Health Consultation

THE VIEW-MASTER FACTORY SUPPLY WELL
(a.k.a. MATTEL PORTLAND OPERATIONS)
BEAVERTON, WASHINGTON COUNTY, OREGON

EPA Facility Number: ORD050123504

Prepared by
Oregon Department of Human Services
under cooperative agreement with the
Agency for Toxic Substances and Disease Registry

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Summary

The View-Master stereoscopic slide viewer has been a popular children's toy since the 1950s. For nearly half a century, the sole U.S. manufacturing site for the View-Master product was a factory located on Hall Boulevard in Beaverton, Oregon. Throughout this period, an on-site supply well provided water for industrial purposes and for human consumption. In March 1998, chemical analysis of the View-Master factory supply well revealed the presence of the degreasing agent trichloroethylene (TCE) at concentrations as high as 1,670 micrograms per liter (µg/L).

TCE had been used at the View-Master factory for cleaning manufacturing equipment and for degreasing metal parts prior to painting. Drums of degreaser waste were dumped on-site from the 1950s to the 1970s. The factory began recycling the spent solvent in the 1970s and discontinued the large-scale use of TCE in 1980 (1). Based on examination of the site's hydrology, the Oregon Department of Environmental Quality (ODEQ) has estimated that TCE was present in the View-Master plant supply well for more than 20 years (2). Soon after this contamination was discovered, the View-Master supply well was shut down. The well therefore does not currently pose a public health hazard.

TCE has been classified by the Environmental Protection Agency (EPA) as a probable human carcinogen (3), and it has been implicated in a variety of noncancerous adverse health outcomes as well. The contamination at the View-Master plant has been covered extensively in local news media, and former workers and their families have raised concerns about cases of cancer and birth defects. In response to these concerns, Oregon Department of Human Services (ODHS) and the Agency for Toxic Substances and Disease Registry (ATSDR) entered into a cooperative agreement to determine both the need for, and the feasibility of, an epidemiological study.

As part of this cooperative agreement, ODHS conducted a preliminary mortality analysis. The results of this analysis indicate higher than expected percentages of deaths from pancreatic and kidney cancers and lower than expected levels for liver and lympho/hematopoetic cancers among the factory's former employees. Although the analysis was limited by the lack of complete data—including the lack of exposure information—the initial findings suggest the need to fully investigate the public health impact of TCE exposure at the View-Master site.

ODHS has compiled the results of the initial investigation within this report. The report also contains an evaluation of the public health significance of the TCE contamination in the View-Master factory supply well. On the basis of the levels of TCE found in the supply well, the past use of the well as a source of drinking water, and the potential for adverse health effects resulting from past exposure to TCE, ODHS determined that the site posed a public health hazard to people who worked at or visited the plant prior to the discovery of the contamination.

Background

Site History

The View-Master facility is located at 8585 SW Hall Boulevard in the city of Beaverton, Washington County, Oregon. The site is approximately 6 miles southwest of Portland, Oregon. Figure 1 in Appendix A shows the location of the site.

Historically, the site has had numerous owners. Figure 2 in Appendix A provides a chronology of the property's ownership and operation. The first occupant, Sawyer's Inc., moved to the site in 1950 to manufacture the View-Master stereo viewer, which had been invented in 1939 by William Gruber. In 1966, General Aniline and Film Corporation (GAF) acquired Sawyer's Inc. as a wholly owned subsidiary and continued operations at the plant until 1981. In that year GAF sold its pictorial products business to View-Master International Group. In 1989 View-Master became a subsidiary of Tyco; in 1997 Tyco merged with Mattel.

During the original construction of the facility in 1950, a 160-foot-deep well was drilled to supply water for drinking, sanitation, fire suppression, and industrial use. The well was initially the factory's sole source of water. In 1956, Sawyer's joined the Progress Water District for fire control and prevention purposes, and installed water lines to supply the sprinkler system and some fire hydrants, and to provide a backup source for the water tower that held water from the well (4). Site investigation reports indicate that the municipal water system had been extended to supplement the boiler and other facilities and also served some drinking and sanitary uses, although it is uncertain which taps were supplied by city water or when these lines were added (5, 6). The production well and municipal water system did, however, remain independent of one another. Although municipal water was directed to some parts of the plant, the production well continued to serve most of the facility's needs, including fire hydrants and most of the drinking and sanitary water (5).[1]

In addition to View-Master viewers, the plant at one time turned out photographic equipment, slide projectors, and other products. Specific operations included preparing metal parts (metal stamping, cleaning, and painting), creating plastic parts by injection molding, lens grinding, assembly, photographic production, and printing of packaging and reels. Employees used TCE to degrease metal parts, with most of the degreasing taking place in one building known as the "Paint Shop." TCE was used in large

[1] Although the View-Master facility would have been considered a public water system, the operators of the facility had failed to report the use of the well as a public water system. Monitoring of public water systems for volatile organic compounds (VOCs) was added in 1986 to Oregon Administrative Rules (OARs) under the Oregon Drinking Water Quality Act. In 1998, the Oregon Drinking Water Program found that the View-Master facility would have been responsible for performing analyses for VOCs beginning in 1991, when the definition of a Non-Transient Non-Community Public Water System was introduced to the OARs.

quantities[2], for vapor degreasing until 1980 at which time GAF phased out the manufacture of slide and movie projectors, both of which required metal parts (1).

Historical practices resulted in releases of hazardous substances at the site. Sanitary wastes from the facility were directed to a septic tank and drain field from 1951 to 1962, at which time the facility joined the municipal sewer system (7). Frequent chemical spills allegedly occurred in the paint shop, and an inspection of the degreaser in 1964 determined that TCE vapors near the degreaser exceeded threshold limits (1). A runaway chemical reaction and subsequent fire occurred in the degreaser on September 12 and 13, 1969 (1). Former GAF employees report that waste TCE from the degreaser was routinely placed in 55-gallon drums, transported by truck to other sites on the premises, and discharged to the ground (1).

Chemical Analysis of the Supply Well

In March 1998, an environmental assessment of the View-Master site was conducted by SECOR, an environmental consulting firm (6). SECOR identified several concerns, including possible contamination in a former drain field and in oil-filled transformers, historical use of chlorinated solvents, and possible metals contamination beneath the film processing building.

As part of its investigation, SECOR analyzed samples from the on-site production well. The first sample from the well was collected on March 16, 1998. On March 24, 1998, SECOR took two additional samples from sample ports on the wellhead manifold. SECOR's analyses indicate that the on-site water supply well contained up to 1,520 μg/L of TCE. The EPA has set a maximum contaminant level for TCE in drinking water at 5 μg/L, or 5 parts of TCE per billion (ppb) parts water. SECOR's analyses also detected two other VOCs in the production well: cis-1,2-dichloroethylene (DCE) and tetrachloroethylene (PCE) at levels up to 33 μg/L and 56 μg/L, respectively. The maximum contaminant level (MCL) for cis-1,2-DCE is 70 μg/L. The MCL for PCE is 5 μg/L.

Tyco, a subsidiary of Mattel, was the property tenant and facility operator at the time of the sampling. On March 25, 1998, the parent company Mattel was informed of the well sampling results. The following day, Seattle-based Hart Crowser Earth and Environmental Technologies collected verification samples from the well that confirmed the presence of TCE above maximum contaminant levels (8). Table 1 on the following page shows the levels of VOCs that were detected in the View-Master supply well, and the MCLs for each chemical.

[2] A GAF list of chemicals used in facility operations dated July 1, 1980 (1), refers to 200 gallons per month historic TCE use.

Table 1. Volatile organic compounds in the View-Master supply well

Sample ID	Consultant	Date collected	TCE (µg/L)	Cis-1,2-DCE (µg/L)	PCE (µg/L)
Prod. Well	SECOR (6)	16 March 98	1220	15.2	34.5
Tyco 2S		24 March 98	1520	20.5	56.0
Tyco 3S		24 March 98	1390	33.0	42.3
Wellhead	Hart Crowser (8)	26 March 98	1460	14.1	38.2
B1150/SHIP		26 March 98	1670	14.7	42.4
Maximum contaminant level*			5	70	5

*U.S. Environmental Protection Agency Drinking Water Standards and Health Advisories

Mattel shut down the well for all water distribution purposes on March 26, 1998. During the weekend of March 28 and 29, 1998, the facility water system was flushed and fully connected to municipal water. All water flushed from the system was collected and disposed of as hazardous waste (approximately 27,000 gallons). On March 30, 1998, the system was charged with municipal water (5). The factory continued to operate until May 2001.[3]

Public Health Response

In April 1998, ODHS informed ATSDR about the groundwater contamination at the View-Master site, and the two agencies undertook a review of the existing information about the site. In 2000-2001, Mattel released to ODHS and ATSDR a list of approximately 13,700 people who were employed at the factory during the years 1951 to 1998. The list comprises 6,857 individuals who worked for Sawyer's or GAF during the years 1951 to 1981 (GAF Period), 6,468 who worked for Mattel or Mattel's subsidiaries during 1981 to 1998 (Mattel Period), and 373 who worked during both periods.

ODHS has considered using the U.S. Internal Revenue Service (IRS) tax records to verify the completeness of the employee list. ODHS is actively negotiating with Mattel to receive IRS records that would identify all those employed during the Mattel Period. The use of IRS records to identify persons employed during the GAF period may not be feasible, however. GAF had employees at more than 200 sites throughout the country. When GAF filed its withholding tax returns it used the same federal identification number for all its sites. Moreover, GAF is now in bankruptcy proceedings and might not be able to assist ODHS with the retrieval of records from past View-Master operations.

Since May of 1998, Mattel has sponsored medical screening examinations for former employees, and for children who might have been exposed in utero.[4] The medical

[3] Mattel ceased the manufacture of View-Master viewers and reels at the Beaverton site and has relocated these operations. Mattel retained administrative staff in Beaverton to inform former employees about the TCE contamination and coordinate company-sponsored medical screening examinations.

[4] Women constituted about 60% of the workforce. Many women had children while employed at the

screening program allows former employees to consult their own physicians to discuss their individual health concerns. The examination includes the following procedures: a general physical exam; blood work and urinalysis; and a chest x-ray if indicated. The pediatric examinations additionally include neurological and developmental evaluation, and an electrocardiogram if indicated. In selecting procedures for the medical screening program, Mattel consulted toxicologists, epidemiologists, and specialists in occupational medicine, solvent exposure, and pediatrics at Oregon Health Sciences University, ATSDR, and ODHS, among others. Although the screening procedures are not so specific as to fully diagnose or rule out diseases such as cancer, the clinical consultation provides opportunities to detect signs and symptoms that may warrant further evaluation.

Health Implications

Pathways of Exposure

Water from the production well was distributed throughout the facility via a 100,000-gallon water tower. This water was used for drinking and for various industrial processes. A completed exposure pathway therefore exists for people who drank well water from the faucets and water fountains of the plant. This would include management and office staff, assembly line workers, and family members of employees, as well as others who visited the site.

According to Mattel, some of the faucets and drinking water fountains at the site were supplied directly by the municipal water system instead of the onsite well. While it is possible that some employees may not have been exposed to the contamination because they derived their drinking water from municipal sources, until further investigation has been completed it will not be known whether individual exposures to TCE were mitigated by the relative availability of municipal water.

Workers who used the degreasing machine, or who otherwise handled the solvent, may have been directly exposed to undiluted TCE via inhalation, dermal contact or both. The factory used TCE as a degreaser from 1950 to 1980, but most of the factory's employees did not work with it during those years. Because TCE was no longer used in large quantities after degreasing operations ceased in 1980, even fewer employees handled TCE from 1980 to 1998. The pathway of exposure to TCE, therefore, was most likely limited to drinking water for the vast majority of the potentially exposed population, which Mattel has estimated to comprise about 25,000 people.

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factory, and worked during pregnancy.

Studies of the Health Effects of TCE

TCE has been shown to cause liver and kidney cancer in experimental animals, and the EPA has classified TCE as a probable carcinogen for humans. Studies on the epidemiology of cancer among people exposed to TCE have found increases in kidney cancer, liver cancer, non-Hodgkin's lymphoma, cervical cancer, Hodgkin's disease, multiple myeloma, and pancreatic cancer, although the association between exposure to TCE and cancer has been inconsistent across studies (9, 10, 11). TCE has also been linked with a variety of noncancerous conditions, including anemia and other blood disorders, stroke, urinary tract disorders, liver problems, kidney dysfunction, diabetes, eczema, and skin allergies (12).

The potentially exposed population at the View-Master site includes those whose exposure occurred in utero. A study on the reproductive effects of TCE suggests that more miscarriages might occur when mothers drink water that contains TCE (13). Other studies have linked prenatal TCE exposure with congenital heart disease, eye malformations, neural tube defects, and oral cleft palates (13, 14). The combined results of these studies are unclear, however, and further study is needed to understand the risk of reproductive and developmental effects associated with TCE exposure.

The children of employees might have consumed TCE-contaminated water during visits to the View-Master factory. Children might be more vulnerable than adults to TCE exposure because of age-dependent differences in metabolism, and because children might be more vulnerable to organ damage if toxic exposures occur during critical growth stages. Children listed in the National Exposure Subregistry of persons exposed to TCE[5] were reported to have higher rates of hearing and speech impairment (12). An elevated incidence of childhood leukemia was observed among people in Woburn, Massachusetts, who used water for several years from two wells that were contaminated with TCE (15).[6]

Other Contaminants in the Supply Well

In addition to TCE, PCE was detected in the View-Master supply well at levels above the MCL. There is no known history of PCE use in the View-Master factory's manufacturing processes. Bruce Gilles, project manager at Oregon DEQ, has observed the presence of low levels of PCE at other sites in which TCE is the primary groundwater contaminant, and speculates that small amounts of PCE might have been present in the solvent-grade TCE product that was used in the past.

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[5] The TCE Subregistry was established in 1988 to assess the long-term health consequences of long-term exposure to TCE. Residents at the selected sites derived drinking water from TCE-contaminated private wells.

[6] The single compound found in highest concentration in Wells G and H in Woburn was TCE, at 267 ppb; tetrachloroethylene, chloroform, methyl chloroform, trichlorotrifluoroethane, 1,2-dichloroethylene, and inorganic arsenic were also present.

Both PCE and TCE are reasonably anticipated to be human carcinogens. The average concentration of TCE found in the View-Master supply well was nearly 300 times the federal safety standard for TCE in drinking water. The average concentration of PCE, by contrast, was approximately 8.5 times the federal safety standard for PCE.

Low levels of cis-1,2-DCE were detected in the supply well. The presence of this substance is probably attributable to the decomposition of other chlorinated chemicals in the well.[7] Cis-1,2-DCE is considered a non-carcinogen by EPA and other organizations. The quantity of cis-1,2-DCE observed in the well was within federal safety limits.

Review of Existing Mortality Data

Information about the incidence of cancer in Oregon is available as of 1996, when the Oregon State Cancer Registry (OSCaR) was established. Other than OSCaR, there is no source of information about morbidity among former View-Master employees. Examining the contribution of TCE exposure to disease among the plant workers would require currently unavailable data about individual health outcomes and exposures (i.e., employment histories and water consumption), and about historical TCE concentrations in the drinking water. Environmental analyses and interviews with former workers would be necessary to rectify the deficiencies in the factual record.

To ascertain the causes of death among deceased former workers of the View-Master plant, ATSDR linked the employee list with the Pensions Benefits Index, the National Death Index, and ODHS linked the list with the Oregon vital records database. The combined search identified 992 individuals who died during the years 1952 through 2001.

Under a cooperative agreement with ATSDR's Division of Health Studies, ODHS conducted a preliminary analysis of the mortality data for the years 1995-2001. These years represented the most complete data set currently available. The analysis compared the causes of death among former View-Master workers against the causes of death in the general Oregon population, and specifically examined outcomes linked in previous studies to TCE exposure, such as cancers of the liver, pancreas, kidney, blood, and lymphatic system. The analysis revealed that the deaths from the selected causes accounted for a small percentage of all deaths in both populations studied (see Table 2, Appendix B). The proportions of deaths due to pancreatic and kidney cancers, however, were greater among the View-Master workers than among the general population. There was no evident excess in the proportions of deaths from liver cancer, lymphomas, or hematopoietic cancers among former View-Master workers.

[7] Cis-1,2-dichloroethylene (cis-1,2-DCE) should not be confused with ethylene dichloride. Ethylene dichloride is also known as 1,2-dichloroethane, abbreviated 1,2-DCA. Although ethylene dichloride was used at the View-Master factory for the assembly of projectors and small products (1), ethylene dichloride was not a contaminant found in the supply well.

These findings do not conclusively show whether deaths from TCE-related causes among former View-Master workers were excessive in number, as information about actual exposures to TCE is lacking. The analysis did not adjust for age and gender, presenting an additional limitation. Furthermore, the analysis does not show how the overall survival rates of former View-Master employees compare with those of the general public, as such a determination would require the identification and follow-up of the entire population of former View-Master workers, including all who are still living. The methods, results, and limitations of the mortality analysis are discussed in greater detail in Appendix B.

The mortality data presented in this public health consultation are preliminary. The results of the initial analysis will further undergo critical review to ensure scientific integrity. These results will be included in a forthcoming report of the feasibility investigation that ODHS conducted under cooperative agreement with ATSDR.

Special Characteristics of the View-Master Site

The number of people potentially affected at the View-Master site is at least 13,700, and Mattel has estimated that the number might be as great as 25,000. At its height, the plant was one of the largest manufacturing facilities in Beaverton, employing more than 1,000 people at a time.

TCE was by far the most prevalent and significant contaminant in the View-Master factory supply well. The concentration of TCE discovered in the View-Master well was exceptionally high[8], at levels ranging from 1,220 to 1,670 µg/L. PCE was present as a co-contaminant at much lower levels, ranging from 34.5 to 56 µg/L. Moreover, because PCE has occurred as a co-contaminant at other TCE sites (12), an investigation of health effects at the View-Master site could provide meaningful information for other sites where TCE has contaminated the groundwater.

Drinking water was by far the most common pathway of exposure. The potential TCE exposures of View-Master Plant employees are also exceptional in that they might have occurred over a long period.

Conclusions

A combination of factors militates for a more in-depth study of this site: the levels of TCE were high; the potentially exposed population is very large; the nature of the exposure was primarily confined to one contaminant and one pathway; and the exposure and follow-up time might have been unusually protracted. Owing to these circumstances, the direct effects of drinking the TCE-contaminated water at the View-Master site are particularly susceptible to analysis. Further investigation of this site would advance the

[8] The median level of TCE in the View-Master well was 1,460 ppb. By contrast, the median levels of TCE among the sites included in the National Exposure Registry TCE Subregistry ranged from 6 to 234 ppb (12).

existing medical and scientific knowledge about the impact of oral TCE exposure on human health. More importantly, ODHS considers the View-Master factory site **a past public health hazard**, and the Department perceives a pressing need for more thorough investigation of the impact of this hazard on the local community. The preliminary findings and limitations of the proportional mortality analysis further underscore this need.

Recommendations

ODHS recommends further investigation to include

1. an environmental exposure assessment to confirm ODEQ's estimate of how long TCE was present in the supply well, and to provide a historical understanding of the concentration of TCE in the well, and

2. an epidemiological study to evaluate whether adverse health and reproductive outcomes are associated with TCE exposures among former workers.

Specifically, ODHS recommends the following:

1. ATSDR Division of Health Assessment and Consultation, or another appropriate agency, should conduct analyses of groundwater and fate transport to reconstruct the migration of the contaminant from the source areas to the production well. The analysis could help to establish the following:

    a. When the TCE contamination initially reached the well, and

    b. The degree to which the concentration of TCE might have varied throughout the operation of the View-Master plant.

2. An appropriate agency should conduct a retrospective occupational cohort study to evaluate whether adverse health and reproductive outcomes are associated with TCE exposures among former workers. Specific methods could include:

    a. identifying and contacting all potentially exposed persons or their next of kin, or developing a method for identifying and contacting a valid and representative sample of potentially exposed person or their next of kin,

    b. collecting information about exposures, risk factors, and health outcomes by interviewing former workers or their survivors; investigating deceased former workers' causes of death; and reviewing the state cancer registry,

    c. estimating individual cumulative TCE dose based on length of employment, calendar years of employment, types of jobs held, source of water, and amount of water consumed,

    d. conducting a nested case-control study of childhood health outcomes among people who were potentially exposed *in utero*, and

    e. comparing rates of morbidity and mortality among the former worker population to those of the general population of Oregon, an occupational referent population (16), or other relevant comparison groups.

Public Review

The draft version of this public health consultation (PHC) was available for public review at Albina Library, Beaverton City Library, Oregon City Library, Newberg Public Library, Multnomah County Central Library, and Tigard Public Library. The document was released on January 10, 2003 and was available for public comment until March 28, 2003. This comment period includes a 30-day extension requested by a community activist. The document was also available on the web at http://www.dhs.state.or.us/publichealth/eoe/viewmaster/.

The public comment period was announced in local newspapers. The PHC was sent to Oregon Center for Environmental Health; the Environmental Justice Action Group; Victims of TCE Exposure; Oregon Department of Environmental Quality; officials at the City of Portland, the City of Beaverton, Washington County, Multnomah County, and Clackamas County; the Governor of Oregon and members of the Oregon legislature; and members of U.S. Congress. A notice of the availability of the public health consultation was sent by Mattel to 7,780 former View-Master workers.

Comments were received from Mattel Corporation and Victims of TCE Exposure. The comments and ODHS's responses to them can be found in Appendix C.

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Certification

This View-Master Public Health Consultation was prepared by the Oregon Department of Human Services under cooperative agreement with the Agency for Toxic Substances and Disease Registry. It is in accordance with approved methodology and procedures at the time the health consultation was begun.

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Technical Project Officer, SSAB, DHAC

The Division of Health Assessment and Consultation, ATSDR, has reviewed this health consultation and concurs with the findings.

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Chief, State Programs Section, SSAB, DHAC

Appendix A – Figures

Figure 1 goes here

Insert Figure 2 here

Appendix B – Proportional Mortality Analysis

Proportional Mortality Analysis

A commonly used measure of relative mortality in studies of occupational and other hazards is the "observed-to-expected ratio." This is the ratio of observed deaths among exposed people to a hypothetical estimate of expected deaths, based on the experience of a reference (or non-exposed) population. Computing the expected number of deaths generally requires information about the size of the population at risk. Specifically, one must discern the number of person-years of follow-up on the workers under study.

When information about the entire at-risk population is unavailable, a common practice is to compute the proportional mortality ratio (PMR). Such a computation considers deceased subjects only. The premise of the PMR analysis is as follows:

> if an exposure causes a specific fatal illness, there should be a greater proportion of deaths from that illness among those who had been exposed, than among other decedents who had not been exposed. The PMR can be interpreted as the observed-to-expected ratio only if one assumes that the total death rates for the exposed and the reference (non-exposed) populations are equal (17).

The size and person-years of the entire View-Master worker population are not yet known. ODHS therefore conducted a preliminary PMR analysis of existing mortality information, comparing the causes of death among former View-Master workers against the causes of death in the general Oregon population. ODHS examined the deaths that occurred from 1995 through 2001 because these years represented the most complete data set currently available. The analysis examined outcomes linked in previous studies to TCE exposure, such as cancers of the liver, pancreas, kidney, blood, and lymphatic system.

Table 2 in this Appendix shows the proportions of deaths due to selected causes in 1995 through 2001. The PMR values in Table 2 represent the ratio comparing the percentage of deaths in the View-Master population to that in the general Oregon population (i.e., %VM ÷ %OR), for each cause of death.

As previously stated, the actual numbers of deaths from the selected causes were very small. ATSDR has requested that this report not specify the exact number of deaths, not only because these results are preliminary and will be subject to further review, but because releasing such data about a small number of people in a known population can lead to identification of individuals and does not protect the confidentiality of their medical information.

The PMR analysis revealed that deaths from the selected causes accounted for a small percentage of all deaths in both populations studied. The proportions of deaths from pancreatic and kidney cancers, however, were greater among the View-Master workers than among general Oregon population (i.e., the PMR value exceeded 1.00 for the specified cause of death). There was no evident excess in the proportions of deaths from liver cancer, lymphomas, or hematopoietic cancers among former View-Master workers.

The lack of exposure information is a critical limitation of this analysis. The analysis does not account for variations in length of employment, calendar years of employment, occupational exposures, water consumption, or historical levels of TCE in the supply well, so it cannot account for the differences in cumulative TCE exposures that would have resulted from these variations. Additionally, the existing data provide no basis for comparison of the View-Master population to the general Oregon population or to other similar worker populations with respect to other risk factors for disease.

This preliminary analysis did not adjust for age at death, presenting another important limitation. This is important because the risk of death from specific causes is partly a function of age. To make a better comparison of the causes of death between the View-Master population and the general Oregon population, it will be necessary to account for any differences in age distribution between the two populations.

According to Mattel, women constituted about 60% of the workforce throughout the factory's operation. Women in the U.S. have a lower baseline risk than men do for developing cancers of the kidney, liver, pancreas, and lympho-hematopoietic system (18). The mortality from specific cancers should therefore be analyzed separately among men and women in the View-Master workforce. Stratification by gender was not feasible in this analysis, however, because the existing data on deceased View-Master workers contains incomplete gender information. This has presented an additional limitation to the analysis.

The results of the PMR analysis do not show how the overall survival rates of former View-Master employees compare with those of the general public. The calculation of rates would require the identification and follow-up of the entire cohort of former View-Master workers, including all who are still living. The comparison of rates would also require statistical adjustment for demographic characteristics that are not yet known about the View-Master workforce. The health consultation report recommends methods for undertaking this investigation.

ODHS is conducting further analyses of the mortality data that will undergo critical review to ensure scientific integrity. The results of the additional analyses will be presented in a forthcoming report of the activities that ODHS conducted, under cooperative agreement with ATSDR's Division of Health Studies, to examine the need for and the feasibility of conducting a health study.

Table 2. Proportions of deaths due to selected causes among View-Master workers and the general Oregon population[a], 1995-2001 – Preliminary findings

Cause of death	Percentage (%) of deaths[b]		PMR[c]
	View-Master	Oregon	
Kidney cancer	1.53	0.52	2.94
Liver cancer	0.00	0.40	0.00
Lympho/hemato-poietic cancers	1.75	2.53	0.69
Pancreatic cancer	2.62	1.25	2.10
All causes	100.00	100.00	1.00

a Aged 18 and older

b Percent, attributed to selected cause, of all deaths within the specified population

c Unadjusted proportional mortality ratio = %VM ÷ %OR

Appendix C – Responses to Public Comments

Responses to Public Comments

All comments to the health consultation report are reproduced here in their entirety. Comments were grouped together where an author submitted several similar comments. Comments by different authors have not been combined.

Comment 1: The draft public report, and subsequent Oregon Department of Human Services (DHS) statements regarding the contents of the report, were widely misunderstood by the media and the public. While we understand that the Agency for Toxic Substances and Disease Registry (ATSDR) and the OHD cannot be held entirely accountable for the reporting of health related environmental issues in the press, it is imperative that public health materials be presented in a clear and transparent manner to reach our shared objective of providing useful information to the concerned public. In particular, it is important that care is taken to accurately relay the preliminary nature of the draft report and DHS/ATSDR's resulting recommendation that more study is required. Following release of the draft report, the largest newspaper in the area, The Oregonian reported the ATSDR's and OHD's issuance of the draft report in a story on January 22, 2003 with the headline, "Study links cancer toll, View-Master site." The story reports that the draft report prepared by the ATSDR and DHS links cancer deaths to employee exposure to TCE at the View-Master site.

Two other local Portland [television] *channels also covered the draft report (KATU and KGW) and apparently over interpreted the significance of the findings. KGW Channel 8, the NBC affiliate in Portland, reported on January 22 that "health officials now confirm that workers from Beaverton's old View-Master plant are dying from cancer at far higher rates than most Oregonians."*

Later media reports were even more out of proportion with the level of findings. For example, on March 15, 2003, CNN falsely reported: "A new state study confirms what former workers feared. Nearly 15,000 workers like [former employee name] and thousands more in their families are coming down with cancers at elevated rates." The CNN report quoted a DHS official describing the finding of the draft report: "What we found was an elevated risk of two kinds of cancer."

Of course no one intended this outcome, but it occurred, and now this misperception needs to be addressed. These media reports have caused widespread misunderstanding, public alarm, and a general spreading of confusion and distrust. Neither the media nor health officials have successfully communicated two important facts:

That no definitive study has been performed to date by either the ATSDR or the DHS regarding a increased risk in cancer or any other injury to View-Master employees as compared to the general public. This was the objective of the draft report, to determine whether such a definitive scientific study be performed in the future.

That the health consultation performed by the ASTDR and the DHS, as reported in the draft report, was not a study. It was intended to be a preliminary screening tool to help

determine whether funding for a scientifically valid study is recommended. The health consultation was not intended to be a definitive account of potential risks for former View-Master employees and did not have the capacity by design to determine whether there was an elevated risk of cancer.

These facts have been verbally confirmed to us by officials at both ATSDR and DHS, and as the draft report states on page 5:

"These findings do not conclusively demonstrate whether mortality from TCE-related causes among former View-Master workers is significantly excessive, as such a determination would require statistical adjustments for other risk factors and demographic characteristics, such as age and gender, that are not yet known. ODHS will perform further analysis as more information becomes available. The final result of the mortality analysis will be addressed in a separate report."

We understand that the ATSDR and the OHD, as public health agencies, are principally concerned with providing accurate, factual information to the public. We request that ATSDR and DHS consider undertaking extra measures to set the record straight and to clarify the misunderstandings. ...Previous Agency for Toxic Substances and Disease Registry (ATSDR) communications relating to this project, both verbal and written, have been educational in nature with clear, factual statements reflecting the history of Hall Street site operations and the uncertain status of TCE science relating to humans. The draft Consultation Report does not represent previous ATSDR communications and unfairly distresses a population with serious concerns.

The final report should acknowledge and reference the widespread misunderstanding of the draft report in the media and by the public during the draft comment period. The final report should clarify the findings of the initial Health Consultation and clearly set forth the facts that (1) That no definitive study has been performed to date by either the ATSDR or the DHS regarding a increased risk in cancer or any other injury to View-Master employees as compared to the general public; and (2) That the health consultation performed the survey performed [sic] *by the ASTDR and the DHS, as reported in the draft report, was a preliminary screening tool that did not account for basic variables, and was not intended to be a scientific study of the risk assessment to former View-Master employees or any other person.*

Response: ODHS agrees that it has a duty to the public to present information as clearly as possible. ODHS has made changes to enhance the clarity of the document, and added information to provide perspective to the mortality findings. ODHS has amended the final report to reduce the potential for misinterpretation by the media and the general public.

As stated in the initial PHC report, the findings of the health consultation do not conclusively demonstrate that mortality among former View-Master workers is excessive. The final report discusses the limitations of the existing data in greater detail.

Comment 2: ATSDR and DHS may also wish to emphasize that the final report should not be taken by former employee as a conclusion about their individual health and that Mattel employees concerned about their individual health situation should consider taking advantage of the free medical screening program offered by Mattel. We believe that this individualized consultation with a doctor is the best means for former employees to obtain answers to their specific health questions.

Response: ODHS acknowledges that the results of the mortality analysis are population-based and cannot confirm whether any individual death is linked with TCE exposure. ODHS agrees that former employees should consult their health care providers with any personal health concerns they may have. ODHS has added information about the company-sponsored medical screening examinations to the Public Health Response section of the final report.

Comment 3: The report title, which includes the wording "(a.k.a. Mattel Portland Operations)," does not accurately represent the Mattel role within the 50-year history of this site.

In 1997, Mattel merged with Tyco Toys and assumed the existing property lease agreement and certain previous merger agreements. In total, based upon merger history, the Mattel umbrella includes the period of July 1981 through trichloroethene (TCE) discovery in the supply well in March 1998. In the years from 1952 to 1981 the facility was owned and managed by several entities, with the residual entity being GAF or G1, who retains most of the liability for site cleanup. TCE was used and disposed on the site between 1952 and 1980, prior to the Mattel era. Nevertheless, Mattel has been and remains committed to providing appropriate assistance to former Hall Street employees.

The report title reference to Mattel should be deleted and replaced, if necessary, with something more historically descriptive, such as "a/k/a Hall Street Site" or "the former View-Master manufacturing facility."

Response: The title of this public health consultation is The View-Master Factory Supply Well. The title page also includes the wording "(a.k.a. Mattel Portland Operations)" because that is the name of the site as identified in ATSDR's and EPA's records. ATSDR and EPA use consistent naming on projects to ensure that documents and the activities they record can be properly tracked and identified by the public and companies like Mattel. Because Mattel was operating the facility when the contamination was discovered, EPA named the site according to the facility's then current owner. The EPA identification number on the title page is the Resource Conservation and Recovery Act (RCRA) facility number. This number was listed incorrectly in the original draft, and has since been corrected.

Comment 4: The draft report addresses a preliminary analysis of previous employee death data for the years 1995–2001 and indicates pancreatic and kidney cancer excesses among this population when compared to the general Oregon population.

The basis for these estimates should be clearly described along with the limitations of this finding. For example, the DHS web site provides an additional description of the methodology by which ODHS looked at health outcomes for purposes of the draft report. From that description, it is apparent that the list of former View-Master workers who died during the years 1995-2001 was incomplete and not corrected for key variables needed to determine whether there was an excess in cancer mortality. The final report should clearly describe the methodology used in the health consultation and the inputs to that methodology, together with specific numbers of deaths evaluated, proportion of the population surveyed and the background rates. That is, the final report should clearly describe the methodology so that the reader can understand how the health consultation was conducted and its limitations.

Without this context, the preliminary findings have resulted in a high degree of alarm, which is not warranted given the level of evidence of adverse effects. The scientific community does not uniformly accept that TCE is a kidney carcinogen and the studies identifying a link with kidney cancer have been the subject of much debate within the SAB analysis of the TCE reassessment document. The report should be structured in a way to accurately inform previous employees and the public while not assuming a tone of neither inflating nor diffusing valid health concerns.

…As a general comment, there is no place in the report that clearly indicates the basis for the identified finding of elevated cancer mortality. Specifically, the proportion of the exposed population should be identified (i.e., the degree of follow-up), and the number and types of cancer deaths and the basis for comparison need to be documented. Without this description, the report findings are difficult for the general public to understand and the absence of underlying methodology does not allow peer review by other health professionals.

The draft report should provide a clear discussion of the basis of the findings and include a clear discussion of why these findings are preliminary. Specifically, because not all of the former workers were evaluated, and because workers may not have other risk factors that are comparable to the general population, it is not possible to make any definitive conclusions regarding differences in mortality. As stated in the Recommendations section of the draft report, the cohort (or some logical subset) must be better developed and this cohort must be compared with a reference population matched on relevant variables.

Response: ODHS has appended the report to provide detailed information about the methods, results, and limitations of the mortality analysis. The additional information is supplied in Appendix B.

The actual numbers of deaths from the selected causes were very small. ATSDR has requested that this report not specify the exact number of deaths, not only because these results are preliminary and will be subject to further review, but because releasing such data about a small number of people in a known population can lead to identification of individuals and does not protect the confidentiality of their medical information.

The calculation of rates requires information about the size of the population at risk, specifically the number of person-years of follow-up. The size and person-years of the entire View-Master worker population are not yet known. Rates, therefore, cannot currently be calculated based on the existing information about the site.

The limitations of the mortality analysis are stated in the report and discussed further in Appendix B. The report recommends methods for rectifying the deficiencies in the existing information, such as the need to identify all exposed persons and to collect complete information about exposures, risk factors, and health outcomes.

Comment 5: Mattel staff has received many calls indicating a high degree of confusion and distress among previous employees of Hall Street, some of their adult children, and members of the adjacent businesses and the surrounding community regarding the draft report's findings. The draft report has been interpreted as providing conclusive evidence of harm related to TCE exposure at the Hall Street site. The draft report does state that the findings are inconclusive due to the lack of "statistical adjustment for other risk factors and demographic factors, that are not yet known." However, a nonscientific audience does not easily understand this and other statements within the report that clarify the preliminary and inconclusive status of certain health-related comments.

The draft report would benefit from a more complete discussion of the inconclusive and controversial nature of existing studies of TCE toxicity conducted on other populations, particularly regarding potential for human cancer. In fact, the lack of conclusive evidence regarding health effects of TCE exposure, and the inability to give the population answers to its questions, is the primary and justifiable reason for health evaluation funding and scientific research.

...The final report should be constructed in a way that gives interested and concerned persons an accurate account of historical Hall Street site TCE practices. TCE medical studies, both animal and human, and other related health data referred to within the report, should be presented in an informative and factual manner. The final report should clearly define health issues that are known and can be answered. The report should also address other health concerns for which answers are not clear and further scientific study is needed.

...Due to high-volume use as a solvent in industry and persistence in groundwater, TCE is one of the most commonly detected chemicals in groundwater at sites. Although it has been studied extensively, epidemiological studies and scientific debate regarding TCE toxicity have not reached a consensus. The review by Wartenberg (2000)[9] referenced in the draft report provides a useful summary of papers reviewed, but does not include all the relevant studies and does not provide a complete and accurate analysis of the state of the science regarding TCE. The U.S. Environmental Protection Agency (EPA) Science Advisory Board (SAB) identified limitations in the Wartenberg (2000) study in the review

9 Wartenberg, D., D. Reyner, and C.S. Scott. 2000. Trichloroethylene and cancer: The epidemiologic evidence. Environ. Health Perspect. 108(2):161-176.

of the draft TCE reassessment document and urged EPA to consider all of the relevant data, including studies that did not find adverse effects related to TCE exposure.

The draft report should be revised to better characterize the preliminary nature of the findings and the uncertainties related to health effects of TCE within the scientific community.

Response: ODHS acknowledges that the evidence for TCE's role in a variety of health conditions has been inconsistent across studies. ODHS has revised the report to convey that previous investigations of the association between TCE exposure and cancer have had conflicting results. Despite the uncertainties in the existing scientific knowledge, EPA has developed new guidelines that have increased the calculated risks of cancer from TCE exposure, based on a review of current information about TCE and its associated health risks. The EPA's new guidelines call for more stringent cleanup measures to be more protective of human health. Although there is disagreement about these new guidelines and not all states have uniformly accepted them, Oregon Department of Environmental Quality has accepted the new EPA guidelines for cleanup decisions such as at the View-Master site.

The health consultation report conclusions are based on the existing information about the site, and on existing scientific literature about the health effects of TCE. The report refers to such literature, which is already available elsewhere and so need not be fully recapitulated. Regarding the contamination of the View-Master/Hall Street site, the report discusses the deficiencies in existing information, and suggests methods for rectifying them.

Comment 6: It is reported that "an on-site supply well provided water for industrial uses and for human consumption." In addition to the on-site well, the facility was also supplied by water from the local water district. This water was supplied to various sources throughout the facility. …The draft report would also benefit from a discussion of dose-response relationships regarding TCE toxicity. For example, the draft report should discuss the TCE exposure safety standards identified by the U.S. Occupational Safety and Health Administration. The draft report should also discuss the pathways of exposure at the facility (i.e., past ingestion of water, dermal contact with TCE and inhalation of vapors). The fact that some parts of the plant were on municipal water supplies must also be considered to provide an accurate assessment of exposure potential.

Response: ODHS agrees that it will be important to consider whether drinking water was derived from municipal water rather than from well water during further investigations. While it is possible that some employees may not have been exposed to the contamination because they derived their drinking water from municipal sources, until further investigation has been completed, it will not be known whether individual exposures to TCE were mitigated by the relative availability of municipal water. The source of water is an important factor that should be evaluated in both the exposure reconstruction groundwater modeling analysis and the epidemiological investigations

proposed. Such an evaluation would allow a more precise classification of exposure and should therefore provide more sensitive epidemiological analyses.

In the health consultation report, ODHS focused on the public health hazard resulting from the contamination of the View-Master supply well. The report does not discuss the Occupational Safety and Health Administration (OSHA) standards for TCE because OSHA standards do not apply to drinking water. ODHS has added to the final report a discussion about exposure pathways and the availability of municipal water at the View-Master plant, as suggested.

Comment 7: Mattel remains committed to the process of assisting former Hall Street employees. A complete and accurate health investigation depends on a high degree of participation by informed former employees. Thus, providing previous employees with accurate information regarding TCE exposure, and inviting their participation in an evaluation process to find accurate answers to health-related questions, are critical goals within the final report recommendations. Modifications to the report discussions that will improve accessibility for the general public will further this aim. A more balanced discussion that incorporates more of the uncertainties about the degree of carcinogenic potency of TCE will also avoid causing undue fear and alarm, particularly given the relatively long timeframe for the proposed study process.

Response: The inclusion of additional discourse on TCE in the public health consultation would be inappropriate as it goes beyond the stated purpose of the document. ODHS would, however, support efforts by Mattel to develop educational materials that would provide former employees and the general public with information on the toxicological facts and uncertainties about TCE. ODHS would be willing to assist in the development of such materials. In addition, we suggest that these materials be developed with input from the community advisory group for the View-Master site.

Comment 8: Other descriptions and wording within the report are potentially misleading and have caused undue alarm without offering substantive medical information to either support or deny the heightened health concerns. As an example, paragraph 2 on page 3 states, "A runaway chemical reaction and subsequent fire occurred … resulting in a catastrophic release of TCE." The remedial investigation identified the main source of release of TCE into the environment to be routine disposal of TCE onto the ground, as was a typical practice at the time. The use of the term catastrophic is not descriptive of the incident, nor the primary means that groundwater became contaminated (i.e., the degreaser equipment was relatively small, no injuries or major property damage occurred, and this incident was not a primary source of TCE later detected in groundwater).

Response: The remedial investigation of the site identified the former paint shop and degreaser area as a primary source of volatile organic chemicals (19). Although there is documentary evidence of a chemical release from the degreaser in 1969 (1), ODHS acknowledges that the existing information does not indicate whether the incident directly contributed to the TCE contamination in the groundwater. In the final report,

ODHS has removed the imputation that the fire in the degreaser caused a substantial release of TCE into the environment.

Comment 9: The report states, "…View-Masters were made exclusively … in Beaverton, Oregon." Starting with the completion of plant construction in 1951, the Hall Street site was the sole U.S. manufacturing site for View-Master product. Certain internationally distributed products were manufactured outside the United States.

Response: ODHS has revised the report accordingly.

Comment 10: The summary of the report would also be improved by addition of a discussion of how this report fits into an overall investigation strategy.

Consider adding a description of the context of the consultation to the summary. We suggest the following: The consultation was conducted as an initial step because the Oregon Department of Health Sciences and ATSDR are currently reviewing existing information about the Hall Street population to determine the feasibility of an epidemiological investigation of the former factory workers.

Response: ODHS has incorporated this recommendation in the introductory section of the document.

Comment 11: The summary closes by stating, "… ODHS considers this site a public health hazard." This is not an accurate statement, a fact that we have confirmed with the DHS. The Oregon Department of Environmental Quality (ODEQ) has supervised site investigation and remedy and can confirm that the site does not present a current public health hazard. Instead, when contamination was identified in the supply well, steps were immediately taken to remove any potential for exposure, thus removing the current public health hazard.

Response: ODHS has revised the report to clarify the public health implications of the contamination.

Comment 12: It is reported that "Tyco merged with Mattel in 1996." The Tyco and Mattel merger occurred in 1997.

Response: ODHS has confirmed the date of the merger as 1997 and corrected the report accordingly.

Comment 13: The final text should be revised to be more reflective of Mattel's commitment to assist in this process. From the beginning, Mattel cooperated with all regulatory agencies to provide records in a manner consistent with company policies regarding employee confidentiality. Mattel is coordinating with IRS and the U.S. Social Security Administration to determine the feasibility and cost of records retrieval.

Response: ODHS acknowledges Mattel's voluntary efforts to assist in identifying former workers of the View-Master plant. The report accurately states that ODHS is actively negotiating with Mattel to receive IRS records.

Comment 14: Footnote 2 describes the relocation of manufacture to Mexico "under the Free Trade Agreement." This text is not relevant to the draft report and does not reflect the current degree of Mattel's involvement and commitment to the issue.

Response: ODHS has revised the wording of the relevant footnote accordingly.

Comment 15: Footnote should be revised to read, "Although Mattel ceased manufacturing at the facility, Mattel administrative staff are present in Portland to coordinate communications with former staff and to administer company-sponsored medical screening examinations."

Response: This information was included in the initial report. The final report contains additional information about the medical screening program.

Comment 16: The draft report describes effects on children following consumption of drinking water during visits to their parent's workplace. Although such exposures could occur, they likely would result in minimal exposure. More significant exposures for children of working mothers (i.e., in utero exposures) were the basis of Mattel's providing health exams to children of mothers who worked at Hall Street.

Response: There was probably some exposure to young children visiting their parents at the plant, but the extent of such exposure, if any, is not yet known. The health consultation report therefore includes visiting children, as well as developing fetuses, within the potentially exposed population.

Comment 17: The draft report indicates that the "pathway of exposure was essentially limited to drinking water." However, during operation of the degreaser, exposures through inhalation and dermal contact were likely higher than those related to drinking water. These additional exposures must be considered in order to accurately evaluate any effects of TCE at Hall Street. In addition, in the last paragraph on page 6, the statement that this site is unique in that it is one of a very few that has only TCE exposure is incorrect. There are many sites where TCE exposure is the main or only contaminant of concern. Also, the draft report appears to be incomplete in its assessment of water supplied to the facility by the local water district, and how those supplies may affect the statements in the draft report.

As a final comment regarding exposure, the characterization of TCE exposure as quite high is accurate relative to other water exposures, but inaccurate relative to allowable levels of exposure in workplace settings. The data from workplace settings do provide valuable context to evaluate the likelihood of adverse effects regardless of the exposure pathway.

Response: ODHS acknowledges that the effects of direct occupational exposure to undiluted TCE among workers who handled the solvent should be evaluated in a full epidemiological investigation. As specified in Recommendation 2c of the initial report, the types of jobs held should be considered in determining individual TCE exposure. In addition, information should be collected about where employees worked within the site, the activities in which they were engaged, and what chemicals they handled, if any.

While the factory used TCE as a degreaser from 1950 to 1980, most of the factory's employees did not work with the degreaser during those years. Because TCE was no longer used in large quantities after degreasing operations ceased in 1980, even fewer employees handled TCE from 1980 to 1998. The pathway of exposure, therefore, was most likely limited to drinking water for the vast majority of the potentially exposed population, which comprises about 25,000 people according to Mattel's estimates.

ODHS has added a discussion about occupational exposures to TCE in the final report. The report does not discuss the allowable workplace standards for TCE exposure because those standards do not apply to drinking water. Regarding the municipal water system, please refer to the response to Comment 6 in this Appendix. ODHS has also added information about the municipal water system to the final report.

Comment 18: The recommendations of the draft report are generally well presented. In particular, Mattel continues to support development of a well-designed and careful study.

Existing studies about TCE and its influence on human health are conflicting, with some indicating no adverse effects while others identify a range of potential health problems. The funding and implementation of a comprehensive and carefully conducted health evaluation, based upon scientifically valid data and analysis, allow the best opportunity to provide the answers sought by those exposed to TCE.

It is recommended that the final report be written in a factual, information-based format that clearly describes the past exposures to TCE and other chemicals during operations at Hall Street, indicates the aims and objectives of the planned investigation, and provides a clearer analysis of the basis and the limitations of this preliminary consultation and its role in the overall investigation plan. This is the manner of education and information previously provided by ATSDR and would be the most constructive means to finalize the health consultation.

Response: The final report addresses the basis and limitations of the preliminary consultation, as well as recommendations for further investigation especially regarding past exposures.

Comment 19: There are several difficulties with the Public Health Consultation report in that it repeatedly says there is one source of exposure and one contaminant, TCE. First, PCE is also at a range where cancers and birth defects have been seen in other drinking water studies (with 5 ppm being the EPA maximum contaminant level and data showing PCE level at 56 ppb).

Response: The report focuses on TCE as the primary contaminant because the average concentration of TCE found in the View-Master supply well was nearly 300 times the federal safety standard for TCE in drinking water. The average concentration of PCE, by contrast, was approximately 8.5 times the federal safety standard for PCE.

The report focuses on the source of TCE exposure because the source of PCE at the site is unknown. There is no known history of PCE use in the View-Master factory's manufacturing processes. Bruce Gilles, project manager at Oregon DEQ, has observed the presence of low levels of PCE at other sites in which TCE is the primary groundwater contaminant, and speculates that small amounts of PCE might have been present in the solvent-grade TCE product that was used in the past.

Both PCE and TCE are reasonably anticipated to be human carcinogens, and when they occur together as contaminants to which people are exposed, it is generally not possible to separate the health effects of PCE from those of TCE. It is, however, unlikely that one carcinogenic component (PCE) representing 3% of a mixed contaminant would have a greater impact on the human body than a carcinogenic component (TCE) representing 97% of the contaminant, especially given that the two compounds are believed to be comparable in their carcinogenicity. There have been no studies that have linked cancers or birth defects to PCE alone at the range found in the View-Master well.

ODHS recommends a comprehensive health investigation of View-Master workers that would assess a range of outcomes, including various cancers and birth defects. Any health outcomes that might be associated specifically with PCE would not likely be overlooked in such a study. Moreover, because PCE has occurred as a co-contaminant at other TCE sites (12), an investigation of health effects at the View-Master site could provide meaningful information for other sites where TCE has contaminated the groundwater.

ODHS has added to the final report a discussion about the other contaminants that were detected in the well.

Comment 20: The second difficulty is there are other sources of exposure, i.e., working with the solvents in the degreasing process, fumes from exposure to vaporized TCE (i.e., hand and face washing, toilet flushing, etc.) and also the "disposal" of these solvents. It would be important to differentiate those workers who only would have exposures from drinking water from workers to had exposures from working in the degreasing process or from "disposal" activities. There were multiple exposure scenarios for both pathways and chemical types – this report repeatedly states incorrectly that it was one contaminant and one exposure source. See pages 6 and 7 of the PHC. Some workers would have exposures to TCE and PCE (and other solvents) from sources other than drinking water.

Please refer to the response to Comment 17, in this Appendix.

Comment 21: Another issue of importance is finding a suitable comparison (unexposed or lesser exposed) group. In the preliminary analyses, workers were compared to state rates (i.e., the general population of Oregon), but this is problematic because of healthy worker effect biases. (It would have been nice if the report described the preliminary analyses and provided the results!) One way to minimize healthy worker effect biases is to do what is called an "internal analysis" of the cohort, i.e., identify some workers in the plant who had no or lower exposures and use that group as a comparison for those who had higher exposures. But here it looks like everyone had considerable exposures. So some outside comparison group that is similar to this workforce except for the TCE and PCE exposures must be found. Using the general population of Oregon will produce biased results.

A major difficulty in conducting an epidemiological study of this cohort is tracking the whereabouts and vital status of those workers who were employed at the site in the earlier years. For cancers, it is possible to identify incidence cases among those workers who did not leave the state and were diagnosed in Oregon by checking with the Oregon cancer registry. Unfortunately, the registry started in 1996 so to identify incidence cases before this would require a search of hospital medical records. For those who died of a cancer, these cases would be identified through the death certificate. For those who may have left the state and were diagnosed elsewhere, it would require tracking these people to determine where they resided and then checking with that state's cancer registry. So a cancer incidence study would not be easy!

Even more difficult would be a study of birth defects since the state does not have a birth defect registry. If the focus is on maternal exposures, then the women in the workforce would have to be interviewed, and then medical record confirmation of birth defects would have to be obtained.

Certain non-cancer outcomes, such as spontaneous abortion and neurological symptoms and neurobehavioral test deficits, will not be as feasible to study.

Response: Comment 21 incorrectly states that workers were compared to state rates in the preliminary analyses. The analysis compared proportions, rather than rates. The information required for comparison of rates is currently unavailable, as discussed in the response to Comment 4 in this Appendix.

The term “healthy worker effect” usually refers to a tendency for any particular employed population to have lower mortality, from all causes combined, than the general population. This phenomenon is thought to result from the selective entry of healthy persons into the workforce, and early removal of unhealthy persons from the workforce. The healthy worker effect can be minimized if the use of the general population as a comparison group is replaced by the use of an occupational population with comparable job entry and exit factors (16, 20). In the recommendations of the final report, ODHS has included the use of an occupational referent population as a possible comparison group for the View-Master cohort.

The health consultation report recommends that an epidemiological study be conducted. Comment 21 elaborates on basic methodological concepts that would be considered during the planning and design of an epidemiological study. These issues, among many others, would be addressed in a full investigation of the View-Master site. The inclusion of additional discourse on epidemiological methods would be inappropriate in the health consultation report, however, as it goes beyond the stated purpose of the document.

Comment 22: If the workers whereabouts and vital status can be tracked, and if workers (or next of kin) can be interviewed, and if the cancers and birth defects can be verified by cancer registry, death certificate, or medical record, then it would be feasible to do a study.

Please refer to Recommendation 2, at the end of the health consultation report.

Comment 23: To work with the agencies involved they must answer these questions: What are the goals of the investigation? How will the investigators get the information they need? What are they going to do with the results?
...We will need a discussion on what actions need to be taken as a result of the findings of the study.

Response: As stated in the Recommendations of the health consultation report, the purpose of an epidemiological study of the View-Master site would be to determine whether former workers have experienced adverse health and reproductive outcomes as a result of TCE exposure. This report specifically suggests that information about exposures and health outcomes be collected by interviewing former workers or their survivors, investigating deceased former workers' causes of death, and reviewing the state cancer registry.

The purpose of the proposed epidemiological study is to understand the public health impact of the contamination. Because the proposed epidemiological study will be population-based, the results of the study will not be able to confirm whether any individual case of disease is linked with TCE exposure.

Comment 24: We understand that neither the state nor the federal government have the funds or the authority to do anything to relieve the suffering of these victims. The federal government under Superfund could implement a medical monitoring program. This site was never declared a Superfund site but rather was a state led response with no provisions for such health care needs.

Response: Under the Superfund program, the EPA, on behalf of the federal government, assesses and directs cleanup of some of the nation’s most contaminated sites. In the case of the View-Master site, the EPA has not listed it as a Superfund site, but the State of Oregon is handling the cleanup actions at the site.

Superfund directs ATSDR to conduct medical monitoring for populations at significant increased risk at some Superfund sites. It is our understanding that Mattel already

provides former workers with medical screening that is somewhat similar to the medical monitoring that has been provided under Superfund.

Comment 25: As effected [sic] *citizens we will concern ourselves with the design of a health study and request to have input at every step of the investigation, including: how the study is designed; how the study is actually carried out; the evaluation and interpretation of the results; the dissemination of the results;*

…If the study is poorly designed, then nothing will come from the study. No amount of after-the-fact analysis can change a poorly designed study. We will need help reviewing the study design and protocols to participate in this process in a meaningful way. We would like to hire an independent medical or scientific expert(s) to review these health study designs and will request funding from the federal government or the state government to hire our own experts.

…If the suggestions in the Consultation are accepted it is crucial that our voices be heard, along with our local politicians and local physicians, as a major input into the design and implementation of the studies. If those studies proceed without substantial input from the community the results are likely to be supportive of the view that exposures were limited in time and not very high and that no health problems were created. This would be a questionable conclusion.

Response: ODHS acknowledges the importance of community involvement in the issues surrounding the contamination at the View-Master site, and has convened a Citizen Advisory Group to gather input into the development of the proposed epidemiological study. ODHS announced the formation of the Community Advisory Group on January 28, 2003, during a public meeting with former workers and concerned citizens.

As with any scientific investigation, the results of the health study cannot be known before it is undertaken. The study may or may not indicate a positive association between exposure and disease. To help ensure that the study will yield the most accurate possible information about how former workers may have been affected by their exposures at the plant, ODHS is gathering input from the community members as well as experts in the fields of medicine, toxicology and epidemiology. An external scientific advisory board will be convened to further review the study design. Working together to develop the study is the best way to achieve valid results that are accepted by all parties involved.

ODHS and ATSDR do not have the resources to supply funds for a technical assistance grant (TAG). However, the Technical Outreach Services for Communities (TOSC) Program provides free technical assistance to communities with environmental contamination. TOSC is funded by the EPA and is administered in Oregon by the Western Region Hazardous Substance Research Center and Oregon State University. TOSC is not limited to National Priorities List Superfund sites, unlike the TAG program. This makes TOSC available to communities with hazardous-substance problems that cannot receive help from a TAG. More information about TOSC is available online at http://tosc.oregonstate.edu. TOSC can be reached by calling 1-800-653-6110.