Morbidity study of former Marines, dependents, and employees potentially exposed to contaminated drinking water at USMC Base Camp Lejeune

Supporting Statement

Part A

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SUPPORTING STATEMENT PART A FOR OMB REVIEW AND APPROVAL

OF

Morbidity Study of former Marines, dependents, and employees potentially exposed to contaminated drinking water at USMC Camp Lejeune

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request (ICR). U.S. Marine Corps (USMC) Base Camp Lejeune, North Carolina was established in 1942. In 1982, the Marine Corps discovered specific volatile organic compounds (VOCs) in the drinking water provided by two of the eight water treatment plants on base. On January 28, 2008, President Bush signed H.R. 4986: National Defense Authorization Act for Fiscal Year 2008 (see Attachment A) which requires the Agency for Toxic Substances and Disease Registry (ATSDR) to develop a health survey of individuals possibly exposed to contaminated drinking water at Camp Lejeune that would collect: "…personal health information that may lead to scientifically useful health information associated with exposure to trichloroethylene (TCE), [tetrachloroethylene or perchloroethylene] (PCE), vinyl chloride, and the other contaminants identified in the ATSDR studies that may provide a basis for further reliable scientific studies of potentially adverse health impacts of exposure to contaminated water at Camp Lejeune." The Act requires the survey to be developed within 120 days of enactment and to be conducted within one year of enactment. There is therefore an urgency to obtaining OMB/PRA approval as quickly as possible so that ATSDR can meet this legislative mandate.

Additionally, in 2005, ATSDR convened a Scientific Advisory Expert Panel to explore opportunities for conducting additional health studies at Camp Lejeune. The panel recommended that the agency:

- Identify cohorts of individuals with potential exposure, including adults who lived on base; adults who resided off base, but worked on base; children who lived on base; and those who may have been exposed while in utero; and
- Conduct a feasibility assessment to address the issues involved in planning future studies of mortality, cancer incidence, and other health outcomes of interest at the base.

In response, ATSDR prepared a report on the feasibility of conducting future epidemiological studies at the base. ATSDR concluded that it is feasible to use the health survey to evaluate cancer incidence using available Department of Defense (DOD) personnel databases to identify active duty Marine and Navy personnel and civilian employees who were stationed at the base during the period when the Hadnot Point and Tarawa Terrace drinking water systems were contaminated with VOCs.

As specified by law, the health survey will be mailed to everyone identified as having lived or worked at Camp Lejeune during the period of drinking water contamination. This includes anyone who registers with the USMC or ATSDR as well as those identified by computerized databases from the Defense Manpower Data Center (DMDC) or ATSDR. However, in order to have an unbiased sampling frame, the study population will consist of those identified by computerized databases who lived or worked at Camp Lejeune during the period of drinking water contamination. Included in the study population will be those with accurate and complete addresses among the

Marine and Naval personnel identified by DMDC who were stationed at Camp Lejeune any time during the period June 1975 to December 1985; civilians identified by DMDC as having worked at Camp Lejeune anytime during the period December 1972 to December 1985; the parents and children (who are now adults) included in the 1999-2002 ATSDR survey of 12,598 births who were carried or conceived at Camp Lejeune during 1968-1985; and a comparison group randomly sampled from Marines and civilian employees who were stationed at Camp Pendleton during 1975-1985 and never stationed at Camp Lejeune during the period of drinking water contamination. Prior to June 1975, the DMDC personnel data on active duty Marines and Navy personnel did not have the unit code which is the basis for determining where the individual was stationed. The DMDC civilian personnel file has data starting in December 1972. Some active duty Marines will be included in both the DMDC and the ATSDR databases.

The law also required the USMC to provide information concerning the drinking water contamination to former Marines, dependents, and civilians that lived or worked at Camp Lejeune through 1987. In order to notify as many people as possible, the USMC embarked on an extensive media campaign and created a notification registry. As of September 28, 2009, more than 140,000 individuals have registered with the USMC; however, there is considerable overlap between the DMDC-identified cohorts, the ATSDR 1999-2002 survey participants, and the USMC registry. The "registered group", consisting of individuals identified solely by the fact that they registered with the USMC or ATSDR, will not be included in the study population because they possibly constitute a biased sample (e.g., because those who registered may have more health problems and may know they

were exposed compared to those who did not register). Instead, the health surveys completed by this group will be analyzed separately.

ATSDR plans to contact approximately 247,000 former Camp Lejeune residents and employees (210,000 former active duty Marines and Navy personnel; 8,000 former civilian workers; and approximately 29,000 former Marines and Navy personnel and their dependents who lived at Camp Lejeune during the period of drinking water contamination and were included in the 1999-2002 ATSDR survey [i.e., about 4,000 former Marines and Navy personnel not included in the DMDC data, and about 12,500 spouses and 12,500 children, now adults, who were included in the ATSDR survey]). ATSDR also plans to contact 50,000 Marines and 10,000 civilians stationed or employed at Camp Pendleton anytime during the period 1975-1985 who were never stationed at Camp Lejeune during the period of drinking water contamination.

Camp Pendleton was chosen for the comparison population because the base is similar to Camp Lejeune. Camp Pendleton provides training for Marines residing west of the Mississippi while Camp Lejeune provides training for Marines residing east of the Mississippi. Camp Pendleton has toxic waste sites just like Camp Lejeune. The major difference is that Camp Pendleton did not have a contaminated drinking water supply. Additionally, the available personnel records are similar for both bases. The inclusion of the Camp Pendleton samples would address two major issues: (1) inadequate statistical power for internal comparisons because there may be too few members of the Camp Lejeune cohorts who are unexposed to the drinking water contamination and (2) doubts that have been raised concerning whether anyone was unexposed to contaminated drinking water at the base (e.g., because of water consumption during field training and

the use of Hadnot Point water to re-supply the Holcomb Boulevard system during summer months when the golf courses were watered).

ATSDR will also send surveys to those who registered with the USMC but who were not included in the DMDC or ATSDR survey databases ("registered group"). The "registered group" is not included in the study population but will be mailed a survey in order to comply with the Congressional mandate. Since registration is ongoing, it is not known how large the "registered group" will be at the time the surveys are mailed. However, we anticipate that this group could be as large as 50,000.

This ICR proposes to examine the relationship between specific cancers or non-fatal, non-cancer diseases (Parkinson's disease, kidney failure and other severe kidney diseases, severe liver diseases, lupus, aplastic anemia, TCE-related skin disorders, scleroderma, multiple sclerosis, amyotrophic lateral sclerosis, infertility, endometriosis and miscarriages) and exposures to drinking water contaminated with volatile organic compounds including TCE,PCE, and BTEX (benzene, toluene, ethylbenzene and xylenes). The survey questions will be constructed to obtain sufficient information on cancers and other diseases to facilitate medical records confirmation.

The exposure assessment will be based on the levels of contamination in the drinking water serving the person's residence on base or, for civilian employees working on base, the drinking water serving their workplace location. Historical monthly averages of the levels of contaminants in the drinking water systems at the base will be estimated using available water data and mathematical models of (1) groundwater contamination fate and transport and (2) the water distribution systems. The primary exposure assessment will be based on the contaminant levels in the drinking water serving

the person's residence (or workplace for civilian employees). Each month of residence (or employment) will be linked to the estimated levels of contaminants in the drinking water serving that location for that month. The person's cumulative exposure will be calculated as well as the average exposure, maximum exposure, and exposure duration. Cumulative exposure, average exposure, maximum exposure, and exposure duration will also be categorized *a priori* into meaningful categories (based on the contaminant level distribution) and using a smoothing technique (e.g., LOESS). Other possible exposures (i.e., to contaminated drinking water at the work location of the active duty personnel or by working with solvents in the motor pool) will be explored if sufficient information is obtained from the health survey and personnel databases to assess these exposures.

The military occupation specialty (MOS) code will be obtained from the DMDC data on active duty personnel. Based on discussions with knowledgeable former Marines and current occupational hygiene employees at Camp Lejeune, ATSDR obtained information on the types of chemicals used in various military and civilian occupations at the base. The MOS codes will be linked to this information to assess potential exposures to chemicals at the workplace. The locations of these workplaces (and the water system serving these locations) will be based on further discussions with knowledgeable former Marines and current staff at Camp Lejeune. Drinking water in the field was provided in tanks and "buffaloes"; the water could have come from anywhere on base, but most likely came from Hadnot Point. For this reason, it was deemed possible that all active duty personnel were exposed to contaminated drinking water at Camp Lejeune during their field training and this will be addressed in the data analysis.

Determining the water quality at residences and workplaces at Camp Lejeune is simplified by the fact that, within each water system, the water was completely mixed so all locations served by a water system received similar levels of contamination. It is therefore only necessary to determine which broad area of the base the residence or workplace is located. The information from the family housing records (for married active duty personnel), the unit identification codes (for single active duty personnel), the MOS code (for active duty workplaces), and the occupation code (for civilian employees), when combined with the information obtained from command chronologies and discussions with knowledgeable former Marines and current base staff, is sufficient to identify the area of the base where a residence or workplace was located and to determine which water system served that residence or workplace.

The information gained during the proposed ICR will help advance research on this topic and may help future populations. Very few studies have been conducted that evaluated estimated contaminant levels of PCE or TCE in public water systems and adult cancers. For example, only two studies have been conducted of TCE-contaminated public drinking water supplies and adult cancers, and both of these studies evaluated towns in northern New Jersey (Fagliano et al 1990; Cohn et al. 1994). Only two populations exposed to PCE-contaminated public drinking water supplies have been studied for the risk of adult cancers: northern NJ and the Upper Cape Cod, MA (Aschengrau et al. 1993; Aschengrau et al. 1998; Aschengrau et al. 2003; Paulu et al. 1999; Fagliano et al 1990; Cohn et al. 1994). No studies have been conducted of public water systems contaminated with TCE or PCE and the risks of medically confirmed, non-cancer diseases.

Privacy Impact Assessment

(i) Overview of the data collection system

The 60 day Federal Register Notice (see Attachment B) provides an overview of the data collection system. The survey is included as Attachment C. Using Dillman's Tailored Design Method (Dillman 2007), participants will be mailed a personalized pre-notice letter signed by the highest ranking officer of the USMC (see Attachment D) explaining that a survey would be arriving soon and encouraging participation. A personalized letter of invitation (see Attachment E), hardcopy survey (see Attachment C), and a preaddressed stamped return envelope will be mailed one-two weeks after the pre-notice letter; the letter of invitation will also direct participants to a web-based version of the survey if they prefer to answer on-line. An e-mail invitation (see Attachment F) will also be sent when an e-mail address is available. Within two weeks, a stamped postcard reminder/thank you (see Attachment G) will be sent via U.S. mail as well as an email reminder/thank you (see Attachment H) if possible. A second survey mailed with a letter (see Attachment I) similar to the initial survey mailing and a second email reminder (see Attachment J) if possible will be sent to those participants who have not responded within four weeks after receiving the postcard reminder. Included with the mailing will be a postcard to be completed by people who chose not to participate. Telephone reminders (see Attachment K) will also be conducted if participants have not responded to the survey within two weeks after the second mailing. Registrants only will be mailed pre-notice and invitation letters (see Attachments D and E); the Dillman Total Design Method will not be employed. Informed consent, either hardcopy or electronic, will be obtained from the participants; instructions for submitting the informed consent are

provided (see Attachment L). Registrants only will have a separate informed consent (see Attachment M). The information will be maintained for 20 years. The protocol for the data collection instrument is included as Attachment N.

(ii) Items of information to be collected

The following Information in Identifiable Form (IIF) will be collected: name, date of birth, social security number, address, telephone number, medical information, email address, military status, employment status, and other. The health survey will collect information on the following diseases an individual may have had that were diagnosed by a health provider: any cancer, Parkinson's disease, kidney failure and other severe kidney diseases, severe liver diseases, lupus, aplastic anemia, TCE-related skin disorders, scleroderma, multiple sclerosis, motor neuron disease/amyotrophic lateral sclerosis, infertility and endometriosis. Self-reported cancers and other diseases will be confirmed by medical records or cancer registrations. In order to facilitate the acquisition of medical records, the survey will request information about the type of disease, the date of diagnosis, the hospital of diagnosis, and doctor who diagnosed the disease. For cancers, state of diagnosis will also be obtained to facilitate acquisition of cancer registry data. In addition, to facilitate medical record confirmation, the participant will be asked to provide a copy of the medical record to ATSDR or to sign a medical records release form (Attachment O) allowing ATSDR to gain access to the medical record.

The health survey will also include questions on miscarriages occurring to women who were pregnant while residing or working on base. Because medical records are generally unavailable for miscarriages, no attempt will be made to confirm self-reports of miscarriages. Instead, two questions shown to improve the accuracy of self-reports of miscarriages will be included in the survey: "Did you have a positive pregnancy test before

the miscarriage occurred?" and "Was the miscarriage confirmed by a physician or other health provider?" (Axelsson 1990). A miscarriage will be considered "confirmed" if the respondent answers affirmatively to both questions.

The survey will also collect information on residential history on base, an occupational history, and information on several risk factors (e.g., socio-economic status, demographics, smoking, alcohol consumption, etc). A space will also be provided so that the respondent can report other disease conditions. The collected information will be used to assign exposure status and to assess potential confounding.

(iii) Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

No web site will be directed at children under 13 years of age. The website will only be directed at adults. The information collection (IC) involves web-based data collection. Computerized data analysis files will contain identification numbers only. To access the web-based survey, participants will receive a Personal Identification Number (PIN) to be used for authentication to ensure that only the study population can participate in the survey and that the survey is not completed more than once by the same participant. Data collected over the internet will be transmitted in an encrypted format to ensure that any data intercepted during transmission cannot be decoded; data will also be stored in an encrypted format on password-controlled servers to protect personally identifiable information. No cookies will be used. The on-line consent form will specify the rules of conduct and the privacy policy.

A.2. Purpose and Use of Information Collection

This IC fulfills ATSDR's responsibilities under H.R. 4986: National Defense Authorization Act for Fiscal Year 2008 which requires the Agency for Toxic Substance

and Disease Registry (ATSDR) to develop a health survey of individuals possibly exposed to contaminated drinking water at Camp Lejeune that would collect personal health information that may provide a basis for further reliable scientific studies of potentially adverse health impacts of exposure to contaminated water at Camp Lejeune. This IC is also responsive to the recommendations made by the 2005 Scientific Advisory Expert Panel and to the Community Assistance Panel (CAP) created by ATSDR to voice the concerns of the affected community of marines and their families and to provide input for future health studies.

This IC targets the Centers for Disease Control and Prevention's (CDC) mission category of Applied Research, Scientific Assessments, Research and Information Dissemination and research theme of Health Effects of Toxic Exposures. ATSDR will use the data collected to 1) describe exposures to hazardous substances in the study population, 2) determine the risk between cancers and specific non-fatal diseases and VOC-contaminated water, and 3) make recommendations based on the findings. The results will allow ATSDR to better understand the impact of exposures to hazardous substances at Camp Lejeune, North Carolina. The purpose of understanding exposure-disease associations through basic research of this type is the implementation of primary prevention. Primary prevention should eliminate cancers and specific non-fatal diseases of hazardous waste site etiology in the general public, so that the attributable risk approaches zero.

Privacy Impact Assessment Information

This IC will be used to examine the relationship between medically confirmed cancers and other non-cancer diseases and VOC-contaminated drinking water by

estimating the historical monthly and annual average levels of contaminants in the drinking water serving residences and workplaces at Camp Lejeune. Groundwater contamination fate and transport models and water distribution system models will be used to make these estimations.

The relationship between the following diseases that can be confirmed by medical records and VOC-contaminated drinking water will also be examined: Parkinson's disease, kidney failure and other severe kidney diseases, severe liver diseases, lupus, aplastic anemia, TCE-related skin disorders, scleroderma, multiple sclerosis, amyotrophic lateral sclerosis, infertility and endometriosis. The health survey will also evaluate miscarriages occurring to women who were pregnant while residing or working on base.

Sensitive information will be collected in this IC and there would likely be an effect on the respondent's privacy if there were a breach of confidentiality. In collecting information, ATSDR's contractor must verify full names and locating information on respondents because certain information (date of birth, social security number) must be verified or obtained in order to conduct the study and analyze the data. Privacy Act clauses will be included in the contract to protect against inappropriate data disclosures. Records will become part of the ATSDR Privacy Act system of records 09-19-0001, "Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances". Under the Privacy Act of 1974 (5 U.S.C. Section 552(e)), employees of federal agencies are responsible for protecting data collected on identifiable persons or organizations where the supplier of information has not given the agency consent to make that data public. This responsibility for protection includes unauthorized visual observation of private material, accidental loss, and theft of data. Accordingly, private records will be

kept out of sight of unauthorized persons, stored in locked cabinets or locked in rooms when not being used, copied only when absolutely necessary, and stored in sealed containers when transferred to archives. To assure privacy and confidentiality, each participant will be assigned a unique identification number that will be placed on the survey, consent forms, and any other information collected from the participant. Computerized data analysis files will contain identification numbers only.

To access the web-based survey, participants will receive a PIN to be used for authentication to ensure that only the study population can participate in the survey and that the survey is not completed more than once by the same participant. Data collected over the internet will be transmitted in an encrypted format to ensure that any data intercepted during transmission cannot be decoded; data will also be stored in an encrypted format on password-controlled servers to protect personally identifiable information.

ATSDR will publish a final report of the study which will be distributed to the general public. Reports of statistics derived from private data will be presented in aggregate form in such a way as to avoid inadvertent disclosure about specific study subjects. Final reports from this study will not contain medical information or findings in association with any individual subject. Because the study population is dispersed over a wide geographic area, ATSDR will develop a web broadcast that discusses the results of the study. Study participants will be mailed a letter that provides the internet address for the web broadcast and also tells them how to receive a copy of the web broadcast on CD-ROM if they do not have internet access. The web broadcast will be archived on the ATSDR Camp Lejeune website for later viewing.

A.3. Use of Improved Information Technology and Burden Reduction

Respondents will be offered a choice of response formats for data collection (completion of a paper survey or a web-based survey). ATSDR expects 33% of the respondents to respond using the web-based survey. Respondents can participate at a time convenient to them (the paper survey or web-based survey will be available any time of day). This IC will only collect the minimum information necessary for the purposes of this project.

A.4. Efforts to Identify Duplication and Use of Similar Information

ATSDR is not aware of any other agency that is presently collecting this type of data. This knowledge comes from literature searches and communication with other agencies, including the USMC. No similar data are available to investigate the associations between specific cancers and non-cancer diseases and exposures to VOCs in drinking water at Camp Lejeune. Except for the few types of adult cancers that were evaluated in studies of a population in northern New Jersey and a population in Cape Cod, MA, there are no human data on the relationships between exposures to VOCs in public drinking water and adult cancers and non-cancer diseases.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses or other small entities will be affected by this data collection.

A.6. Consequences of Collecting the Information Less Frequently

On January 28, 2008, President Bush signed H.R. 4986: National Defense Authorization Act for Fiscal Year 2008. The act requires ATSDR to develop a health survey of individuals possibly exposed to contaminated drinking water at Camp Lejeune within 120 days of enactment and to conduct the survey within one year of enactment. If the data collection is not conducted, ATSDR will not be in compliance with the

requirements of this act. This request is for a one time study. There are no legal obstacles to reduce the burden.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day notice was published in the *Federal Register* on July 16, 2008, Volume 73, Number 137, Page 40876 (see Attachment B). No comments were received in response to the *Federal Register* notice.

B. The following individuals were consulted on March 18, 2008 to provide recommendations on the data elements to be included in the survey and on the methods of survey conduct:

1. Han Kang, Dr. PH
Director, Environmental Epidemiology Service
Department of Veteran Affairs
202-254-0370
han.kang@va.gov

2. Kyle Steenland, PhD
Professor, Department of Environmental Health
Rollins School of Public Health
Emory University
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3. Elizabeth Denzell, SD
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Department of Epidemiology & International Health
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4. Richard Clapp, ScD, MPH
Professor, Environmental Health
Boston University

617-638-4731
rclapp@bu.edu or richard.clapp@gmail.com

5. Kenneth P. Cantor, Ph.D., M.P.H.
Senior Investigator, National Cancer Institute
Executive Plaza South, Room 8106
301-435-4718
cantork@mail.nih.gov

6. Maria Schymura, Ph.D
Director, New York State Cancer Registry
518-474-2255
mjs08@health.state.ny.us

7. Chris Rennix, CIH, Sc.D
Division Officer, Epidata Center Division
Health Promotion and Preventive Medicine Department
Navy and Marine Corps Public Health Center
757-953-0955
rennixc@nehc.med.navy.mil

Representatives of those from whom information is to be obtained are members of the Camp Lejeune Community Assistance Panel (CAP) and meet quarterly with ATSDR. The CAP has reviewed the content of the survey and the survey methodology in the protocol (see Attachment N). Members of the CAP are:

1. Jeff Byron – community member
4050 Schroeder Drive
Hamilton, Ohio 45011
513-860-5810 home
513-543-0268 cell
Byron768@aol.com

2. Jerry Ensminger – community member
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3. Tom Townsend – community member
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4. Sandra Bridges – community member
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5. Mike Partain – community member
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6. Richard Clapp, ScD, MPH
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7. Mary Ann Simmons
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Portsmouth, VA 23708-2103
757-953-0945 office
757-274-5490 cell
maryann.simmons@med.navy.mil

The following individuals served as peer reviewers of the protocol; the comments and recommendations provided by these reviewers involved clarifications and more details on data analysis being added to the protocol.

1. Elizabeth Delzell, SD
University of Alabama at Birmingham - School of Public Health
Department of Epidemiology & International Health
Birmingham, AL 35294-0022
(205) 934-5857
Email: edelzell@epi.soph.uab.edu

2. Han Kang, DrPH
Director, Environmental Epidemiology Service
Department of Veteran Affairs

202-254-0370
Email: han.kang@va.gov

3. Leslie Stayner, PhD
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University of Illinois Chicago School of Public Health (M/C 923)
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Chicago, IL 60612
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A.9. Explanation of Any Payment of Gift to Respondents

There are no payments or gifts made to the respondents.

A.10. Assurance of Confidentiality Provided to Respondents

ATSDR's contractor must verify full names and locating information on respondents because certain information (i.e., medical history) must be verified or obtained in order to conduct the study and analyze the data. Response data will be collected in identifiable form. The survey page with personal identifiers will be stored separately from the rest of the survey. Each participant will be assigned a unique identification number that will be placed on the survey, consent forms, and any other information collected from the participant. Both ATSDR and the contractor will have access to the list linking names to identification numbers; therefore, the Privacy Act applies. All records will be maintained in compliance with the Privacy Act of 1974.

IRB Approval

The protocol (see Attachment N) received CDC Institutional Review Board (IRB) approval on 11/12/2008 (see Attachment P) and IRB approval for amendments on 3/15/2010 (see Attachment Q).

Privacy Impact Assessment Information

A. This submission has been reviewed and it has been determined that the Privacy Act does apply. The applicable System of Records Notice is 09-19-0001, "Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances."

B. Under the Privacy Act of 1974 (5 U.S.C. Section 552(e)), employees of federal agencies are responsible for protecting data collected on identifiable persons or organizations where the supplier of information has not given the agency consent to make that data public. This responsibility for protection includes unauthorized visual observation of private material, accidental loss, and theft of data. Data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Accordingly, private records will be kept out of sight of unauthorized persons, stored in locked cabinets or locked in rooms when not being used, copied only when absolutely necessary, and stored in sealed containers when transferred to archives. Computerized data analysis files will contain identification numbers only. Safeguarding measures will include limiting access to files to a small number of authorized staff, password protecting computer files, and utilizing a computer system with security measures that protect information against accidental loss and theft. Privacy Act clauses will be included in the contract to protect against inappropriate data disclosures. Data collected over the internet will be transmitted in an encrypted format to ensure that any data intercepted during transmission cannot be decoded; data will also be stored in an encrypted format on password-controlled servers to protect personally identifiable information.

C. All respondents will be asked to give consent before participating in the survey (see Attachments L and M). Respondents participating using the hard copy survey will be asked to sign the consent form and mail it back in the pre-addressed stamped envelope provided. An extra copy of the consent form will be enclosed for their records. Respondents participating using the web-based survey will be asked to click on the "I agree" button and will be informed that they can print a copy of the consent form for their records. The consent form specifies that if the respondent signs the medical release form (see Attachment O), ATSDR will be able to read and use information about respondents that is kept in medical records and other restricted files. The consent form tells respondents that no data that identifies them or where they live will be included in any report.

D. Respondents will be informed that providing the requested information is entirely voluntary. The consent form specifies that if respondents choose not to participate there will be no penalty and they will not lose any benefits if they decide not to continue. ATSDR will publish a final report of the study which will be distributed to the general public. Reports of statistics derived from private data will be presented in such a way as to avoid inadvertent disclosure about specific study subjects. Final reports from this study will not contain medical information or findings in association with any individual subject. Because the study population is dispersed over a wide geographic area, ATSDR will develop a web broadcast that discusses the results of the study. Study participants will be mailed a letter that provides the internet address for the web broadcast and also tells them how to receive a copy of the web broadcast on CD-ROM if they do not have

internet access. The web broadcast will be archived on the ATSDR Camp Lejeune website for later viewing. Participants will not be provided with individualized study results. Data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

A.11. Justification for Sensitive Questions

No information will be collected regarding sexual behaviour and attitudes, religious beliefs, or illegal drug use. However, some of the questions can be considered sensitive by at least some of the population. The questions included are necessary for the successful completion of the study. Questions regarding smoking and alcohol consumption and race and ethnicity are included because they may be potential risk factors for the health outcomes of interest. Questions regarding medical conditions are necessary to assess if there are any associations between the particular health outcomes and VOC-contaminated drinking water at Camp Lejeune. It is necessary to obtain Social Security Numbers (SSNs) in order to link the respondent with their medical data. The data collection form (see Attachment C) specifies that the SSN will kept private and will ONLY be used if we need to link the respondent with their medical data.

A.12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

Respondents will be interviewed once using the same form. The questionnaire takes no more than 45 minutes. The burden was determined by pilot testing the questionnaire on five volunteers. With the assumption of a 40% response rate, the total burden for the three year approval time we are requesting, combining the study population and the "registered group," is based on a maximum of 142,803 respondents for a burden of 108,600 hours;

the annualized burden for the three years is 36,200 hours from 47,601 respondents. We are seeking approval for 3 years to collect the information due to the time involved in obtaining and editing the necessary data from the DMDC, locating and contacting the potential respondents, and confirming self-reported diagnoses with health providers and cancer registries.

Table A12. Total annualized burden (three years)

Type of Respondent	**No. of Respondents**	**No. Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden Hours**
Former active duty marines and navy personnel – Camp Lejeune	28,000	1	45/60	21,000
Former civilian workers – Camp Lejeune	1,067	1	45/60	800
Former dependents (now all adults) and former Marines who lived at Camp Lejeune and were identified only through the 1999-2002 ATSDR survey	3,867	1	45/60	2,900
Former active duty marines and navy personnel – Camp Pendleton	6,667	1	45/60	5,000
Former civilian workers – Camp Pendleton	1,333	1	45/60	1,000
"Registered Group"	6,667	1	45/60	5,000
Total	**47,601**			**35,700**

The annualized cost for each of three years is $608,685.00 as shown below.

Table B12. Estimated Annualized Burden Costs (three years total)

Type of Respondent	**No. of Respondents**	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**

Former active duty marines and navy personnel – Camp Lejeune	28,000	21,000	$17.05	$358,050.00
Former civilian workers – Camp Lejeune	1,067	800	$17.05	$13,640.00
Former dependents (now all adults) and former Marines who lived at Camp Lejeune and were identified only through the 1999-2002 ATSDR survey	3,867	2,900	$17.05	$49,445.00
Former active duty marines and navy personnel – Camp Pendleton	6,667	5,000	$17.05	$85,250.00
Former civilian workers – Camp Pendleton	1,333	1,000	$17.05	$17050.00
"Registered Group"	6,667	5,000	$17.05	$85,250.00
Total	**47,601**	**35,700**		**$608,685.0**

The hourly wage rate is based on the US Department of Labor, Bureau of Labor Statistics 2009 annual median hourly earnings of full time private industry employees (http://www.bls.gov/ncs/ocs/sp/nctb1347.txt). All of the participants are adults, and the vast majority are between the ages of 40 and 55 (e.g., they began active duty as a Marine after high school graduation during the period 1975-1985). The dependents of these Marines will have similar ages (spouses) or will be younger. Therefore, we assumed that most of the participants are not retired and working in the private sector.

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital, start-up, or maintenance costs to the respondents resulting from this information collection.

A.14. Annualized Cost to the Government

The total cost to the federal government for the collection of this information for the three-year project is $14,700,000 as itemized below.

Contractor	$13,500,000
Office, supplies, printing, mailing..	$195,000
ATSDR personnel costs	$1,000,000
Travel	$5,000
Total figure	$14,700,000

These figures are based on a total of 142803 respondents. The average **annual cost** for this three- year project would be $4,900,000. Funds for this project are to be provided by the Department of Navy.

A.15. Explanation for Program Changes of Adjustments

This is a new data collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

A.16-1 Project Time Schedule	
Activity	**Time Schedule**
Edit mailing list and obtain current contact information for respondents	1-2 months after contractor IRB approval
Surveys sent to respondents	2-4 months after OMB approval **(note: H.R 4986: National Defense Authorization Act for Fiscal Year 2008 [signed on January 28, 2008] requires the survey to be conducted within one year of the date of enactment; additionally surveys cannot be sent out until the 2010 Census is completed)**
Expert panel meeting and recommendations for medical confirmations	2-4 months after OMB approval
Data processing Patient records management QA/QC	9-25 months after OMB approval
Begin preliminary data analyses concurrent with data processing and patient records management; finalize data analyses; draft final report	26– 30 months after OMB approval
Peer review, public comment, and agency clearance of report	31 – 33 months after OMB approval
Publish final report	34 months after OMB approval

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The expiration date for OMB approval of the information collection will be displayed.

A.18. Exceptions to Certification for Paperwork Reduction act Submissions

There are no exceptions to the certification.

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