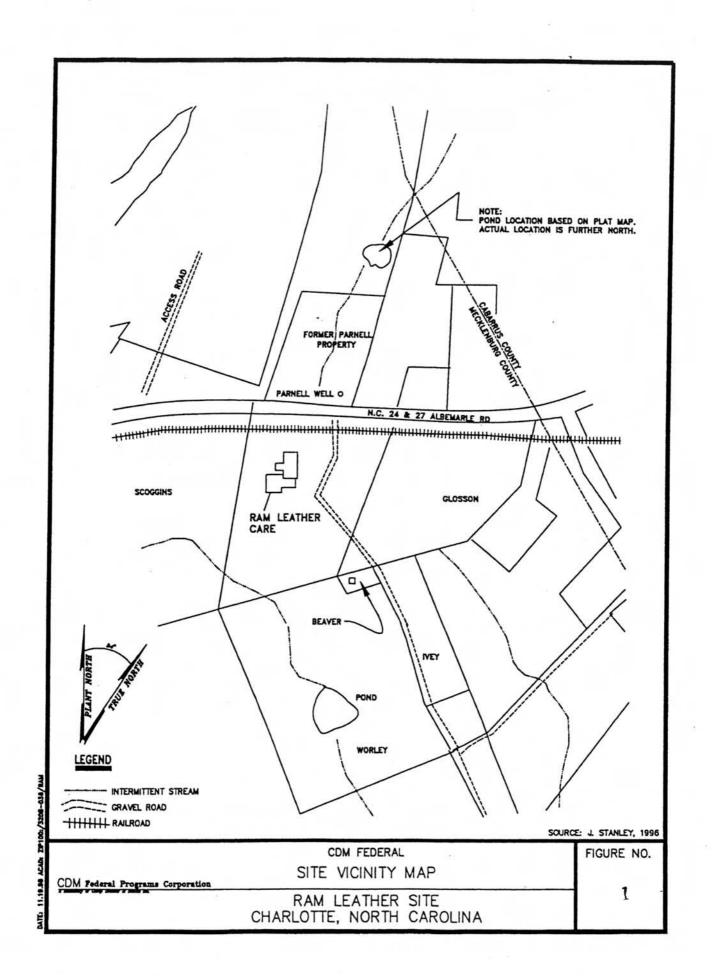
Benjamin Moore, MS Regional Representative Region 4

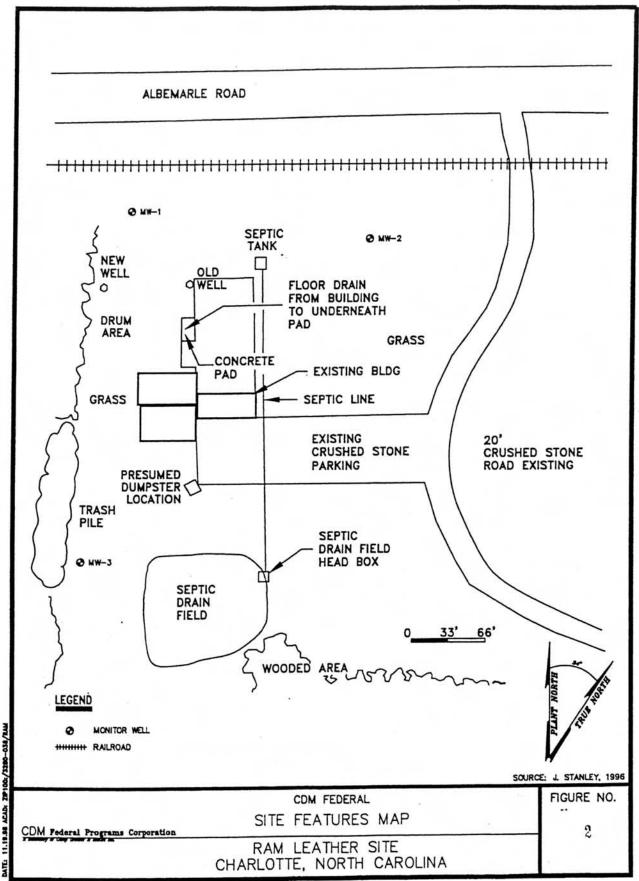
XIII. REFERENCES

- 1. CDM Federal Programs Corporation. Final work plan for remedial investigation/feasibility study. Vol. I. Ram Leather Care Site. November 16, 1999. Prepared for U.S. Environmental Protection Agency. Region 4.
- 2. US Environmental Protection Agency Region 4, Science and Ecosystem Support Division. Remedial investigation report, phase I. Ram Leather Care. SESD Project Numbers: 99-0376, 99-0377, 99-0590, 99-0626. 1999
- 3. US Environmental Protection Agency HRS documentation record. Ram Leather Care Site. Washington, DC: US Environmental Protection Agency, January 10, 2003.
- 4. CDM Federal Programs Corporation. Final borehole geophysics investigation report. Ram Leather Care. July 12, 2003. Prepared for US Environmental Protection Agency. Region 4. USEPA Region 4. Action
- 5. Memorandum from Jeffrey J. Crowley to Winston A. Smith. Request for a removal action 12-month exemption at the Ram Leather Care Site in Charlotte, Mecklenburg County, North Carolina. May 14, 2003.
- 6. North Carolina Department of Environment and Natural Resources. Memo from Jeanette Stanley to Beverly Hudson, EPA RPM. September 5, 2002.
- US Environmental Protection Agency. Exposure factors handbook. Volume I: General factors. Washington, DC: US Environmental Protection Agency, National Center for Environmental Research, 1997. EPA/600/8-89/043. Available from: URL: <u>http://www.epa.gov/ncea/exposfac.htm</u>.
- 8. Andelman JB. Inhalation exposure in the home to volatile organic contaminants of drinking water. Sci Total Environ 1985;47:443–60.
- 9. Brown HS, Bishop DR, Rowan CA. The role of skin absorption as a route of exposure for volatile organic compounds in drinking water. Am J Public Health 1984;74:479–84.
- 10. Agency for Toxic Substances and Disease Registry. Draft toxicological profile for tetrachloroethene (update). Atlanta: US Department of Health and Human Services, 1997.
- 11. Agency for Toxic Substances and Disease Registry. Draft toxicological profile for trichloroethylene (update). Atlanta: US Department of Health and Human Services, 1997.

- 12. Agency for Toxic Substances and Disease Registry. Draft toxicological profile for 1,2-dichloroethene (update). Atlanta: US Department of Health and Human Services, 1996.
- 13. Agency for Toxic Substances and Disease Registry. Draft toxicological profile for vinyl chloride (update). Atlanta: US Department of Health and Human Services, 1997.
- 14. International Agency for Research on Cancer (IARC). Available at http://www.iarc.fr/.
- 15. Hayes, J.R., L.W. Condie, Jr. and J.F. Borzelleca. 1986. The subchronic toxicity of tetrachloroethylene (perchloroethylene) administered in the drinking water of rats. Fund. Appl. Toxicol. 7: 119-125.
- 16. Buben, J.A. and E.J. O'Flaherty. 1985. Delineation of the role of metabolism in the hepatotoxicity of trichloroethylene and perchloroethylene: A dose- effect study. Toxicol. Appl. Pharmacol. 78: 105-122.
- 17. Agency for Toxic Substances and Disease Registry. Interaction profile for: 1,1,1trichloroethane, 1,1-dichloroethane, trichloroethylene, and tetrachloroethylene. Atlanta: US Department of Health and Human Services, 2004.
- 18. Agency for Toxic Substances and Disease Registry. Public Health Assessment Guidance Manual (Update). Atlanta: U.S. Department of Health and Human Services, January 2005.

APPENDIX A (Figures 1 -3)





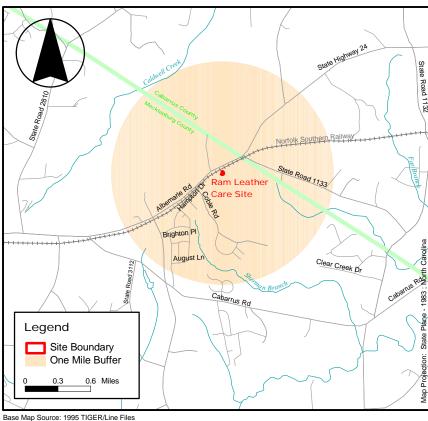
ACAD

2

Ram Leather Care Site

INTRO MAP

Charlotte, North Carolina EPA Facility ID NCD982096653

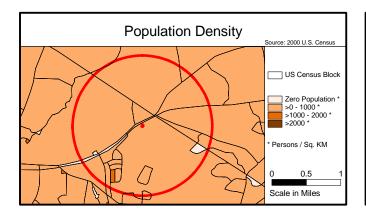


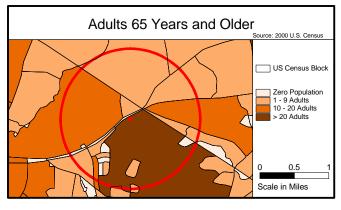


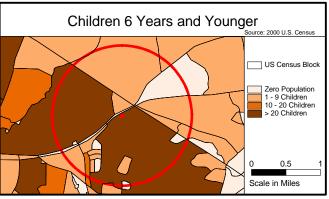
Mecklenburg County, North Carolina

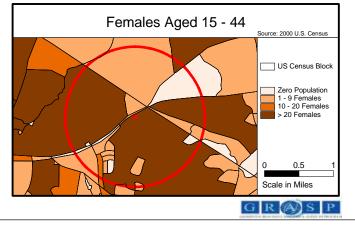
Demographic Statistics Within Area of Concern*	1mi	4mi
Total Population	928	16032
White alone Black alone Am. Indian & Alaska Native alone Asian alone Native Hawaiian and Other Pacific Islander alone Some other race alone Two or More races	851 42 8 15 0 0 12	13728 1711 80 206 1 118 196
Hispanic or Latino	17	325
Children Aged 6 & Younger Adults Aged 65 & Older Females Aged 15 - 44	103 61 216	1909 1037 3682
Total Housing Units	319	5894

Demographic Statistics Source: 2000 US Census *Calculated using an area-proportion spatial analysis technique









APPENDIX B (Tables 1 - 3)

Contaminant	Frequency of Detection	Range ofConcentrationsMeasured atLevels > CV (ppb)	Comparison Value (CV) (ppb)	Type of CV	Number of Detections > CV
On-site Ram We	ll(s)				
PCE	16/16	225-4,500	5	MCL	16
TCE	16/16	9–259	5	MCL	16
cis-1,2-DCE	13/16	220-1,200	70	MCL	13
Vinyl chloride	1/16	8.5	2	MCL	1
Private Residenti	ial Wells				
PCE	22/28	7–204	5	MCL	21
TCE	15/28	8–26	5	MCL	2
cis-1,2-DCE	16/28	None	70	MCL	None

Table 1. Private Well Sampling Data for 1991–2002 Ram Leather Care Site

MCL = EPA's maximum contaminant level

	Exposure Pathway Elements					
Pathway Name	Source	Medium	Point Of Exposure	Route Of Exposure	Exposed Population	Time
Groundwater	Improper disposal of chemicals at Ram Leather Care	Groundwater	Private Wells	Ingestion Inhalation Dermal	Persons already identified as having contaminated wells	Past

Table 2. Completed Exposure Pathway

Table 3. Potential Exposure Pathway

	Exposure Pathway Elements					
Pathway Name	Source	Medium	Point Of Exposure	Route Of Exposure	Potentially Exposed Population	Time
Groundwater	Improper disposal of chemicals at Ram Leather Care	Groundwater	Private Wells	Ingestion Inhalation Dermal	Persons not yet identified as having contaminants in their well but whose well might be in the path of contaminant migration	Present Future

APPENDIX C (ATSDR's Evaluation Process)

Comparison Values and the Screening Process

In evaluating these data, ATSDR used comparison values (CVs) to determine which chemicals to examine more closely. CVs are the contaminant concentrations found in a specific medium (soil or water) and are used to select contaminants for further evaluation. CVs incorporate assumptions of daily exposure to the chemical and a standard amount of water and soil that someone may inhale or ingest each day.

As health-based thresholds, CVs are set at a concentration below which no known or anticipated adverse human health effects are expected to occur. Different CVs are developed for cancer and noncancer health effects. Noncancer levels are based on valid toxicologic studies for a chemical, with appropriate safety factors included, and the assumption that small children (22 pounds) and adults are exposed every day. Cancer levels are the media concentrations at which there could be a one in a million excess cancer risk for an adult eating contaminated soil or drinking contaminated water every day for 70 years. For chemicals for which both cancer and noncancer numbers exist, the lower level is used to be protective. Exceeding a CV does not mean that health effects will occur, just that more evaluation is needed.

CVs used in this document are listed below:

Environmental Media Evaluation Guides (EMEGs) are estimated contaminant concentrations in media where noncarcinogenic health effects are unlikely. The EMEG is derived from the Agency for Toxic Substances and Disease Registry's (ATSDR) minimal risk level (MRL).

Reference Dose Media Evaluation Guides (RMEGs) are estimated contaminant concentrations in media where noncarcinogenic health effects are unlikely. The RMEG is derived from the Environmental Protection Agency's (EPA's) reference dose (RfD).

Cancer Risk Evaluation Guides (CREGs) are estimated contaminant concentrations that would be expected to cause no more than one additional excess cancer in one million persons exposed over a lifetime. CREGs are calculated from EPA's cancer slope factors (CSFs).

Risk-Based Concentrations (RBCs) are the estimated contaminant concentrations in media where noncarcinogenic health effects are unlikely. The RBCs used in this PHA were derived by EPA's Region 3 toxicologists.

EPA Soil Screening Levels (SSLs) are estimated contaminant concentrations in soil at which additional evaluation is needed to determine if action is required to eliminate or reduce exposure.

Estimation of Exposure Dose

The next step is to consider those contaminants that are above the CVs and further identify which chemicals and exposure situations are likely to be a health hazard. Child and adult exposure doses are calculated for the site-specific exposure scenario, using our assumptions of who goes on the site and how often they contact the site contaminants. The exposure dose is the amount of a contaminant that gets into a person's body.

Non-Cancer Health Effects

The doses calculated for exposure to each individual chemical are then compared to an established health guideline, such as a MRL or RfD, in order to assess whether adverse health impacts from exposure are expected. These health guidelines, developed by ATSDR and EPA, are chemical-specific values that are based on the available scientific literature and are considered protective of human health. Non-carcinogenic effects, unlike carcinogenic effects, are believed to have a threshold, that is, a dose below which adverse health effects will not occur. As a result, the current practice for deriving health guidelines is to identify, usually from animal toxicology experiments, a No Observed Adverse Effect Level (or NOAEL), which indicates that no effects are observed at a particular exposure level. This is the experimental exposure level in animals (and sometimes humans) at which no adverse toxic effect is observed. The NOAEL is then modified with an uncertainty (or safety) factor, which reflects the degree of uncertainty that exists when experimental animal data are extrapolated to the general human population. The magnitude of the uncertainty factor considers various factors such as sensitive subpopulations (for example; children, pregnant women, and the elderly), extrapolation from animals to humans, and the completeness of available data. Thus, exposure doses at or below the established health guideline are not expected to result in adverse health effects because these values are much lower (and more human health protective) than doses that do not cause adverse health effects in laboratory animal studies. For non-cancer health effects, the following health guidelines are described below in more detail. It is important to consider that the methodology used to develop these health guidelines does not provide any information on the presence, absence, or level of cancer risk. Therefore, a separate cancer evaluation is necessary for potentially cancer-causing chemicals detected in samples at this site. A more detailed discussion of the evaluation of cancer risks is presented in the following section.

Minimal Risk Levels (MRLs) – developed by ATSDR

ATSDR has developed MRLs for contaminants commonly found at hazardous waste sites. The MRL is an estimate of daily exposure to a contaminant below which non-cancer, adverse health effects are unlikely to occur. MRLs are developed for different routes of exposure, such as inhalation and ingestion, and for lengths of exposure, such as acute (less than 14 days), intermediate (15-364 days), and chronic (365 days or greater). At this time, ATSDR has not developed MRLs for dermal exposure. A complete list of the available MRLs can be found at <u>http://www.atsdr.cdc.gov/mrls.html</u>.

References Doses (RfDs) – developed by EPA

The RfDs are an estimate of the daily, lifetime exposure of human populations to a possible hazard that is not likely to cause non-cancerous health effects. RfDs consider exposures to sensitive sub-populations, such as the elderly, children, and the developing fetus. EPA RfDs have been developed using information from the available scientific literature and have been calculated for oral and inhalation exposures. A complete list of the available RfDs can be found at http://www.epa.gov/iris.

If the estimated exposure dose for a chemical is less than the health guideline value, the exposure is unlikely to result in non-cancer health effects. If the calculated exposure dose is greater than the health guideline, the exposure dose is compared to known toxicological values for the particular chemical and is discussed in more detail in the text of the PHA. The known toxicological values are doses derived from human and animal studies that are presented in the ATSDR Toxicological Profiles and EPA's Integrated Risk Information System (IRIS). A direct comparison of site-specific exposure doses to study-derived exposures and doses found to cause adverse health effects is the basis for deciding whether health effects are likely to occur. This in-depth evaluation is performed by comparing calculated exposure doses with known toxicological values, such as the no-observed adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from studies used to derive the MRL or RfD for a chemical.

Cancer Risks

Exposure to a cancer-causing compound, even at low concentrations, is assumed to be associated with some increased risk for evaluation purposes. The estimated excess risk of developing cancer from exposure to contaminants associated with the site was calculated by multiplying the site-specific adult exposure doses, with a slight modification, by EPA's chemical-specific cancer slope factors (CSFs or cancer potency estimates), which are available at <u>http://www.epa.gov/iris.</u> Calculated dermal doses were compared with the oral CSFs.

An increased excess lifetime cancer risk is not a specific estimate of expected cancers. Rather, it is an estimate of the increase in the probability that a person may develop cancer sometime during his or her lifetime following exposure to a particular contaminant. Therefore, the cancer risk calculation incorporates the equations and parameters (including the exposure duration and frequency) used to calculate the dose estimates, but the estimated value is divided by 25,550 days (or the averaging time), which is equal to a lifetime of exposure (70 years) for 365 days/year.

Suggestions vary among the scientific community regarding an acceptable excess lifetime cancer risk because of the uncertainties regarding the mechanism of cancer. The recommendations of many scientists and EPA have been in the risk range of 1 in 1 million to 1 in 10,000 (as referred to as 1×10^{-6} to 1×10^{-4}) excess cancer cases. An

increased lifetime cancer risk of one in one million or less is generally considered an insignificant increase in cancer risk. Increased cancer risk less than 1 in 10,000 are not typically considered a health concern. An important consideration when determining cancer risk estimates is that the risk calculations incorporate several conservative assumptions that are expected to overestimate actual exposure scenarios. For example, the method used to calculate EPA's CSFs assumes that high-dose animal data can be used to estimate the risk for low-dose exposures in humans. As previously stated, the method also assumes no safe level for exposure. Lastly, the method computes the 95% upper bound for the risk, rather than the average risk, suggesting that the cancer risk actually is lower, perhaps by several orders of magnitude.

Because of the uncertainties involved with estimating carcinogenic risk, ATSDR employs a weight-of-evidence approach in evaluating all relevant data. Therefore, the carcinogenic risk is also described in words (qualitatively) rather than giving a numerical risk estimate only. The numerical risk estimate must be considered in the context of the variables and assumptions involved in their derivation and in the broader context of biomedical opinion, host factors, and actual exposure conditions. The actual parameters of environmental exposures have been given careful and thorough consideration in evaluating the assumptions and variables relating to both toxicity and exposure. A complete review of the toxicological data regarding the doses associated with the production of cancer and the site-specific doses for the site is an important element in determining the likelihood that exposed persons are at greater risk for cancer.

Exposure Dose Calculations and Results for the Ram Leather Care site

When chemical concentrations at the site exceed established CVs, the chemical needs more thorough evaluation. To evaluate the potential for human exposure to contaminants present at the site and potential health effects from site-specific activities, ATSDR estimates human exposure to the site contaminant from different environmental media by calculating exposure doses. A brief discussion of the calculations and assumptions is presented below.

Well Water Pathway (Ingestion, Inhalation, Dermal Contact)

The ATSDR exposure dose formula used for the well water pathway is:

$$ED = \frac{C \times IR \times EF}{1000 \times BW}$$

where

ED = exposure dose in milligrams per kilogram per day (mg/kg/day) C = concentration of contaminant in water in parts per billion (ppb or µg/L) IR = ingestion rate in liters per day (L/day) EF = exposure factor, days of exposure divided by 365 (unitless) 1000 = conversion factor in micrograms per milligram (µg/mg)BW = body weight in kilogram (kg)

Assumptions used were based on default values and/or professional judgment. The drinking water ingestion rate for adults was assumed to be 2 L/day and 1 L/day for children. For average body weight, 70 kg and 11 kg were used for adults and children, respectively.

The exposure factor was 1 for highly exposed persons because they were assumed to be exposed for 365 days per year (365/365). The exposure factor was 0.96 for reasonably exposed persons because they were assumed to be exposed to 350 days per year (350/365). The exposure dose for each group was multiplied by 2 to account for dermal and inhalation exposure during showering or bathing.

The doses derived from this calculation, along with the applicable health guideline, are presented in Table 4 below.

	Maximum concentration	Mean concentration		ld Dose /kg/day)		llt Dose (kg/day)	Health Guideline
Contaminant	in water (ppb)	in water (ppb)	High	Average	High	Average	(mg/kg/day) and source
PCE	204	37.4	0.04	0.006	0.01	0.002	0.01 - Oral RfD
TCE	26	2.4	0.005	0.0004	0.001	0.0001	0.0003 – Oral RfD

Table 4. Adult and Child Exposure Doses Calculated for Residential Wells

Excess theoretical cancer risk is estimated by multiplying the adult exposure dose by the CSF. This then is multiplied by the fraction 25/70 or 9/70, because the CSF assumes a 70-year lifetime of exposure, whereas ATSDR assumed the maximum time anyone at this site could have been exposed was 25 years for a highly exposed person and 9 years for a reasonably exposed person. Table 5 below presents the results of these calculations for the contaminants of concern in residential wells. The oral CSF for TCE and PCE were not available from EPA's Integrated Risk Information System at the time of the writing of this document; therefore, EPA Region 9 Preliminary Remedial Goal (PRG) values were used instead.

Table 5. Excess Theoretical Cancer Risk Calculations for Residential Wells

Contaminant	Maximum concentration	Mean Cancer concentration slope factor,		Excess ca	ncer risk
	in water (ppb)	in water (ppb)	1/ (mg/kg/day)	High Exposure	Average Exposure
PCE	204	37.4	0.54	2 x 10 ⁻³	1 x 10 ⁻⁴
TCE	26	2.4	0.4	1 x 10 ⁻⁴	5 x 10 ⁻⁶

ATSDR also wanted to know whether health effects could be expected for former employees who worked at Ram Leather Care or for the occasional trespasser who drank water from the on-site well. Using the formula above, ATSDR calculated doses for adult employees and trespassers. The drinking water ingestion rate was assumed to be 1 L/day for former employees and 0.5 L/day for trespassers. The average body weight was assumed to be 70 kg for adults. The exposure factor was assumed to be 260/365 for former employees and 30/365 for trespassers. Dermal and inhalation exposures were not accounted for because the former employees and trespassers are not expected to shower or bathe in the water. The calculated doses for former employees and trespassers are presented in Table 6 below.

Contaminant	Maximum Concentra- tion in Water (ppb)	Employee Dose (mg/kg/day)	Trespasser Dose (mg/kg/day)	Health Guideline (mg/kg/day)	Source
PCE	4,500	0.05	0.003	0.01	Oral RfD
TCE	259	0.003	0.0001	0.0003	Oral RfD
cis-1,2-DCE	1,200	0.01	0.0007	0.01	Oral RfD
Vinyl chloride	8.5	0.00009	0.000005	0.003	Oral RfD

	ll
Table 6. Former Employee and Trespasser Exposure Doses for On-Site We	

RfD = EPA's reference dose

We estimated excess cancer risk by multiplying the exposure doses for former employees and trespassers by the CSF for each chemical of concern. We then multiplied the result by 7/70 for former employees because the CSF a 70-year lifetime of exposure, whereas ATSDR assumes the average employee worked 7 years at Ram Leather Care. The number (7 years) is based on population studies for average occupational tenure based on EPA's *Exposure Factor's Handbook*. The maximum time trespassers might be exposed is conservatively estimated to be 5 years; therefore, the resulting calculation is multiplied by 5/70. Table 7 below presents the results of these calculations for former employees and trespassers for the contaminants of concern in the on-site well. The oral CSFs for TCE and PCE were not available from EPA's Integrated Risk Information System at the time of the writing of this document; therefore, EPA Region 9 Preliminary Remedial Goal (PRG) values were used instead.

 Table 7. Excess Theoretical Cancer Risk Calculations for Former Employees and Trespassers for On-Site Well

Contaminant	Maximum Concentra- tion in Water (ppb)	Cancer Slope Factor, 1/ (mg/kg/day) ⁻¹	Excess Cancer Risk, Employee	Excess Cancer Risk, Trespasser
PCE	4,500	0.54	3 x 10 ⁻³	1 x 10 ⁻⁴
TCE	259	0.4	1 x 10 ⁻⁴	3 x 10 ⁻⁶
cis-1,2-DCE	1,200	Not a carcinogen	None	None
Vinyl chloride	8.5	0.72	6 x 10 ⁻⁶	3 x 10 ⁻⁷

Assessment of Chemical Interactions

To evaluate the risk for noncancerous effects in a mixture, ATSDR's guidance manual (*Guidance Manual for the Assessment of Joint Toxic Action of Chemical Mixtures*, 2004) prescribes the calculation of a hazard quotient (HQ) for each chemical. The HQ is calculated using the following formula:

 $HQ = estimated dose \div applicable health guideline$

Generally, whenever the HQ for a chemical exceeds 1, concern for the potential hazard of the chemical increases. Individual chemicals that have HQs less than 0.1 are considered unlikely to pose a health hazard from interactions and are eliminated from further evaluation. If all of the chemicals have HQs less than 0.1, harmful health effects are unlikely, and no further assessment of the mixture is necessary. If two or more chemicals have HQs greater than 0.1, then these chemicals are to be evaluated further as outlined below.

The HQ for each chemical then is used to determine the hazard index (HI) for the mixture of chemicals. An HI is the sum of the HQs and is calculated as follows:

$$HI = HQ_{1 + \dots +} HQn$$

The HI is used as a screening tool to indicate whether further evaluation is needed. If the HI is less than 1.0, significant additive or toxic interactions are highly unlikely, so no further evaluation is necessary. If the HI is greater than 1.0, then further evaluation is necessary, as described below.

For chemical mixtures with an HI greater than 1.0, the estimated doses of the individual chemicals are compared with their NOAELs or comparable values. IF the dose of one or more of the individual chemicals is within one order of magnitude of its respective NOAEL (0.1 x NOAEL), then potential exists for additive or interactive effects. Under such circumstances, an in-depth mixtures evaluation should proceed as described in ATSDR's *Guidance Manual for the Assessment of Joint Action of Chemical Mixtures*.

If the estimated doses of the individual chemicals are less than 1/10 of their respective NOAELs, then significant additive or interactive effects are unlikely, and no further evaluation is necessary.

ATSDR also provides guidance on certain chemical mixtures in documents called Interaction Profiles. Interaction Profiles recommend specific approaches to be used with site-specific exposure data to assess potential health hazards from joint toxic action of certain mixtures. The Interaction Profile should be used whenever one exists.

APPENDIX D LEVELS OF PUBLIC HEALTH HAZARD

ATSDR categorizes exposure pathways at hazardous waste sites according to their level of public health hazard to indicate whether people could be harmed by exposure pathways and site conditions. The categories are:

Urgent Public Health Hazard:	This category applies to exposure pathways and sites that have certain physical features or evidence of short-term (less than 1 year), site- related chemical exposure that could result in adverse health effects and require quick intervention to stop people from being exposed.
Public Health Hazard:	The category applies to exposure pathways and sites that have certain physical features or evidence of chronic (long-term), site-related chemical exposure that could result in adverse health effects.
Indeterminate Public Health Hazard:	The category applies to exposure pathways and sites where important information is lacking about chemical exposures, and a health determination cannot be made.
No Apparent Public Health Hazard:	The category applies to pathways and sites where exposure to site- related chemicals may have occurred in the past or is still occurring, however, the exposure is not at levels expected to cause adverse health effects.
No Public Health Hazard:	The category applies to pathways and sites where there is evidence of an absence of exposure to site-related chemicals.

APPENDIX E ATSDR's GLOSSARY OF ENVIRONMENTAL HEALTH TERMS

ATSDR'S GLOSSARY OF ENVIRONMENTAL HEALTH TERMS

The Agency for Toxic Substances and Disease Registry (ATSDR) is a federal public health agency with headquarters in Atlanta, Georgia, and 10 regional offices in the United States. ATSDR's mission is to serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and diseases related to toxic substances. ATSDR is not a regulatory agency, unlike the U.S. Environmental Protection Agency (EPA), which is the federal agency that develops and enforces environmental laws to protect the environment and human health.

This glossary defines words used by ATSDR in communications with the public. It is not a complete dictionary of environmental health terms. If you have questions or comments, call ATSDR's toll-free telephone number, 1-888-42-ATSDR (1-888-422-8737).

Absorption

The process of taking in. For a person or animal, absorption is the process of a substance getting into the body through the eyes, skin, stomach, intestines, or lungs.

Acute

Occurring over a short time [compare with chronic].

Acute exposure

Contact with a substance that occurs once or for only a short time (up to 14 days) [compare with **intermediate duration exposure** and **chronic exposure**].

Additive effect

A biologic response to exposure to multiple substances that equals the sum of responses of all the individual substances added together [compare with **antagonistic effect** and **synergistic effect**].

Adverse health effect

A change in body function or cell structure that might lead to disease or health problems.

Aerobic

Requiring oxygen [compare with anaerobic].

Ambient

Surrounding (for example, *ambient* air).

Anaerobic

Requiring the absence of oxygen [compare with aerobic].

Analyte

A substance measured in the laboratory. A chemical for which a sample (such as water, air, or blood) is tested in a laboratory. For example, if the analyte is mercury, the laboratory test will determine the amount of mercury in the sample.

Analytic epidemiologic study

A study that evaluates the association between exposure to hazardous substances and disease by testing scientific hypotheses.

Antagonistic effect

A biologic response to exposure to multiple substances that is **less** than would be expected if

the known effects of the individual substances were added together [compare with **additive effect** and **synergistic effect**].

Background level

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

Biodegradation

Decomposition or breakdown of a substance through the action of microorganisms (such as bacteria or fungi) or other natural physical processes (such as sunlight).

Biologic indicators of exposure study

A study that uses (a) **biomedical testing** or (b) the measurement of a substance [an **analyte**], its **metabolite**, or another marker of exposure in human body fluids or tissues to confirm human exposure to a hazardous substance [also see **exposure investigation**].

Biologic monitoring

Measuring hazardous substances in biologic materials (such as blood, hair, urine, or breath) to determine whether exposure has occurred. A blood test for lead is an example of biologic monitoring.

Biologic uptake

The transfer of substances from the environment to plants, animals, and humans.

Biomedical testing

Testing of persons to find out whether a change in a body function might have occurred because of exposure to a hazardous substance.

Biota

Plants and animals in an environment. Some of these plants and animals might be sources of food, clothing, or medicines for people.

Body burden

The total amount of a substance in the body. Some substances build up in the body because they are stored in fat or bone or because they leave the body very slowly.

CAP

See Community Assistance Panel.

Cancer

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

Cancer risk

A theoretical risk of for getting cancer if exposed to a substance every day for 70 years (a lifetime exposure). The true risk might be lower.

Carcinogen

A substance that causes cancer.

Case study

A medical or epidemiologic evaluation of one person or a small group of people to gather information about specific health conditions and past exposures.

Case-control study

A study that compares exposures of people who have a disease or condition (cases) with people who do not have the disease or condition (controls). Exposures that are more common among the cases may be considered as possible risk factors for the disease.

CAS registry number

A unique number assigned to a substance or mixture by the American <u>Chemical Society</u> <u>Abstracts</u> <u>Service</u>.

Central nervous system

The part of the nervous system that consists of the brain and the spinal cord.

CERCLA [see Comprehensive Environmental Response, Compensation, and Liability Act of 1980]

Chronic

Occurring over a long time (more than 1 year) [compare with acute].

Chronic exposure

Contact with a substance that occurs over a long time (more than 1 year) [compare with **acute exposure** and **intermediate duration exposure**].

Cluster investigation

A review of an unusual number, real or perceived, of health events (for example, reports of cancer) grouped together in time and location. Cluster investigations are designed to

confirm case reports; determine whether they represent an unusual disease occurrence; and, if possible, explore possible causes and contributing environmental factors.

Community Assistance Panel (CAP)

A group of people, from a community and from health and environmental agencies, who work with ATSDR to resolve issues and problems related to hazardous substances in the community. CAP members work with ATSDR to gather and review community health concerns, provide information on how people might have been or might now be exposed to hazardous substances, and inform ATSDR on ways to involve the community in its activities.

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 during the public health assessment process. Substances found in amounts greater than their CVs might be selected for further evaluation in the public health assessment process.

Completed exposure pathway [see exposure pathway].

Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)

CERCLA, also known as **Superfund**, is the federal law that concerns the removal or cleanup of hazardous substances in the environment and at hazardous waste sites. ATSDR, which was created by CERCLA, is responsible for assessing health issues and supporting public health activities related to hazardous waste sites or other environmental releases of hazardous substances.

Concentration

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

Contaminant

A substance that is either present in an environment where it does not belong or is present at levels that might cause harmful (adverse) health effects.

Delayed health effect

A disease or injury that happens as a result of exposures that might have occurred in the past.

Dermal

Referring to the skin. For example, dermal absorption means passing through the skin.

Dermal contact

Contact with (touching) the skin [see route of exposure].

Descriptive epidemiology

The study of the amount and distribution of a disease in a specified population by person, place, and time.

Detection limit

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

Disease prevention

Measures used to prevent a disease or reduce its severity.

Disease registry

A system of ongoing registration of all cases of a particular disease or health condition in a defined population.

DOD

United States Department of Defense.

DOE

United States Department of Energy.

Dose (for chemicals that are not radioactive)

The amount of a substance to which a person is exposed over some time period. Dose is a measurement of exposure. Dose is often expressed as milligram (amount) per kilogram (a measure of body weight) per day (a measure of time) when people eat or drink contaminated water, food, or soil. In general, the greater the dose, the greater the likelihood of an effect. An "exposure dose" is how much of a substance is encountered in the environment. An "absorbed dose" is the amount of a substance that actually got into the body through the eyes, skin, stomach, intestines, or lungs.

Dose (for radioactive chemicals)

The radiation dose is the amount of energy from radiation that is actually absorbed by the body. This is not the same as measurements of the amount of radiation in the environment.

Dose-response relationship

The relationship between the amount of exposure [**dose**] to a substance and the resulting changes in body function or health (response).

Environmental media

Soil, water, air, **biota** (plants and animals), or any other parts of the environment that can contain contaminants.

Environmental media and transport mechanism

Environmental media include water, air, soil, and **biota** (plants and animals). Transport mechanisms move contaminants from the source to points where human exposure can

occur. The **environmental media and transport mechanism** is the second part of an **exposure pathway**.

EPA

United States Environmental Protection Agency.

Epidemiologic surveillance

The ongoing, systematic collection, analysis, and interpretation of health data. This activity also involves timely dissemination of the data and use for public health programs.

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 assessment

The process of finding out how people come into contact with a hazardous substance, how often and for how long they are in contact with the substance, and how much of the substance they are in contact with.

Exposure-dose reconstruction

A method of estimating the amount of people's past exposure to hazardous substances. Computer and approximation methods are used when past information is limited, not available, or missing.

Exposure investigation

The collection and analysis of site-specific information and biologic tests (when appropriate) to determine whether people have been exposed to hazardous substances.

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: a **source of contamination** (such as an abandoned business); an **environmental media and transport mechanism** (such as movement through groundwater); a **point of exposure** (such as a private well); a **route of exposure** (eating, drinking, breathing, or touching), and a **receptor population** (people potentially or actually exposed). When all five parts are present, the exposure pathway is termed a **completed exposure pathway**.

Exposure registry

A system of ongoing followup of people who have had documented environmental exposures.

Feasibility study

A study by EPA to determine the best way to clean up environmental contamination. A number of factors are considered, including health risk, costs, and what methods will work well.

Geographic information system (GIS)

A mapping system that uses computers to collect, store, manipulate, analyze, and display data. For example, GIS can show the concentration of a contaminant within a community in relation to points of reference such as streets and homes.

Grand rounds

Training sessions for physicians and other health care providers about health topics.

Groundwater

Water beneath the earth's surface in the spaces between soil particles and between rock surfaces [compare with **surface water**].

Half-life (t_{1/2})

The time it takes for half the original amount of a substance to disappear. In the environment, the half-life is the time it takes for half the original amount of a substance to disappear when it is changed to another chemical by bacteria, fungi, sunlight, or other chemical processes. In the human body, the half-life is the time it takes for half the original amount of the substance to disappear, either by being changed to another substance or by leaving the body. In the case of radioactive material, the half life is the amount of time necessary for one half the initial number of radioactive atoms to change or transform into another atom (that is normally not radioactive). After two half lives, 25% of the original number of radioactive atoms remain.

Hazard

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

Hazardous Substance Release and Health Effects Database (HazDat)

The scientific and administrative database system developed by ATSDR to manage data collection, retrieval, and analysis of site-specific information on hazardous substances, community health concerns, and public health activities.

Hazardous waste

Potentially harmful substances that have been released or discarded into the environment.

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 [compare with **public health assessment**].

Health education

Programs designed with a community to help it know about health risks and how to reduce these risks.

Health investigation

The collection and evaluation of information about the health of community residents. This information is used to describe or count the occurrence of a disease, symptom, or clinical measure and to estimate the possible association between the occurrence and exposure to hazardous substances.

Health promotion

The process of enabling people to increase control over, and to improve, their health.

Health statistics review

The analysis of existing health information (i.e., from death certificates, birth defects registries, and cancer registries) to determine if there is excess disease in a specific population, geographic area, and time period. A health statistics review is a descriptive epidemiologic study.

Indeterminate public health hazard

The category used in ATSDR's public health assessment documents when a professional judgment about the level of health hazard cannot be made because information critical to such a decision is lacking.

Incidence

The number of new cases of disease in a defined population over a specific time period [contrast with **prevalence**].

Ingestion

The act of swallowing something through eating, drinking, or mouthing objects. A hazardous substance can enter the body this way [see **route of exposure**].

Inhalation

The act of breathing. A hazardous substance can enter the body this way [see **route of exposure**].

Intermediate duration exposure

Contact with a substance that occurs for more than 14 days and less than a year [compare with **acute exposure** and **chronic exposure**].

In vitro

In an artificial environment outside a living organism or body. For example, some toxicity testing is done on cell cultures or slices of tissue grown in the laboratory, rather than on a living animal [compare with **in vivo**].

In vivo

Within a living organism or body. For example, some toxicity testing is done on whole animals, such as rats or mice [compare with **in vitro**].

Lowest-observed-adverse-effect level (LOAEL)

The lowest tested dose of a substance that has been reported to cause harmful (adverse) health effects in people or animals.

Medical monitoring

A set of medical tests and physical exams specifically designed to evaluate whether an individual's exposure could negatively affect that person's health.

Metabolism

The conversion or breakdown of a substance from one form to another by a living organism.

Metabolite

Any product of **metabolism**. **mg/kg** Milligram per kilogram.

mg/cm² Milligram per square centimeter (of a surface).

mg/m³

Milligram per cubic meter; a measure of the concentration of a chemical in a known volume (a cubic meter) of air, soil, or water.

Migration

Moving 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 [see **reference dose**].

Morbidity

State of being ill or diseased. Morbidity is the occurrence of a disease or condition that alters health and quality of life.

Mortality

Death. Usually the cause (a specific disease, condition, or injury) is stated.

Mutagen

A substance that causes **mutations** (genetic damage).

Mutation

A change (damage) to the DNA, genes, or chromosomes of living organisms.

National Priorities List for Uncontrolled Hazardous Waste Sites (National Priorities List or NPL)

EPA's list of the most serious uncontrolled or abandoned hazardous waste sites in the United States. The NPL is updated on a regular basis.

No apparent public health hazard

A category used in ATSDR's public health assessments for sites where human exposure to contaminated media might be occurring, might have occurred in the past, or might occur in the future, but where the exposure is not expected to cause any harmful health effects.

No-observed-adverse-effect level (NOAEL)

The highest tested dose of a substance that has been reported to have no harmful (adverse) health effects on people or animals.

No public health hazard

A category used in ATSDR's public health assessment documents for sites where people have never and will never come into contact with harmful amounts of site-related substances.

NPL [see National Priorities List for Uncontrolled Hazardous Waste Sites]

Physiologically based pharmacokinetic model (PBPK model)

A computer model that describes what happens to a chemical in the body. This model describes how the chemical gets into the body, where it goes in the body, how it is changed by the body, and how it leaves the body.

Pica

A craving to eat nonfood items, such as dirt, paint chips, and clay. Some children exhibit pica-related behavior.

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.

Point of exposure

The place where someone can come into contact with a substance present in the environment [see **exposure pathway**].

Population

A group or number of people living within a specified area or sharing similar characteristics (such as occupation or age).

Potentially responsible party (PRP)

A company, government, or person legally responsible for cleaning up the pollution at a hazardous waste site under Superfund. There may be more than one PRP for a particular site.

ppb Parts per billion.

ppm Parts per million.

Prevalence

The number of existing disease cases in a defined population during a specific time period [contrast with **incidence**].

Prevalence survey

The measure of the current level of disease(s) or symptoms and exposures through a questionnaire that collects self-reported information from a defined population.

Prevention

Actions that reduce exposure or other risks, keep people from getting sick, or keep disease from getting worse.

Public comment period

An opportunity for the public to comment on agency findings or proposed activities contained in draft reports or documents. The public comment period is a limited time period during which comments will be accepted.

Public availability session

An informal, drop-by meeting at which community members can meet one-on-one with ATSDR staff members to discuss health and site-related concerns.

Public health action

A list of steps to protect public health.

Public health advisory

A statement made by ATSDR to EPA or a state regulatory agency that a release of hazardous substances poses an immediate threat to human health. The advisory includes recommended measures to reduce exposure and reduce the threat to human health.

Public health assessment (PHA)

An ATSDR document that examines hazardous substances, health outcomes, and community concerns at a hazardous waste site to determine whether people could be harmed from coming into contact with those substances. The PHA also lists actions that need to be taken to protect public health [compare with **health consultation**].

Public health hazard

A category used in ATSDR's public health assessments for sites that pose a public health hazard because of long-term exposures (greater than 1 year) to sufficiently high levels of hazardous substances or **radionuclides** that could result in harmful health effects.

Public health hazard categories

Public health hazard categories are statements about whether people could be harmed by conditions present at the site in the past, present, or future. One or more hazard categories might be appropriate for each site. The five public health hazard categories are **no public health hazard**, **no apparent public health hazard**, **indeterminate public health hazard**, **public health hazard**, and **urgent public health hazard**.

Public health statement

The first chapter of an ATSDR **toxicological profile**. The public health statement is a summary written in words that are easy to understand. The public health statement explains how people might be exposed to a specific substance and describes the known health effects of that substance.

Public meeting

A public forum with community members for communication about a site.

Radioisotope

An unstable or radioactive isotope (form) of an element that can change into another element by giving off radiation.

Radionuclide

Any radioactive isotope (form) of any element.

RCRA [See Resource Conservation and Recovery Act (1976, 1984)]

Receptor population

People who could come into contact with hazardous substances [see exposure pathway].

Reference dose (RfD)

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.

Registry

A systematic collection of information on persons exposed to a specific substance or having specific diseases [see **exposure registry** and **disease registry**].

Remedial Investigation

The CERCLA process of determining the type and extent of hazardous material contamination at a site.

Resource Conservation and Recovery Act (1976, 1984) (RCRA)

This Act regulates management and disposal of hazardous wastes currently generated, treated, stored, disposed of, or distributed.

RFA

RCRA Facility Assessment. An assessment required by RCRA to identify potential and actual releases of hazardous chemicals.

RfD

See reference dose.

Risk

The probability that something will cause injury or harm.

Risk reduction

Actions that can decrease the likelihood that individuals, groups, or communities will experience disease or other health conditions.

Risk communication

The exchange of information to increase understanding of health risks.

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**].

Safety factor [see uncertainty factor]

SARA [see Superfund Amendments and Reauthorization Act]

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 [see **population**]. An environmental sample (for example, a small amount of soil or water) might be collected to measure contamination in the environment at a specific location.

Sample size

The number of units chosen from a population or environment.

Solvent

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

Source of contamination

The place where a hazardous substance comes from, such as a landfill, waste pond, incinerator, storage tank, or drum. A source of contamination is the first part of an **exposure pathway**.

Special populations

People who might be more sensitive or susceptible to exposure to hazardous substances because of factors such as age, occupation, sex, or behaviors (for example, cigarette smoking). Children, pregnant women, and older people are often considered special populations.

Stakeholder

A person, group, or community who has an interest in activities at a hazardous waste site.

Statistics

A branch of mathematics that deals with collecting, reviewing, summarizing, and interpreting data or information. Statistics are used to determine whether differences between study groups are meaningful.

Substance

A chemical.

Substance-specific applied research

A program of research designed to fill important data needs for specific hazardous substances identified in ATSDR's **toxicological profiles**. Filling these data needs would allow more accurate assessment of human risks from specific substances contaminating the environment. This research might include human studies or laboratory experiments to determine health effects resulting from exposure to a given hazardous substance.

Superfund Amendments and Reauthorization Act (SARA)

In 1986, SARA amended CERCLA and expanded the health-related responsibilities of ATSDR. CERCLA and SARA direct ATSDR to look into the health effects from substance exposures at hazardous waste sites and to perform activities including health education, health studies, surveillance, health consultations, and toxicological profiles.

Surface water

Water on the surface of the earth, such as in lakes, rivers, streams, ponds, and springs [compare with **groundwater**].

Surveillance [see epidemiologic surveillance]

Survey

A systematic collection of information or data. A survey can be conducted to collect information from a group of people or from the environment. Surveys of a group of people can be conducted by telephone, by mail, or in person. Some surveys are done by interviewing a group of people [see **prevalence survey**].

Synergistic effect

A biologic response to multiple substances where one substance worsens the effect of another substance. The combined effect of the substances acting together is greater than the sum of the effects of the substances acting by themselves [see **additive effect** and **antagonistic effect**].

Teratogen

A substance that causes defects in development between conception and birth. A teratogen is a substance that causes a structural or functional birth defect.

Toxic agent

Chemical or physical (for example, radiation, heat, cold, microwaves) agents which, under certain circumstances of exposure, can cause harmful effects to living organisms.

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.

Tumor

An abnormal mass of tissue that results from excessive cell division that is uncontrolled and progressive. Tumors perform no useful body function. Tumors can be either benign (not cancer) or malignant (cancer).

Uncertainty factor

Mathematical adjustments for reasons of safety when knowledge is incomplete. For example, factors used in the calculation of doses that are not harmful (adverse) to people. These factors are applied to the lowest-observed-adverse-effect-level (LOAEL) or the no-observed-adverse-effect-level (NOAEL) to derive a minimal risk level (MRL). Uncertainty factors are used to account for variations in people's sensitivity, for differences between animals and humans, and for differences between a LOAEL and a NOAEL. Scientists use uncertainty factors when they have some, but not all, the information from animal or human studies to decide whether an exposure will cause harm to people [also sometimes called a **safety factor**].

Urgent public health hazard

A category used in ATSDR's public health assessments for sites where short-term exposures (less than 1 year) to hazardous substances or conditions could result in harmful health effects that require rapid intervention.

Volatile organic compounds (VOCs)

Organic compounds that evaporate readily into the air. VOCs include substances such as benzene, toluene, methylene chloride, and methyl chloroform.