U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON SCIENCE AND TECHNOLOGY

SUITE 2321 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515–6301 (202) 225–6375 http://science.house.gov

November 10, 2009

Dr. Ralph Cicerone President, National Academy of Sciences 500 Fifth Street, NW Washington, DC 20001

Dear Dr. Cicerone,

In May of this year, the National Academy of Sciences (NAS) contracted with the Department of Defense (DOD) to evaluate issues "pertaining to epidemiologic study protocol and design, exposure assessment, health issues, or environmental impacts related to historic drinking water exposures at U.S Marine Corps Base Camp Lejeune."¹ The DOD task order calls on NAS to:

"Produce one letter report by May 1, 2010 evaluating at least one study protocol, epidemiologic study, or health survey. The Contractor shall produce at least one additional letter report by November 1, 2010 evaluating an additional research question."²

Within a few weeks of the task order being issued, your Committee on Contaminated Drinking Water at Camp Lejeune issued their long-anticipated report, <u>Contaminated Water</u> <u>Supplies at Camp Lejeune: Assessing Potential Health Effects</u>. This report was commissioned at the direction of Congress in the 2007 National Defense Authorization bill. This statute states:

"In conducting the review and evaluation, the Academy shall include a review and evaluation of . . . the completed and on-going Agency for Toxic Substances Disease Registry (ATSDR) studies on potential trichloroethylene and tetrachloroethylene exposure at Camp Lejeune."³

Given that NAS was in the process of completing a congressionally mandated report that included a review of pending Lejeune studies at ATSDR, it is not clear why the Academies would

³ P.L. 109-364. pp. 2143-2144

¹ Quotes from a DOD "Order for Supplies or Services" dated May 1, 2009, p. 6. The task order is attached to this letter. ² Ibid, p. 7.

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enter into a second contract with the Department of the Navy (DON) to evaluate the same studies it was then reviewing. The finalized report makes multiple recommendations regarding the direction of proposed future ATSDR studies on Camp Lejeune drinking water, including the study of birth outcomes and the health survey. This second contract appears to be duplicative of the first, as the "Contaminated Water Supplies at Camp Lejeune" report had already fulfilled Congressional intent to review the work of ATSDR.

The findings of this first report also call into question the wisdom of accepting a contract with DOD to evaluate future proposed studies. The congressionally directed report concluded that further studies were not necessary for the Navy and Marine Corps to make a decision for how to deal with veterans and their families.⁴ In light of the findings, only made final with the report's release on June 13, 2009, it seems inappropriate for the Academy to remain under a contract for services with DOD to evaluate proposed Lejeune studies that the Academy has already concluded are unnecessary.

In addition to questioning the wisdom of entering into another contract, we are particularly concerned about the open nature of this new contract to review the work of ATSDR, which states:

"A committee under the oversight of the Standing Committee on Toxicology will respond, in letter report form, to *research questions posed by the United States Marine Corps (USMC)* pertaining to epidemiologic study protocol and design, exposure assessment, health issues, or environmental impacts related to historic drinking water exposures at U.S. Marine Corps Base Camp Lejeune" (*emphasis added*).⁵

The lack of a stated, specific report topic or area of study creates the appearance that the Department of the Navy is using NAS to inject uncertainty into ATSDR's studies, when their research questions or findings are at odds with the DON's own preferred findings. As it stands, the Navy has made representations in Congress that the highly regarded National Academy is still involved in reviews of Lejeune work. NAS's involvement with ATSDR studies has the potential to slow down the important work of ATSDR. By this contract, the Academy may be putting itself into a position where their ongoing studies create a "paralysis by analysis" situation.

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) established ATSDR as the government agency responsible for assessing the presence and nature of health hazards at specific Superfund sites such as Camp Lejeune.⁶ While the Committee on Toxicology (COT) at NAS has provided valuable toxicological services to DOD since 1947, *ATSDR, not COT, has the statutory responsibility to study the public health impacts from contamination at Superfund sites.* ATSDR appropriately considered information from multiple sources when developing its plans for future studies of contaminated drinking water and health

⁶ 42 U.S.C 9604(i)

 ⁴ Committee on Contaminated Drinking Water at Camp Lejeune; National Research Council, <u>Contaminated Water</u>
 <u>Supplies at Camp Lejeune</u>: <u>Assessing Potential Health Effects</u>, (National Academies Press, Washington D.C.: 2009).
 ⁵ Ibid. p.6.

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effects at Camp Lejeune. These sources include its own internal assessment of the feasibility for future studies, recommendations from a 2009 Expert Panel which assessed ATSDR's plans to reconstruct the history of drinking water contamination, comments from the Community Assistance Panel, and the findings and recommendations of your own June 2009 report.

Given that the Academy has already weighed in on proposed ATSDR studies, and given the strong argument by the NAS's own Committee on Contaminated Drinking Water at Camp Lejeune that they do not believe further study is needed for policy decisions to be made, I strongly encourage you to withdraw from this agreement for further study. The Academy does not have a clear role moving forward and further involvement in the proposed studies seems to serve no point but to stall real work and real choices. I greatly appreciate the role that NAS plays in national scientific dialogues, and we hope that the Academy will not allow itself to be used to delay or derail efforts to provide answers to the men and women who served at Camp Lejeune.

Sincerely,

Pard Ste

Brad Miller Chairman Subcommittee on Investigations and Oversight

The Honorable Bart Stupak Chairman

Subcommittee on Investigations and Oversight House Committee on Energy and Commerce

Dr. Thomas Sinks Deputy Director National Center for Environmental Health/ Agency for Toxic Substances and Disease Registry Center for Disease Control

CC:

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Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	EST . QUANTITY	UNIT	UNIT PRICE	AMOUNT
2003AB	,	QU	Dollars, U.S.		\$600,000.00
EXERCISED OPTION	Drinking Water at Camp L COST	ejeune Report			
	01 May 2009 through 01 N 01 May 2010 and an additi provide toxicology service	· · ·			
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	PURCHASE REQUEST N	IUMBER: W23M	WP8354S001		
				ESTIMATED COST	\$600,000.00 (EST.)
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ITEM NO 2003 EXERCISED OPTION	SUPPLIES/SERVICES	EST . QUANTITY	UNIT	UNIT PRICE	AMOUNT
	Special Toxicology Studie COST	S			\$0.00
	Special Toxicology Studies: 2nd Option Period of 29 September 2008 to 28 September 2009				
	FOB: Destination				
				ESTIMATED COST	\$0.00

1

Section C - Descriptions and Specifications

PWS - TASK ORDER 0005

PERFORMANCE WORK STATEMENT (PWS) FOR THE REVIEW OF THE ARMY'S ENHANCED PARTICULATE MATTER SURVEILLANCE PROJECT REPORT

C.1.0 GENERAL. The U.S. Army has had the responsibility of contracting for the toxicology services of the National Academy of Sciences (NAS) for the joint services since 1982. The NAS was chartered by Congress to conduct studies in the field of science when called upon by the Government. The Federal Government-NAS relationship is defined in the 1863 Congressional Act of Incorporation which required the Academy to investigate, examine, experiment, and report upon any subject of sciences. The primary resources for addressing the relevant needs of the Department of Defense (DoD) sponsors (Dept. of the Army, Dept. of the Air Force and Dept. of the Navy) are the NAS Committee on Toxicology (COT), its professional staff, and the staff and collection of the Toxicology Information Center (TIC). The combination of these resources, with broad policy guidance of the Board on Environmental Studies and Toxicology, provides an efficient and economic utilization of scientific expertise and technical support facilities. The purpose of this contract is to obtain surveys, analysis and studies from leading experts in the field of Toxicology as ordered by the Departments of the Army, Navy and Air Force. The Contractor shall execute its responsibilities under this contract in a manner that is consistent with the performance standards.

C.1.1. SCOPE OF WORK. The Department of Defense (DoD) has the need for the Committee on Toxicology (COT) and its staff to provide nonpersonal services for the following:

C.1.1.1. Evaluation of toxicity information: This service provides for an analysis of the quality and value of toxicological information. The COT and its staff will assemble and organize data and provide bibliographies for wide-ranging toxicologic subjects requested by the sponsor. The committee and its staff will assess the appropriateness and applicability of the data in the individual studies to the problems identified in specific requests from the sponsors. Since the time frame of response will vary from subject to subject, the COT will notify the sponsor within 30 days of receipt of the request of the time that it is expected to respond to a specific request.

C.1.1.2 Toxicologic advice: The forte of the National Research Council is its capacity to assemble the groups of leading scientific experts to deliberate issues. The COT has functioned well in this capacity for more than 57 years. The scope of its work has expanded considerably in recent years, and is reflected in the wide expertise of the current membership. The committee is composed of internationally known experts in toxicology, medicine, occupational medicine, industrial hygiene, immunotoxicology, pharmacokinetics, biochemistry, pharmacology, inhalation toxicology, neurotoxicology, epidemiology, and risk assessment. When needed, the committee also has been able to call upon additional scientists with expertise in particular areas to provide added strengths as appropriate.

C.1.1.3 Toxicology analysis: The role of the committee will be the in-depth analyses of requests for toxicologic advice, including specialized safety evaluations for military personnel. The committee will plan symposia and workshops to consider specific topics of interest to DoD which will result in proceedings or reports. The products of the committee's deliberations will be technical reports which are formally peer reviewed prior to transmittal to the sponsors.

C.1.1.4 Toxicology information collection: Collect and maintain toxicity information from published and unpublished sources on a wide variety of substances to which humans are exposed, occupationally and environmentally.

C.1.1.5 Toxicology Coordination: Assist in coordination of toxicology programs within the sponsoring agencies.

C.1.1.6 Information Source: Serve as a medium of exchange; of toxicity information among the sponsors and between the sponsors and the scientific community.

C.1.2. Relationship to Sponsoring Agency: Each sponsoring agency will be invited to designate liaison

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representatives to serve as formal channels for coordinating requests for assistance and fiscal support to the COT, its staff, and the TIC:

C.2 BACKGROUND. Marine Corps Base, Camp Lejeune covers approximately 233 square miles in Onslow County, North Carolina. It was established in the early 1940s and is the site of six major Marine Corps commands and two Navy commands, including reconnaissance, intelligence, infantry, artillery, and amphibious units.

C.2.1 In the early 1980s, as a result of testing for newly regulated chemicals (Total Trihalomethanes (TTHMs)), two then-unregulated chemicals (trichloroethylene (TCE) and tetrachloroethylene (PCE)) were discovered in some of Camp Lejeune's drinking water systems. It is uncertain as to when the chemicals first affected the groundwater. Some wells may have been impacted as early as the late 1950s. The groundwater was impacted as a result of past disposal practices, leaking storage tanks, and spills of practices of an off-base dry cleaning facility. All impacted drinking water wells were closed in 1985. Camp Lejeune was added to the U.S. Environmental Protection Agency National Priorities List (NPL) in October 1989. An agency within the Department of Health and Human Services, the Agency for Toxic Substances and Disease Registry (ATSDR), is mandated by Congress to assess the public health at all DoD installations listed on the NPL. The purpose of a Public Health Assessment (PHA) is to evaluate environmental data to assess any current or future impact on public health due to environmental conditions on the facility. Based on the results of the PHA, ATSDR may identify studies or actions needed to evaluate, mitigate, or prevent adverse human health effects. ATSDR completed the Camp Lejeune PHA in 1997. One issue the ATSDR evaluated was past exposure to PCEI/TCE in drinking water. They found no link between exposure to these solvents in drinking water and adverse health effects in adults. They did, however, recommend studying children in utero who may have been exposed to these chemicals that were in the drinking water.

C.2.2 Prior to 1985, some individuals at Marine Corps Base Camp Lejeune were exposed to TCE (trichloroethylene) and PCE (tetrachloroethylene) through drinking water. Some former residents have asked questions and raised concerns regarding their possible exposure and possible health consequences due to exposure to TCE and PCE. Trichloroethylene and tetrachloroethylene are common solvents used in industrial settings. Because of their wide use, they are also common environmental contaminants found at many National Priority List (NPL) and Superfund sites across the nation. Studies on animals have shown these chemicals can have a number of adverse health effects when animals are exposed at high concentrations. Numerous epidemiologic studies have been conducted on human populations exposed to TCE and PCE in occupational settings, and there is a growing body of literature on community exposures to these chemicals at lower levels that could be found within the environment. However, studies evaluating effects from non-occupational exposures are still limited. Several government and state agencies have or are in the process of conducting human health risk assessments on TCE and PCE, yet these too are limited and do not address the many questions and concerns of the former Camp Lejeune residents - specifically, whether there is a causal link between drinking water exposure at the levels projected at Camp Lejeune, and incidence of the spectrum of adverse health effects claimed by former residents. Upon completion of this review, the final report should bring clarity to this important issue.

C.2.3 The first study was published in 1998. The Agency for Toxic Substances disease Registry (ATSDR) reviewed birth outcomes of women who may have consumed the impacted drinking water at Camp Lejeune. The women included in the study lived in base housing during their pregnancy between January 1, 1968 and December 3 1, 1985. This study only looked at births at the base and did not include births occurring elsewhere. An evaluation of potential exposure to solvents was not included in the study. The ATSDR concluded there may be an association between exposure to the drinking water and small or decreased average birth weight for gestational age births in infants born to mothers over the age of 35 or in women who had a history of adverse pregnancy outcomes. The ATSDR qualified the association and stated that the results needed to be interpreted with caution because the study was based on a small sample group of potentially exposed births and did not consider confounding factors such as smoking, alcohol use and family history. They also concluded that the impacted drinking water and adverse pregnancy outcome(s) needed additional study. The ATSDR is currently conducting a follow-up study entitled: Exposure to Volatile Organic Compounds (VOCs) in Drinking Water and Specific Birth Defects and Childhood Cancers, United States Marine Corps Base Camp Lejeune, North Carolina. It is expected to be complete in December 2007/January 2008. This study shall assess exposure to VOCs in drinking water and specific birth defects and childhood cancers. Health effects being evaluated include spina bifida, anencephaly, cleft lip, cleft

palate, childhood leukemia, and childhood Non-Hodgkin's lymphoma. The study shall also include modeling of the drinking water systems to determine which VOCs participants might have been exposed to trichlorethylen/tetrachorethyle (TCE/IPCE) in the drinking water and at what concentrations.

C.2.4 In October 2004, Congress directed the GAO to review the history of drinking water quality at Camp Lejeune and ATSDR's ongoing health study, including the design of the ongoing study and the feasibility of studying additional groups at Camp Lejeune. The ATSDR's report Assessment of the Feasibility of Conduting Future Epidemiological Studies at USMC Base Camp Lejeune is now complete.

2.0 DEFINITIONS/ACRONYMS.

Committee on Toxicology (COT).

<u>Contracting Officer (KO)</u>. "Contracting Officer" means a person with the authority to enter into, administer, and/or terminate contracts and make related determinations and findings. The term includes certain authorized representatives of the contracting officer acting within the limits of their authority as delegated by the contracting officer. "Administrative contracting officer (ACO)" refers to a contracting officer who is administering contracts. A single contracting officer may be responsible for duties in any or all of these areas.

<u>Contracting Officer's Representative (COR)</u>. The on-site Government employee responsible for assisting in administration of the Government's quality assurance portion of the contract. This person is designated in writing by the Contracting Officer to be responsible for quality assurance, inspection, surveillance documentation and period acceptance of Contractor's performance. A copy of the letter of designation will be provided to the Contractor.

<u>Contracting Officer's Technical Representative (COTR)</u>. The on-site Government employee responsible for assisting in the technical administration of the Government's quality assurance portion of the contract. This person will function as the government's Subject Matter Expert (SME)</u>

<u>Contracting Officer's Client Representative (CR)</u>. The on-site Government employee functioning as the government's project manager, responsible for overseeing technical administration of the Government's quality assurance portion of the contract.

<u>Nonpersonal Services</u>. In the performance of this effort, the contract personnel are not subject to direct supervision between Governmet personnel and its employees.

Sponsoring Agency (SA) or Agency. Used interchangeably to refer to one of the three military departments, Army, Navy or Air Force.

Department of Defense (DoD).

National Research Council (NRC).

Quality Assurance Survelliance Plan (QASP).

Subject Matter Expert(SME)

Toxicology Information Center (TIC).

U.S. Army Center for Health Promotion and Preventative Medicine (USACHPPM).

C.3. GOVERNMENT REQUIREMENTS:

C.3.1. Acceptance of a report. The survey, analysis, and/or study answers the question that was posed using the current state of science/data available. This will be documented in the form of literature search sources and/or a list

of contributors/attendees as appropriate.

C.3.2. Three copies of each report shall be sent to:

Headquarters, U.S. Marine Corps Code LFL ATTN: Mr. Scott Williams 2 Navy Annex, Room 3109 Washington, DC 20380-1775

Department of the Navy Office of the Deputy Assistant Secretary of the Navy (Environment) Director Environmental Compliance and Restoration Policy ATTN: Mr. Richard Mach 1000 Navy Pentagon Washington, DC 20350-1000

Office of the Army Surgeon General ATTN: DASG-PPM-NC 5109 Leesburg Pike, Suite 538 Falls Church, VA 22041

U.S. Army Medical Command Health Care Acquisition Activity Center for Health Care Contracting ATTN: MCAA-C-CA (Mr. Gonzales) 2107 17th Street, Suite 68 Fort Sam Houston, TX 78234-5068

C.4. CONTACTOR REQUIREMENTS: The contractor shall provide all personnel, travel, supplies, and equipment required to perform the services required by this PWS.

C.4.1 A committee under the oversight of the Standing Committee on Toxicology will respond, in letter report form, to research questions posed by the United States Marine Corps (USMC) pertaining to epidemiologic study protocol and design, exposure assessment, health issues, or environmental impacts related to historic drinking water exposures at U.S. Marine Corps Base Camp Lejeune. For epidemiologic study protocols, review will be conducted after the Agency for Toxic Substances and Disease Registry has considered the findings and recommendations of the previous NRC committee report which evaluated the feasibility of conducting such studies. Additional research questions may be posed under this task order pertaining to epidemiologic study protocol and design, exposure assessment, health issues, or environmental impacts at Camp Lejeune or for related or similar USMC environmental issues. Contractor shall provide toxicology services in accordance with the requirements of the performance work statement and description stated in the task order. Contractor shall provide a quarterly status report every three months during the period of performance updating the Government on the committee's progress.

C.5. DELIVERABLES: Operating under the procedures of the National Research Council (NRC), the COT will provide independent multidisciplinary investigations and assessments on general and specific problems in the fields of toxicology, epidemiology, health hazards, health risk assessment, and related technology bearing on the mission of DoD. The COT and its subcommittees will be constituted to reflect the knowledge and experience necessary to provide an effective response to a broad range of DoD missions and responsibilities.

C.5.1. Surveys, Analyses, and Studies. Conduct surveys, analyses, and studies in the fields named above applicable

to the operation and function of the DoD. Studies will be performed by subcommittees established by the COT in accordance with established National Research Council procedures. The subjects of the requests cannot be predicted in detail, but the kinds of efforts which might be anticipated are:

C.5.1.1. Evaluations of health risks of emergency exposures to toxic substances for which there are no available exposure standards.

C.5.1.2. Reviews of toxicology research programs.

C.5.1.3. Evaluations of available toxicity information.

C.5.1.4. Recommendations for toxicity, epidemiology, or clinical studies.

C.5.1.5. Convening symposia, workshops and conferences on matters involving the interpretation of toxicity data and the evaluation of chemical hazards.

C.5.2. Reports. Reports will be produced in response to requests from DoD sponsors. Reports resulting from this effort shall be prepared in sufficient quantity to ensure their distribution to the sponsor and to other relevant parties, in accordance with Academy policy. The Contractor shall produce one letter report by May 1, 2010 evaluating at least one study protocol, epidemiologic study, or health survey. The Contractor shall produce at least one additional letter report by November 1, 2010 evaluating an additional research question. The report deadlines are contingent upon the USMC providing the study protocol, epidemiologic study, or health survey to the committee at least 10 months before the deadlines.

C.5.2.1. Publicly Available Information. Reports may be made available to the public without restrictions.

C.5.3. Manpower Reporting. The contractor shall provide manpower reporting as follows: "The Office of the Assistant Secretary of the Army (Manpower & Reserve Affairs) operates and maintains a secure Army data collection site where the contractor will report ALL contractor manpower (including subcontractor manpower) required for performance of this contract. The contractor is required to completely fill in all the information in the format using the following web address https://contractormanpower.army.pentagon.mil. The required information includes: (1) Contracting Office, Contracting Officer, Contracting Officer's Technical Representative; (2) Contract number, including task and delivery order number; (3) Beginning and ending dates covered by reporting period; (4) Contractor name, address, phone number, e-mail address, identity of contractor employee entering data; (5) Estimated direct labor hours (including sub-contractors); (6) Estimated direct labor dollars paid this reporting period (including sub-contractors); (7) Total payments (including sub-contractors); (8) Predominant Federal Service Code (FSC) reflecting services provided by contractor (and separate predominant FSC for each subcontractor if different); (9) Estimated data collection cost; (10) Organizational title associated with the Unit Identification Code (UIC) for the Army Requiring Activity (the Army Requiring Activity is responsible for providing the contractor with its UIC for the purposes of reporting this information); (11) Locations where contractor and sub-contractors perform the work (specified by zip code in the United States and nearest city, country, when in an overseas location, using standardized nomenclature provided on website); (12) Presence of deployment or contingency contract language; and (13) Number of contractor and sub-contractor employees deployed in theater this reporting period (by country). As part of its submission, the contractor will also provide the estimated total cost (if any) incurred to comply with this reporting requirement. Reporting period will be the period of performance not to exceed 12 months ending September 30 of each government fiscal year and must be reported by 31 October of each calendar year. Contractors may use a direct XML data transfer to the database server or fill in the fields on the website. The XML direct transfer is a format for transferring files from a contractor's system to the secure web site without the need for separate data entries for each required data element at the web site. The specific formats for the XML direct transfer may be downloaded from the web site."*

C.6. PERFORMANCE REQUIREMENTS SUMMARY (PRS).

C.6.1. The Contractor shall comply with the requirements of the contract. To ensure compliance, the Government has developed a PRS to establish how and how often the services will be monitored and evaluated. The PRS will be

administered by the USACHPPM COR, utilizing input provided by DoD agencies receiving services provided by the contractor under this contract.

PERFORMANCE OBJECTIVE	PERFORMANCE STANDARD	REF PBWS	METHOD OF ASSESSMENT
Provide timely response in providing the Sponsor a timeframe to respond to a specific request.	No more than 2 valid written complaints of per year from DoD sponsors.	Para C1.1.1	COR Maintained Log
Provide symposia and workshops to consider specific topics of interest to DoD sponosrs which result in proceedings or reports.	Technical reports shall be peer reviewed prior to transmittal to sponsors, with no more than 2 valid complaints issued by DoD sponsors each year.	Para C1.1.3 and C.5.1.5	COR Maintained Log, or signed valid complaint instrument developed by DoD Sponsor
Provide timely reports in response to requests from DoD sponsors	Reports shall be provided within the time frame requested by the DoD sponsor or within a reasonable time if not so stated in the request.	Para C.5.2	COR Maintained Log, or signed valid complaint instrument developed by the DoD Sponsor.

(End of Performance Work Statement)

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Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN IN	ISPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
2003 Do	estination	Government	Destination	Government
2003AB Do	estination	Government	N/A	Government
		•		

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Section F - Deliveries or Performance

DELIVERY INFORMATION

QUANTITY SHIP TO ADDRESS UIC CLIN DELIVERY DATE POP 29-SEP-2008 TO N/A USACHPPM W23MWP 2003 28-SEP-2009 ATTN MCHB CS OMD EDGEWOOD AREA BLDG E5185 ABERDEEN PROVING GROUND MD 21010-5000 FOB: Destination

2003AB POP 01-MAY-2009 TO N/A 01-NOV-2010

(SAME AS PREVIOUS LOCATION) FOB: Destination W23MWP

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Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

AA: 97901301181074742484770511000256873BA74W23MWP8354S00197HRA2S18001 AMOUNT: \$600,000.00 CIN W23MWP8354S0010001: \$600,000.00