

Contaminated Drinking Water and Health Effects
at Marine Base Camp Lejeune:
Final Plans of the Agency for Toxic Substances and Disease Registry
August, 2009

Executive Summary

ATSDR has been assessing the human health risks from hazardous substances at U.S. Marine Corps Base Camp Lejeune since the late 1980s. The agency conducted public health assessments, initiated a variety of epidemiological studies, and employed state-of-the-art computational tools (modeling) to reconstruct exposures to volatile organic compounds (VOCs) from drinking water systems. In 1997, ATSDR characterized the VOC drinking water pollutants as a “past public health hazard,” a position ATSDR continues to maintain. Since then, ATSDR has focused on epidemiological studies designed to measure the occurrence of illness and death among the service men and women and their families exposed to the contaminated drinking water.

Several documents or reviews of ATSDR’s work have been completed during the past 14 months. ATSDR finalized *An Assessment of the Feasibility of Conducting Future Epidemiologic Studies at USMC Base Camp Lejeune* in June, 2008. ATSDR later held an April, 2009 Expert Panel to assess ATSDR’s plans for historical reconstruction of drinking water contamination at Hadnot Point and Holcomb Boulevard. In June, 2009 the National Research Council (NRC) issued a report, *Contaminated Water Supplies at Camp Lejeune—Assessing Potential Health Effects*. This document considers this information and defines ATSDR’s plans for completing our research activities at Camp Lejeune

Tarawa Terrace exposure modeling: ATSDR will use its modeling to generate semi-quantitative exposure estimates for the planned epidemiologic studies rather than limit the use of the historic reconstruction to *exposed/unexposed*. ATSDR believes that the models provide a reliable means for assigning individuals to multiple exposure categories useful in epidemiologic studies. ATSDR's approach is supported by two previous expert panels that focused on exposure reconstruction efforts.

Hadnot Point exposure modeling: ATSDR will apply simpler modeling techniques for Hadnot Point and Holcomb Boulevard than those used for Tarawa Terrace. The Hadnot Point area is significantly larger than the Tarawa Terrace area and contains multiple contaminant source locations. Applying the complex numerical models used at Tarawa Terrace to the entire Hadnot Point area would be time consuming, costly, and add another level of uncertainty to the water modeling analysis. This approach is supported by both the NRC report and the ATSDR 2009 expert panel.

Reanalysis of birth outcomes study: ATSDR will proceed with its planned reanalysis of the birth outcomes study to correct for errors in exposure classification. To avoid further exposure misclassification, ATSDR will await the completion of the historic exposure reconstruction of the Hadnot Point drinking water system.

Birth defects and childhood cancer studies: ATSDR will complete its case-control study of birth defects and childhood cancers. The analysis will proceed expeditiously once the historic exposure reconstruction of the Hadnot Point drinking water system is completed.

Further epidemiological studies: ATSDR has proposed mortality and morbidity studies. The morbidity study will be based upon a “health survey” that would solicit information about diagnosed illnesses (e.g., cancer) from former service men and women and their families. ATSDR plans to move forward as quickly as possible to conduct the mortality study which has adequate study power and can be completed in a relatively short time period. ATSDR recognizes that a scientifically valid morbidity study based upon a health survey is time consuming and costly. The utility of the health survey depends upon high participation rates and the ability to secure objective confirmation of reported medical conditions. ATSDR will alter its plans for the health survey by using a phased approach, evaluating participation rates and diagnosis verifiability in advance of a complete survey of all eligible participants. ATSDR will define scientifically sound criteria for evaluating the results of the first phase, and for deciding upon the feasibility of a complete survey.

ATSDR concludes that the portfolio of epidemiologic studies is not only scientifically useful, but also a service to the community of service men and women and their families exposed to contaminated drinking water at USMC Base Camp Lejeune.

Table of Contents

Executive Summary	1
Table of Contents	4
I. History and Purpose	5
II. Science and Service	5
III. Partnerships and Oversight	7
IV. ATSDR Camp Lejeune Portfolio	8
V. The NRC Recommendations	12
VI. Implementation and Timeline	21
VII. References	22

I. History and Purpose

ATSDR has been assessing the human health risks from hazardous substances at U.S. Marine Corps Base Camp Lejeune since the late 1980's. The agency conducted public health assessments, initiated a variety of epidemiological studies, and employed state-of-the-art computational tools (modeling) to reconstruct exposures to volatile organic compounds (VOCs) from drinking water systems. In 1997, ATSDR characterized the VOC drinking water pollutants as a past public health hazard, a position ATSDR continues to maintain. Since then, ATSDR has focused on epidemiological studies designed to measure the occurrence of illness and death among the service men and women exposed to the contaminated drinking water. ATSDR has enlisted four different Expert Panels and a Community Assistance Panel to help guide the development of this work.

Several documents or reviews of ATSDR's work have been completed during the past 14 months. ATSDR finalized *An Assessment of the Feasibility of Conducting Future Epidemiologic Studies at USMC Base Camp Lejeune* in June, 2008. ATSDR later held an April, 2009 Expert Panel to assess ATSDR's plans for historical reconstruction of drinking water contamination at Hadnot Point and Holcomb Boulevard. In June, 2009 the National Research Council (NRC) issued a report, *Contaminated Water Supplies at Camp Lejeune—Assessing Potential Health Effects*. ATSDR has carefully evaluated these reports, comments from the Camp Lejeune Community Assistance Panel, and comments from additional scientists and an environmental non-governmental organization. ATSDR's plans take into consideration the underlying science, our commitment to serving communities exposed to hazardous substances, and address the comments and concerns of the reviewers.

II. Science and Service

ATSDR has a unique mandate to conduct human health research related to community exposures to hazardous substances. Although our knowledge of the relationships between chemical exposures and human health is often based upon studies of highly exposed workers or animal toxicology testing, there remains a pressing need to know whether lower level exposures, away from the workplace, cause human illness. ATSDR identified the drinking water contamination at Marine Base Camp Lejeune as an opportunity for conducting this type of research.

ATSDR recognizes the importance of setting appropriate expectations for our research. Our research studies must be of high quality. ATSDR research should contribute to the understanding of the human health effects of hazardous exposures such as VOCs in drinking water. While no single study can be conclusive, our research should add information to the overall weight-of-evidence regarding associations between hazardous exposures and human health outcomes.

Our science serves a secondary, service-related, function: the right to know. At Camp Lejeune, hundreds of thousand of men and women lived and worked providing service to their country. Many were unknowingly exposed to VOCs in their drinking water. Beyond contributing to our general knowledge about these hazardous substances, ATSDR research studies will provide information that former service men and women of Camp Lejeune want to know about the health risks from these past exposures.

ATSDR believes conditions are appropriate to continue research at Camp Lejeune. ATSDR's research should help inform policy decisions that respond to the health concerns of the service men and women exposed to contaminated drinking water. However, the development of

these policies need not await the results of ATSDR research. The policy decisions should be based a weight-of-evidence assessment of all relevant human and animal studies and consider authoritative assessments that have previously been published. Policies should be flexible enough to incorporate new information, such as the results from the ATSDR studies.

III. Partnerships and Oversight

ATSDR serves the men and women who lived at Camp Lejeune while the drinking water was contaminated. Our work at Camp Lejeune would not be possible without the support and partnership of multiple people and organizations. Although no single person or group represents this diversity of people, many former marines have become active partners by serving on our Community Assistance Panel (CAP). The Department of Navy and United States Marine Corps have dedicated significant resources and efforts to assist ATSDR. Both groups have been instrumental in helping us understand the complexity and history of Camp Lejeune's drinking water systems. The quality of our efforts would have suffered without the dedicated interest and help from these people.

ATSDR recognizes the value of objective scientific review. Over the years ATSDR has assembled four separate expert panels as we developed our epidemiological studies and computer-based models of drinking water contamination. Two panels have addressed the historic reconstruction of contaminated drinking water at Camp Lejeune: first the Tarawa Terrace system and second the Hadnot Point and Holcomb Boulevard systems. A third expert panel focused on whether or not ATSDR should conduct epidemiologic studies of the Camp Lejeune population beyond studies of birth outcomes, birth defects, and childhood cancers. The fourth expert panel provided advice to ATSDR on scientific approaches to a congressionally

mandated health survey. The NRC report provides an additional opportunity for objective external review. In addition, protocols and reports of ATSDR's work have routinely been peer-reviewed by experts outside the Agency.

IV. ATSDR Camp Lejeune Portfolio

ATSDR's work at Camp Lejeune is briefly described below for background purposes.

- **1990: Public Health Assessment for ABC One-Hour Cleaners, Jacksonville, Onslow County, North Carolina.** The first assessment related to Camp Lejeune focused on the contamination of ground water by tetrachloroethylene released from the ABC One-Hour Cleaners. This assessment found that PCE, detected in onsite and offsite wells, was the primary contaminant of concern.
- **1997: Public Health Assessment for U.S. Marine Corps Base at Camp Lejeune, Military Reservation, Camp Lejeune, Onslow County, North Carolina.** This assessment formed the basis for future public health research, including the ongoing water modeling, exposure reconstruction, and epidemiological studies. Although the drinking water section of the report needs to be updated, the report contains valuable and accurate historical information about nine other exposure pathways. ATSDR concluded in this report that exposures from VOCs in the drinking water at Camp Lejeune were a past public health hazard. ATSDR plans to reassess the drinking water pathway once the historic reconstruction efforts are completed.
- **1998: Volatile Organic Compounds in Drinking Water and Adverse Pregnancy Outcomes, United States Marine Corps Base, Camp Lejeune.** In 1995, ATSDR began a study of a variety of adverse pregnancy outcomes at Camp Lejeune in relation to drinking

water VOC exposure. The study analyzed live births to women residing in base family housing when they delivered during the period January 1, 1968, through December 31, 1985. Birth certificates were studied from 6,117 tetrachloroethylene (PCE)-exposed women, 141 short-term trichloroethylene (TCE)-exposed women, 31 long-term TCE-exposed women, and 5,681 unexposed women. Associations between PCE and the study outcomes were observed in two potentially susceptible subgroups: infants of mothers 35 years of age or older and infants whose mothers had histories of fetal deaths. ATSDR also reported a reduction of birth weight for gestational age in male babies within the long-term TCE-exposed group. ATSDR later identified an error in the exposure classifications used in this study. ATSDR is planning to reanalyze this study with updated exposure information.

- **2005: Expert Peer Review Panel Evaluating ATSDR's Water-Modeling Activities in Support of the Current Study of Childhood Birth Defects and Cancer at U.S. Marine Corps Base Camp Lejeune, North Carolina. Analyses of Groundwater Resources and Present-Day (2004) Water-Distribution Systems.** ATSDR requested a panel of nine experts to provide input on the Agency's groundwater resources and water-distribution system modeling activities conducted from March–December 2004 at U.S. Marine Corps Base, Camp Lejeune, North Carolina. Overall, the experts indicated that this was an important study to conduct and were impressed with the quality of work performed to date. The panelists noted specific principal issues that needed to be addressed, and made recommendations for ATSDR's next steps. ATSDR has since followed the advice of the panel members.
- **2005: Report of the Camp Lejeune Scientific Advisory Panel.** In February 2005, ATSDR asked a panel of experts for advice regarding additional epidemiological studies related to

people's exposure to contaminated drinking water at Camp Lejeune. The panel discussed a large range of possible adverse health impacts that could be related to short- and long-term exposure to TCE and other VOCs in the drinking water of Camp Lejeune. Several of these would be extremely challenging to study, and may not be feasible subjects for investigation, such as studies of effects that could involve medical evaluation of hundreds of individuals now living in widely scattered locations. There was agreement, however, that a study of mortality outcomes would be feasible (assuming the availability of adequate personal identifiers) and that a cancer incidence study might be feasible. Before embarking on full-scale studies however, the members recommend that ATSDR conduct one or more feasibility or pilot studies.

- **2007: Analyses of Groundwater Flow, Contaminant Fate and Transport, and Distribution of Drinking Water at Tarawa Terrace and Vicinity, U.S. Marine Corps Base Camp Lejeune, North Carolina: Historical Reconstruction and Present-Day Conditions.** Two of three water-distribution systems that have historically supplied drinking water to family housing at U.S. Marine Corps Base Camp Lejeune, North Carolina, were contaminated with VOCs. Tarawa Terrace was contaminated mostly with tetrachloroethylene (PCE), and Hadnot Point was contaminated mostly with trichloroethylene (TCE). Because limited measurements of contaminant and exposure data are available to support the epidemiological study, ATSDR used modeling techniques to reconstruct historical conditions of groundwater flow, contaminant fate and transport, and the distribution of drinking water contaminated with VOCs delivered to family housing areas. Based on probabilistic analyses, the most likely dates that finished water first exceeded the current maximum contaminant level (MCL) for PCE ranged from October 1957 to August

1958 (95 percent probability), with an average first exceedance date of November 1957.

Exposure to drinking water contaminated with PCE and PCE degradation by-products stopped after February 1987 when the Tarawa Terrace water treatment plant was closed.

- **Ongoing: Exposure to VOCs in Drinking Water and Specific Birth Defects and Childhood Cancers, United States Marine Corps Base Camp Lejeune, North Carolina.** ATSDR has undertaken a study to determine if children born during 1968-1985 to mothers who were exposed to VOC-contaminated drinking water at Camp Lejeune at any time during the pregnancy were more likely to have specific birth defects or childhood cancers. The birth defects include spina bifida, anencephaly, and cleft lip and/or palate. The childhood cancers include leukemia and non-Hodgkin's lymphoma. The study design for the case-control study was completed in 2004 and underwent peer-review. Case-control interviews and the medical records confirmation phase of the study are complete. The study is awaiting completion of the water modeling.
- **2008: An Assessment of the Feasibility of Conducting Future Epidemiological Studies at USMC Base Camp Lejeune.** ATSDR released a feasibility assessment of conducting future epidemiological studies at the base. ATSDR visited the Naval Health Research Center (NHRC), the Defense Manpower Data Center (DMDC), and the DOD Education Activity storage facility at Fort Benning, Georgia, to determine whether available databases could identify adults and children who lived at the base, or civilians who worked at the base, during the period when drinking water was contaminated with VOCs. ATSDR also convened a panel of epidemiologists with experience in military and occupational cohort studies to provide recommendations on future studies (Appendix A of the report). ATSDR concluded that a mortality study and a cancer incidence study are feasible. Available DOD personnel

databases can identify active duty Marines and naval personnel and civilian employees stationed at the base during the period when the Hadnot Point and Tarawa Terrace drinking-water systems were contaminated with VOCs. ATSDR also concluded that it may be feasible to include in the cancer incidence study those who participated in the ATSDR 1999–2002 survey and those who will participate in the congressionally mandated Navy/Marine Corps health survey scheduled for 2009. These studies should have sufficient statistical power to detect moderate excesses (e.g., standardized mortality ratios [SMRs] < 2.0) in specific cancers among those exposed to the contaminated drinking water (see Appendix B). ATSDR completed internal clearance of the feasibility assessment and released it to the public.

2009: Expert Panel Assessing ATSDR’s Methods and Analyses for Historical

Reconstruction of Groundwater Resources and Distribution of Drinking Water at Hadnot

Point, Holcomb Boulevard and Vicinity, U.S. Marine Corps Base, Camp Lejeune, North

Carolina. ATSDR convened a panel of 13 groundwater modeling, water-distribution system

analysis, and epidemiological experts to help the agency evaluate the information, data, and

modeling methods to be applied to Hadnot Point, Holcomb Boulevard, and vicinity at Camp

Lejeune. The panel provided specific recommendations. Individual experts stated that the

project was worthwhile and agreed that it would be possible for ATSDR to reconstruct potential

historical exposures for the proposed epidemiological studies.

V. The June 2009 NRC Recommendations:

The National Research Council released its report, *Contaminated Water Supplies at Camp Lejeune – Assessing Potential Health Effects*, in June 2009. The summary

recommendations directed at ATSDR, and a summary of our science-based position regarding these recommendations, are described below.

NRC Recommendation 1: *For the purpose of epidemiologic studies, the results of the Tarawa Terrace historical reconstruction can be used to characterize people as being exposed or unexposed on the basis of date and location of residence or workplace. The monthly estimates imply more accuracy than is appropriate and should not be used to characterize exposure of individual people.*

ATSDR will use its modeling to generate semi-quantitative exposure estimates for the planned epidemiologic studies rather than limit the use of the historic reconstruction to *exposed/unexposed*. ATSDR believes that the models provide a reliable means for assigning individuals to multiple exposure categories useful in epidemiologic studies. ATSDR's approach is supported by two previous expert panels that focused on our exposure reconstruction efforts.

The usefulness of the Tarawa Terrace model-estimated monthly average PCE concentrations has been clearly demonstrated by its concordance with measured PCE concentrations in water samples taken from the Tarawa Terrace water treatment plant prior to distribution to its customers (i.e. *finished* water samples). A "goodness of fit" comparison between the model calibrations and measurements of *finished* Tarawa Terrace water lead ATSDR, as well as our drinking water panel of experts, to conclude that the modeled monthly estimates can be used to create reasonably accurate exposure categories for the epidemiological studies.

The use of an exposed/unexposed classification for past drinking water contamination would result in a significant loss of important scientific information. ATSDR reviewed the

distribution of modeled monthly drinking water exposures at Tarawa Terrace and documented that significant variability of exposure exists across the study population. Children in the birth defect and childhood cancer study who received drinking water from Tarawa Terrace during the first month of gestation were exposed to estimated average monthly drinking water contamination levels that range from 3 ppb to 182 ppb. A similar distribution is seen for mothers who lived at Tarawa Terrace and were included in the birth outcome study.

The use of an exposed/unexposed classification system would inaccurately assess risk and potentially miss an observed effect if one truly exists. It is important to utilize all relevant information in the exposure assessment so that exposure categories can be created that are as homogeneous as possible with respect to risk. The NRC report (p. 29) acknowledged this point when it emphasized the importance of correctly classifying the magnitude of exposure, differentiating “between those who are exposed at magnitudes that could result in adverse health effects (sensitivity) and those who are exposed at lower magnitudes (specificity).” Moreover, an important research question is whether the risk for a disease increases with increasing exposure. This question cannot be addressed using an exposed vs. unexposed classification.

Recommendation 2: *Because any groundwater modeling of the Hadnot Point system will be fraught with considerable difficulties and uncertainties, simpler modeling approaches should be used to assess exposure from the Hadnot Point water system. Simpler modeling will not reduce the uncertainty associated with the estimates, but they have the advantage of providing a broad picture of the timeframe and magnitude of exposure encountered by people who used water from that system more quickly and with less resources than complex modeling exercises.*

ATSDR will apply simpler modeling techniques for Hadnot Point and Holcomb Boulevard than those used for Tarawa Terrace. The Hadnot Point area is significantly larger than the Tarawa Terrace area and contains multiple contaminant source locations. Applying the complex numerical models used at Tarawa Terrace to the entire Hadnot Point and Holcomb Boulevard areas would be time consuming, costly, and add another level of uncertainty to the water-modeling analyses. This approach is supported by both the NRC report and the ATSDR 2009 expert panel. The information from the models will be used in all of ATSDR's epidemiological studies to classify individuals into categories of exposure and provide a service to the affected community.

The models needed to reliably estimate water concentrations for Hadnot Point and Holcomb Boulevard will be developed specifically to address issues for these areas. If available, better field characterization and details will be added to conceptual models to improve understanding of both hydraulics and transport at selected sites where potential exposure was high. ATSDR will use locally-refined grids to model selected sites of interest. ATSDR will select and develop simulation tools based on site-specific conditions, characteristics, and requirements.

Recommendation 3: *The committee recommends that ATSDR go forward with reanalyzing its study of birth outcomes to correct for errors in exposure classification without awaiting the results of groundwater modeling of the Hadnot Point system. ...Reanalyses should include development of a detailed written analysis plan.*

Despite the committee's concerns about the statistical power of the study of birth defects and childhood cancer, it recommends that the study be completed as soon as possible.

ATSDR will proceed with its planned reanalysis of the birth outcomes study to correct for errors in exposure classification. To avoid further exposure misclassification, ATSDR will await the completion of the historic exposure reconstruction of the Hadnot Point drinking water system. ATSDR will complete its case-control study of birth defects and childhood cancers. The analysis will proceed expeditiously once the historic exposure reconstruction of the Hadnot Point drinking water system is completed. ATSDR has developed a detailed analysis plan for these studies.

ATSDR believes that due to significant variability of exposures among people at Hadnot point and Holcomb Boulevard, it is essential to complete the simpler water modeling for Hadnot Point. Monthly average contaminant levels will likely vary depending on when contaminated wells were operating. In addition, exposure will vary because of the transfer of water from Hadnot Point to Holcomb Boulevard during the dry spring-summer months.

The birth outcome study cannot be reanalyzed without awaiting the Hadnot point water-modeling results. The previous analysis considered the drinking water supplied in Holcomb Boulevard uncontaminated, even though the area had originally been supplied contaminated water from Hadnot Point. The Hadnot Point water models must be completed to accurately classify exposures in Holcomb Boulevard during those years. Once, an acceptable historic dose-reconstruction of exposures at Holcomb Boulevard and Hadnot Point become available the epidemiological data will be analyzed.

Recommendation 4: *The committee found that although ATSDR did consider the major issues bearing on the feasibility of the proposed studies and proposed reasonable approaches to*

conducting the studies, there remain serious, unresolved questions about the feasibility and ultimate value of the studies. ...the committee concluded that most questions about whether exposures at Camp Lejeune resulted in adverse health effects cannot be answered definitively with further scientific study. New studies should be undertaken only if their feasibility and promise of providing substantially improved knowledge on whether health effects have resulted from water exposure at Camp Lejeune are established in advance.

ATSDR has proposed mortality and morbidity studies. The morbidity study will be based upon a "health survey" that would solicit information about diagnosed illnesses (e.g., cancer) from former service men and women and their families. ATSDR plans to move forward as quickly as possible to conduct the mortality study which has adequate study power and can be completed in a relatively short time period. ATSDR recognizes that a scientifically valid morbidity study based upon a health survey is time consuming and costly. The utility of this survey depends upon high participation rates and the ability to secure objective confirmation of reported medical conditions. ATSDR will alter its plans for the health survey by using a phased approach, evaluating participation rates and diagnosis verifiability in advance of a complete survey of all eligible participants. ATSDR will define scientifically sound criteria for evaluating the results of the first phase, and for deciding upon the feasibility of a full study. To determine whether a full research study can be conducted, ATSDR will conduct a pilot study, contacting a 10% sample (35,000 to 40,000) of those targeted for the health survey and evaluate the ability to locate participants, achieve an adequate participation rate, and confirm self-reported diseases. ATSDR will mail a health survey to the remaining 90% of the study group to assure compliance with congressional authorizing language. If the pilot study demonstrates adequate response rates and medical confirmation, the same methods will be extended to the entire population. ATSDR

will develop algorithms to determine the needed participation rate and diagnosis verification rate to assure valid results, and will evaluate the pilot study accordingly. If participation rates and medical confirmation are inadequate for a scientifically valid health survey, ATSDR will analyze and report the survey results without costly efforts to improve participation and assure medical confirmation.

ATSDR has confirmed that adequate personnel data to establish a study cohort are available from the Defense Manpower Data Center's databases. These are the primary sources of data on former active duty and civilian employees for the mortality study and the health survey. These data contain names, social security numbers and dates of birth as well as other information such as rank, job duties, and length of employment or active duty service, and a unit code that places active duty men and women within Camps Pendleton and Lejeune. These data are sufficient for conducting a National Death Index search for the mortality study and initiating the search to contact people for the health survey.

ATSDR has assessed the statistical power of the proposed mortality and morbidity studies. Statistical power is the probability of finding an exposure-disease association if an association does exist. The study power calculations were included in the study protocols which were not reviewed by the NRC committee. The study power estimates for the cancer mortality endpoints are adequate. The study power estimates for the health survey are also considered adequate, the health survey calculations are based upon a 65% participation rate which may be optimistic. The statistical power calculation on comparisons between Camp Lejeune and the general population showed that an SMR of 1.6 could be detected for kidney cancer with 90% power and a type 1 error (α error) of .10. For the comparison with Camp Pendleton, and assuming a similar cancer rate at Pendleton as for the general population, an SMR of 2.0 can be

detected with 90% power and incorporating a 10 year latency. Lower SMRs can be detected with 90% power for other cancers of interest such as non-Hodgkin's lymphoma, leukemia, lung, colon/rectal, liver, and brain cancer. {Note: Because the U.S. rate for each cancer is based on very large numbers, the variability in the rate is ignored in power/sample size calculations. However, the variability in the rate for each cancer at Camp Pendleton must be taken into account in the power/sample size calculations. The result is that the SMR or SIR that can be detected with a specified sample size, latency, type 1 error, and type 2 error will be higher for the comparison between Camp Lejeune and Camp Pendleton than it will be for a comparison between Camp Lejeune and the U.S. population.}. Statistical power was evaluated for the morbidity study protocol that was approved by the CDC IRB and peer-reviewed. Comparing Camp Lejeune with Camp Pendleton, assuming a 65% participation rate, incorporating a 10 year latency period, and using a type 1 error of .10 and a type 2 error of .10 (i.e., 90% power), an RR of <1.6 can be detected for kidney cancer incidence. Lower RRs can be detected for non Hodgkin's lymphoma, lung, and colon/rectal cancer.

Selection bias in the health survey is possible even with a 65% or higher participation rate. The degree to which bias might influence the study results is related to disease prevalence. Rare diseases are more easily influenced by low participation than common diseases. Although a high participation rate decreases the likelihood of bias, a low participation rate does not guarantee that bias will occur. On the other hand, low participation rates do diminish study power and decrease the overall confidence in study results.

The health survey will utilize several approaches to achieve adequate participation rates to reduce the likelihood of selection bias. To enhance participation rates in the Camp Lejeune and Camp Pendleton populations, ATSDR proposes to have the Commandant of the USMC sign

the letter that accompanies the survey encouraging participation. The Commandant's endorsement will ensure that active duty and retired Marines and their families perceive the study as legitimate. The selection of Camp Pendleton as a comparison population should also help to reduce the likelihood of selection bias. Both bases have had problems with toxic waste sites and are likely to have similar workplace exposures. To motivate populations at both bases to participate in the survey, all mailings will encourage those who experienced any environmental or workplace exposures to participate. The health survey will utilize a standard methodology that has been demonstrated to enhance participation rates in mailed surveys (the Dillman method). Participation will be made convenient by giving respondents the choice of completing a hard copy or web-based survey, and the survey instrument will be of optimum length to address the research questions of interest without overburdening the respondent.

ATSDR recognizes the importance of accurately ascertaining adverse health outcomes. For the mortality study, a standard approach will be used: vital status will be determined using an algorithm that utilizes several national databases and the National Death Index will be used to identify causes of death. For the morbidity study, only health outcomes confirmed by medical records or cancer registrations will be evaluated in the analyses. ATSDR plans to utilize all 50 state cancer registries, the VA cancer registry, and the DOD cancer registry to confirm self-reported cancers identified from the health survey. ATSDR will obtain confirm disease status by obtaining medical records for non-cancer outcomes of interest.

ATSDR has been meeting with state cancer registries that are funded by CDC's National Program of Cancer Registries (NPCR) and National Cancer Institute's Surveillance and Epidemiology End Results (NCI SEER). ATSDR also has had discussions with the VA and DoD cancer registries. All are supportive of working with ATSDR to confirm self-reported cancers

from the health survey. In addition, a major consideration in the selection of a contractor for the health survey will be the demonstrated ability of the contractor to obtain medical records for disease confirmation.

VI. Implementation and Timeline:

ATSDR is moving ahead as planned with its portfolio of activities, dependent upon funding from the Department of Navy. ATSDR will provide an updated 2010 Annual Plan of Work based on this final plan. ATSDR hopes to proceed with the Mortality Study immediately if the research contract can be awarded in FY2009. The health survey cannot begin before FY2010 because of limitations with the planned funding mechanism and the decision to conduct a pilot study. A revised time-line will be developed for the morbidity study that is based upon the health survey. The pilot phase of the health survey is likely to begin sometime after March 2010.

VII. References

Agency for Toxic Substances and Disease Registry. Preliminary Public Health Assessment for ABC One-Hour Cleaners, Jacksonville, Onslow County, North Carolina. Atlanta GA: U.S. Department of Health and Human Services; 1990. Report No.: NCD024644494.

Agency for Toxic Substances and Disease Registry. Public Health Assessment for U.S. Marine Corps Base at Camp Lejeune, Military Reservation, Camp Lejeune, Onslow County, North Carolina. Atlanta, GA: U.S. Department of Health and Human Services; 1997. Report No.: NC6170022580.

Agency for Toxic Substances and Disease Registry. Volatile Organic Compounds in Drinking Water and Adverse Pregnancy Outcomes, United States Marine Corps Base, Camp Lejeune. Atlanta, GA: U.S. Department of Health and Human Services; 1998.

Agency for Toxic Substances and Disease Registry. (ATSDR) 2005a. Report of the Camp Lejeune Scientific Advisory Panel. June 24, 2005.
http://www.atsdr.cdc.gov/sites/lejeune/panel_report.html

Agency for Toxic Substances and Disease Registry. (ATSDR) 2005b. ATSDR Response to the Report of the Camp Lejeune Scientific Advisory Panel. 2005.
http://www.atsdr.cdc.gov/sites/lejeune/panel_report_response.html

Contaminated Water Supplies at Camp Lejeune – Assessing Potential Health Effects. National Research Council. June 2009.

Maslia ML. Expert Peer Review Panel Evaluating ATSDR's Water-Modeling Activities in Support of the Current Study of Childhood Birth Defects and Cancer at U.S. Marine Corps Base Camp Lejeune, North Carolina. Atlanta, GA: Agency for Toxic Substances and Disease Registry; 2005.

Maslia ML, Sautner JB, Faye RE, Suárez-Soto RJ, Aral MM, Grayman WM, Jang W, Wang J, Bove FJ, Ruckart PZ, Valenzuela C, Green JW Jr, and Krueger AL. Analyses of Groundwater Flow, Contaminant Fate and Transport, and Distribution of Drinking Water at Tarawa Terrace and Vicinity, U.S. Marine Corps Base Camp Lejeune, North Carolina: Historical Reconstruction and Present-Day Conditions—Chapter A: Summary of Findings. Atlanta, GA: Agency for Toxic Substances and Disease Registry; 2007.

Sonnenfeld N, Hertz-Picciotto I, and Kaye WE. Tetrachloroethylene in Drinking Water and Birth Outcomes at the U.S. Marine Corps Base at Camp Lejeune, North Carolina. *American Journal of Epidemiology*. 2001;154(10):902-908.