

ATSDR/DOD Meeting Minutes, July 8th

Fiscal Year 2009 Planning for Marine Corp Base Camp LeJeune

Washington Navy Yard, 1322 Patterson Avenue, SE, Building 33, Rooms 2008 and 2010,
Washington, D.C., 20374-5065

Attendees:

DOD:

- Richard Mach, Jr., P.E.
Director, Environmental Compliance and Restoration Policy, OASN
- Brian Harrison, M.P.A., P.E.
Director, Environmental Cleanup Division NAVFAC HQ
- Wanda Holmes, M.S., P.E.
Director, Environmental Restoration and Range Assessment, Chief of Naval Operations, N453
- Dan Waddill, Ph.D., P.E.
NAVFAC Atlantic, Head, Engineering Technical Support Section
- Kim Parker Brown, M.S., P.E.
Navy ATSDR Program Manager, NAVFAC HQ
- Scott Williams
USMC HQ
- Lt. Col. Mike Tencate
USMC HQ
- Mary Ann Simmons
Deputy Director of Environmental Program Department, NMCPHC
- Uzo Chukwama
Deputy Division Officer Epi Data Branch, NMCPHC
- Mike White
DOD Liaison for ATSDR
- Elisha French
CH2M HILL

ATSDR:

- Tom Sinks, Ph.D.
Deputy Director, NCEH/ATSDR
- Carol Aloisio M.P.A.
Management Officer, NCEH/ATSDR
- Frank Bove, Sc.D.
Division of Health Studies
- Perri Zeitz Ruckart, M.P.H.
Division of Health Studies
- Morris Maslia, M.S.C.E., P.E., D.E.E.
Division of Health Assessment and Consultation
- Caroline McDonald
Deputy Director (Acting), Division of Health Studies
- Mary Campbell
Team Leader, Office of Financial and Administrative Services

Purpose: To discuss work to be conducted by ATSDR in support of Marine Corp Base Camp Lejeune in Fiscal Year 2009 and beyond

Goal 1: Review current status, planned milestones and deliverables

Goal 2: Gain agreement between DOD and ATSDR on Fiscal Year 2009 milestones and deliverables

Goal 3: Identify next steps on specific milestones and deliverables where agreement does not currently exist

I. Check In

Meeting began 9:30 a.m. with a roundtable introduction

II. Introductions and Opening Comments

Tom, Richard

Richard Mach opened the meeting by explaining the organizational and administrative framework of the assembled Department of the Navy (DON) team. DON is comprised of both the Navy and Marine Corps and there are various offices which have an important and distinct role at Camp Lejeune. DON has made some changes in the management roles of some of these offices. Most notably, the Marine Corps funded previous water modeling and health study efforts related to this Camp Lejeune effort. In FY08, DON designated the Environmental Restoration, Navy (ER,N) as the appropriate source of continued funding. Brian Harrison at NAVFACHQ has the fiduciary responsibility for all funding and execution within the ER, N Program. Wanda Holmes at CNO N45 is the Resource Sponsor for the ER,N Program and develops policy for the Navy. Richard represents over arching policy matters for the Navy's Secretariat. The Marine Corps continues their role as base owner and serves as main point of contact for the public.

Richard stated that one of his goals is to continue to improve interagency communications between all the involved federal agencies. The benefit of improved communications is transparency in the presentation of combined goals and the planned path forward to stakeholders. If issues arise which require further technical discussion, relevant parties should meet and work together to resolve the issues. Additionally, meeting minutes should be jointly reviewed and issued to promote a common understanding of meeting proceedings.

Another goal from Richard for today's meeting is to outline the scope of actions, budget, and schedule for the coming fiscal year. This group has the responsibility to discuss the proposed requirements for this site, make decisions on the requirements, agree to funding levels of effort, and then obtain the funding. The team needs to understand that changes are likely to occur as the projects get implemented and we need to reach agreement on a process to address these future changes.

Tom Sinks made an opening statement that these interagency meetings are important to determine which issues can be agreed upon by each agency, and which may not. The outcome of the meetings may not always be agreement, but we have a common goal of getting answers to individuals in the United States Marine Corps (USMC) and civilians who believe they have been harmed due to past exposure to volatile organic compounds (VOCs) in drinking water. The Agency for Toxic Substances and Disease Registry's (ATSDR's) role is not remediation, but to evaluate the exposure in a valid and scientific way, without prejudice.

Tom explained that he had five specific goals that he felt were important to ATSDR:

1. Scientific Quality Standard - Asking the right questions and developing a method to answer these questions.
2. Transparency - ATSDR often enters circumstances where people have different opinions and expectations. When work is performed transparently, all parties are provided an equal opportunity to understand the work that is being done and the process for getting it done.

3. Communications – There are a large number of stakeholders in this project, which reinforces the importance of establishing trust with the public, and the need to be able to effectively communicate the science and the process. It should be clear to the public that work is being done openly, and communicated to the public with a common voice, and minutes should be developed and shared.
4. Independence - ATSDR is an independent agency, not a partner with DOD and has a responsibility to maintain a level of independence. Although DOD makes decisions on funding, ATSDR needs to maintain its independence as an agency.
5. Efficiency and Efficacy – Everyone should develop goals and make every effort to meet them. ATSDR is a small federal agency with a limited budget, and the work at Camp Lejeune is not part of the standard budget. ATSDR is currently working on the case-control study and will need to reanalyze the reproductive health study we released. The expansion of our health studies (three new discrete projects) will increase the workload on our staff. ATSDR will likely use contract firms to assist with the additional work. The timelines we have developed will need to be monitored and revised as needed.

Tom also wanted to mention concerns expressed by the Camp Lejeune Community Assistance Panel (CAP). The CAP wants improved communications, and wants to be kept informed of proceedings faster. Tom reminded everyone that letters and communications between agencies should be developed in a manner to encourage more constructive communication. Tom noted that once there are agreed goals and a path forward, there should be an effort to begin to reach out to congressional staff and provide them with details, perhaps even before the summer recess. Tom noted that the purpose and goals listed on the meeting agenda had not been commented upon. He hoped that this reflects that everyone present has agreed to these goals.

Tom noted that ATSDR needed more time to address the specific comments we received from DON on the Terrawa Terrace groundwater model and that he did not plan to use much of the time today to address these comments. He stated that getting agreement on budgets and schedule were more important for this meeting. *Action Item - Distribute meeting minutes to interested parties upon request.*

Dan Waddill noted that the Navy is open to having additional meetings to review and address the technical nature of specific comments on the groundwater model. Richard concurred that everyone should be ready to set up side meetings to address specific issues.

Morris Maslia reinforced that ATSDR is attentive to efficiency and effectiveness, and has a limited staff to develop and oversee modeling efforts. Brian Harrison asked if ATSDR is contracting a university. Tom responded that Georgia Tech is providing modeling assistance. Kim Parker Brown asked about ERG (ATSDR subcontractor). Morris replied that overseeing subcontractors requires additional time and resources, such as reviewing materials produced by subcontractors. Brian empathized; because the Navy has similar constraints and performs much of its work through contractors. Tom added that although Morris has assistance from subcontractors, ATSDR has limited internal resources because of static dedicated funding that is declining in real terms. Richard noted that the Navy also has experience with issues of limited resources for internal expertise, and suggested that ATSDR may want to consider using Brian's experience in establishing funding mechanisms and/or subcontract support. Tom concurred, and recommended this topic to the parking lot.

III. Preliminary ATSDR Response to DON letter regarding the Terrawa Terrace Water Modeling *Tom*

Tom opened by noting that although the groundwater model was developed primarily to support the case-control study; it will continue to be relevant as a basis to follow-up work for the health studies among adults. Tom focused his comments on recommendations included in the DON letter. He stated that ATSDR is very open minded with regards to developing ways to improve communications with stakeholders. Tom noted that the recommendation for an additional expert panel to re-examine the Tarawa Terrace model was rejected because ATSDR had already enlisted an expert panel review of Tarawa Terrace and implemented its recommendations. He mentioned that another recommendation, to use lessons learned from the Tarawa Terrace experience for the Hadnot Point modeling, was reasonable. One of these lessons was the use of an expert panel. ATSDR had already agreed to create an expert panel to review the Hadnot Point modeling work. Richard suggested that Morris and Dan work together and discuss individual comments, in order to avoid miscommunication while developing responses to comments.

Kim asked whether or not a qualitative vs. a quantitative model was still being considered. Tom replied that during the budget discussions at the end of May, he had mentioned that a qualitative analysis could be conducted in an epidemiologic study. But he also emphasized that the goal is to have quantitative modeling, because the results are more comparable from one scenario to the next. Morris added that by having a numeric and quantitative model it can be independently reviewed and verified, whereas qualitative analysis is more open to interpretation.

Tom responded to the recommendation of taking into account the inherent uncertainty of modeling results; stating that the protocol and the analysis plan for the use of groundwater model results in the epidemiological analysis will be peer-reviewed, and that the statistical methods for calculating the health effects will be presented.

Morris identified two issues that have surfaced through previous interagency meetings and the summary response letter; one is the perceived lack of consideration for uncertainty. In the last year an ATSDR employee developed a Monte Carlo analysis specifically to quantify the uncertainty of the model; however, technical efforts such as these may not have been presented fully to date. Morris identified the second issue as addressing the results of the first peer-review panel. Morris noted that there are specific sections in the summary chapter (A) that address and accept every recommendation from the panel and offered to review this with DON.

Dan Waddill noted that the Monte Carlo analysis describes how the results of many different model simulations compare with each other, thus providing an estimate of model precision. This does not address the question of model accuracy, which is based on how well model results match real data. Dan suggested that uncertainty identified in the report should be better and more consistently presented to the public and other stakeholders on the website, in reports such as the feasibility assessment, and public presentations. Brian added that because the numbers being discussed have order of magnitude variance, the variance should be more consistently presented; such that the public gets an understanding of the variability in the data. Dan noted that the Navy has experience with contaminant transport models at a variety of sites,

and when model predictions can be verified over time, they are generally less accurate than originally expected.

The group agreed to further discuss this issue outside of this meeting. *Action Item - Morris and Dan will discuss uncertainty associated with the water modeling efforts.*

IV. ATSDR's FY 2009 Water Modeling Plans for Hadnot Point and Holcomb Boulevard

Morris

Morris handed out the project schedule dated June 30, 2008 for discussion. The project schedule task numbers on the timeline match those in the Work Plan. Task 2.1.4; the statistical analysis using a Kalman filter method model, is currently completed through the methods development stage, and is providing acceptable results based on hypothetical test data. The Kalman filter method is described on page 6 of the work plan, and helps in determining the statistical nature of contaminant sources. The results of this analysis will be used in later modeling of groundwater flow and contaminant fate and transport. Newly found information regarding 10-years of continuous well operations is needed to reconstruct the historical well operations.

Dan asked when the Kalman filtering method was selected; Morris responded that ATSDR had an internal technical meeting with the Georgia Tech Principal Investigator (PI) in January 2008. The Kalman filtering method was selected because there was not a single release source or a continuous operation, such as a dry cleaner, to characterize the nature of the source in the model. The PI was in the process of developing newer methods other than inverse modeling with a grid.

Richard asked if there was a decision framework in place to assess whether or not the output of the statistical analyses would be used. The Kalman filter method is in the timeline before initiating groundwater flow and fate and transport modeling to refine development of these models and to determine whether multiple contaminant sources can accurately be modeled.

The group decided that after the completion of Task 2.21a, an expert panel would be convened; the timing coincides with the completion of the database development, and Kalman filtering method statistical analysis. Morris noted that at a similar decision point for Tarawa Terrace, an expert panel was convened and the panel made recommendations to proceed with modeling. Morris also noted that early indications from the current application of the newly developed Kalman filtering model on hypothetical test data seem to be good.

Tom explained that ATSDR would define the charge for the Hadnot Point water-modeling expert panel for evaluating and deciding next steps in applying water-modeling to this area. Dan suggested that the steps in the Hadnot Point water-modeling work plan be further defined.

Dan noted his concern with new statistical methods in general; they don't generate new information, but are tools to help understand what data is present, and there is a lack of available historic field data. Morris concurred that there is a limited amount of data to use for reconstruction, but noted the goal is to find a method to work with the limited historical data. The final methods used in modeling Hadnot Point will be written up and shared with the Navy.

Richard asked what tasks have been funded; and how these relate to the colors in the timeline. After some discussion, Carol Aloisio agreed to provide a breakdown indicating which activities occurring in FY 09 were funded through contracts awarded in FY 08. *Action Item – Add an expert panel to the Hadnot Point timeline; revise any of the schedule items that need to be adjusted, and add financial information to the timeline and color code them appropriately.*

Brian asked if model development would continue if it is decided that the expert panel's recommendations do not support using the model. Tom Sinks replied that the panel's recommendations will be seriously considered but that ATSDR will make the final decision with respect to proceeding with Hadnot Point water modeling. Morris indicated that groundwater modeling has not begun because newly found information is being evaluated. However, this extension in the modeling time was not reflected in the timeline presented at this meeting. Richard noted that because the Navy needs to plan for funding allocation, the timeline should be revised to show when efforts will take place.

Brian asked that the portions of the work which are congressionally mandated be clearly noted such that the Navy is aware of where there may be funding schedule flexibility. Tom noted that the greatest increases in program costs are associated with the additional epidemiology studies that ATSDR has been tasked with.

Morris stated that for Task 2.13, there is 10 years worth of water utility data from up to 80 wells, and there are upwards of 120 pages of records per well. Scott Williams has asked a subcontractor to provide an estimate for the amount of time needed to scan in the records. ATSDR has three full-time employees and a subcontracted hydrogeologist working on interpreting the data. Tom stated that this data analysis task needed to be monitored closely to ensure that it does not push the timetable back.

– Working Lunch –

V. Working Lunch Discussion on the National Academy of Sciences/National Research Council Study Timeline, Scope, and Role for the Future

Mike, Scott

Lt. Col Mike Tencate introduced the charge that the National Academy of Sciences/National Research Council has agreed to, which involves conducting a draft medical and scientific literature review on PCE and TCE toxicity values. Mike then read the statement, "Conduct a comprehensive review and evaluation of the available scientific and medical evidence regarding associations between prenatal child and adult exposure to drinking water contaminated with TCE and PCE at Camp Lejeune, North Carolina; as well as other prenatal child and adult exposures to levels of TCE and PCE similar to those experienced at Camp Lejeune to determine if there is a relationship to birth defects and adverse health effects. Review and summarize the literature, assess the strength of that evidence in establishing a link or association between exposure to TCE and PCE and each birth defect or disease suspected to be associated with such exposure. For each birth defect or disease reviewed, the academy shall determine to the extent practicable with available scientific and commercial data; a) whether the statistical associations with such contaminant exposure exists; b) whether there exists plausible biological mechanisms or other evidence of a causal relationship between contaminant

exposures and the disease.” The statement then specifies specific studies and literature resources which will be reviewed, and a peer review of the research within 18 months. Tom asked whether there was a specific statement relating to the review of further proposed studies in the feasibility study. Mike responded that the council was asked to comment on the proposed feasibility studies. Frank Bove noted that the council’s panel has been asked for recommendations in the past, and it had provided comments on further studies.

Tom offered to explore the possibility of having the Institute of Medicine (IOM) convene an expert panel to review the protocols and final reports for the future health studies, and that this process could possibly be packaged together with the required ATSDR external peer review process, though this would have cost implications as well. Brian asked what the benefits of the IOM expert panel are in addition to the peer review process.

Tom replied that an IOM panel could provide continuity in the review process and its recommendations would be seen as authoritative. However, because there are congressionally mandated deadlines which need to be met, there may not be sufficient time to convene an IOM panel. The ATSDR peer review process can complete a faster turnaround than an IOM expert panel. Richard asked whether the Navy has an opportunity to nominate people for the ATSDR external peer review process. Tom replied that the Navy can make a nomination, but ATSDR selects the reviewers.

Richard asked what the review process would be for the Navy during the development of the survey. Perri Zeitz Ruckart stated that the draft protocol for the health survey has been shared with the Navy, and this survey is separate from the other two studies. Frank stated that ATSDR is open to comments on the survey, and that comments could be informal at this developmental stage. Kim replied that a formal comment process might be appropriate, but that open communication is a good idea. Richard requested that schedules adequately reflect DON review time so we can prepare for and meet review deadlines. Kim asked for more clarification on the proposed IOM expert panel, and whether the proposed IOM expert panel for the health studies will be separate and independent from the water modeling review panel. Morris replied that they would be separate, and that the Navy would be asked to provide recommendations for the water modeling panel. [Note: Tom subsequently found that the IOM would not convene an expert panel to review the health studies’ protocols and reports.]

Perri noted that ATSDR’s normal peer review process is to solicit comments from 3 to 7 individual independent reviewers, and that this process is different from the internal clearance process at ATSDR. Tom pointed out that this project is a multi-year process, and that for stability peer reviewers should be selected who will stay with the process for a long period of time. Further consideration of the peer review process was tabled to the parking lot.

VI. Future Health Studies I: Datasets Defining Those Individuals Who Resided or Worked at the Base *Scott, Frank, Perri*

Scott handed out a presentation on the USMC’s notification registry results to date. The largest number of registrants came from the Defense Manpower Data Center (DMDC) pool. From 1975 to 1985 there were 210,222 individuals with an associated Camp Lejeune code. Frank noted that the cutoff for DMDC records is 1975 because prior to this date there is no code for where individuals were stationed. With the aid of a subcontractor, individuals from the DMDC pool

who had a current address were added to the registration database. Additional registrants were added from inquiries to the call center, emails, and updated registrations through the call center. *Action Item – Scott will address whether the email registrations that Perri forwarded from registrants who made contact through ATSDR’s website have been received.*

Scott reported that a regular communication program will begin in August 2008 with emails being sent to registrants who only provided email address, and postcards being mailed to those that provided mailing addresses. Outreach efforts have been implemented through the Camp Lejeune website. An IRS program was initiated with letters being sent based on social security numbers for those individuals with a Lejeune DMDC code for whom there is no accurate address. Additional outreach programs include newspaper articles, targeted online search engine advertisements and radio advertisements. The most effective medium for outreach so far has been armed forces publications.

Tom reiterated that this is the pool of individuals from which future studies will come, and that every effort should be made to increase the size of the pool. The group discussed methods to increase registration, including encouraging the CAP to register.

VII. Future Health Studies II: Health Survey (Dole Legislation)

Frank, Perri

Perri introduced the health survey, which is being developed to meet legislated mandates, and noted that some of the language in the legislation is not entirely prescriptive. The survey process is set up to take place over 2 to 3 months. First an initial letter with the survey is sent, and then after 2 weeks, a postcard reminder is sent. Four weeks after the postcard reminder, an additional letter with the survey is sent. One concern for the survey is effectively communicating that each family member needs to complete their own survey, and Perri suggested that some of the outreach efforts should target registering family members individually. Perri explained that an initial mailing of the survey to a small sample population within the larger group of registrants in order to fine tune the survey process is scheduled for February.

Perri noted that establishing a control group, potentially from another USMC base without a release, is planned. Frank noted that sampling this additional population was a recommendation from the epidemiology panel; since there could be a public perception that it is difficult to differentiate between exposed and non-exposed populations from Camp Lejeune.

Tom asked what efforts are being undertaken to expand the registrant pool. Perri replied that the survey letter will have language to encourage respondents to encourage and assist friends or family to register. Frank noted that there should be ongoing efforts to expand the outreach effort over the next several months, including getting survey letters and outreach letters signed by high ranking USMC officers. Frank explained that there also needs to be a decision point to stop the registration phase to analyze the population being studied to assess whether or not it is representative. Perri explained that the timeline for the study extends through August 2009 which allows adequate time to account for individuals who register late. Carol suggested that the registration and outreach process should be evaluated after the completion of a phase such as the IRS mailings to determine whether ongoing efforts need to be adjusted. Brian suggested that the decision point should be inserted into the timeline. *Action Item - September 2008 –*

Evaluate the registration results to date and determine whether more outreach efforts are needed; Scott will need results from the IRS survey, the timeline should be revised to show the decision point.

Perri explained that the theoretical pool being targeted for the survey is 300,000 individuals, which includes all possible civilians, military personnel, dependents, and a comparison (unexposed) population. Tom noted that evaluating what participation rate would be considered representative is important.

Scott noted that stakeholder analysis (focus groups) will be conducted to figure out how to maximize survey participation.

Brian asked about the budgets shown on the timeline. Perri explained that the budget shown on the timeline is the estimated value of the external contract, and does not reflect ATSDR FTEs. Carol explained that contract values and salary costs were necessarily separated in this presentation because of the different timelines in which they are expended, but that they can be reported and budgeted. [Brian agreed that seeing both costs on separate timelines is important.]?

Tom noted that there is a discrepancy between the costs presented in the timeline and the summary fiscal year financial tables. Perri responded that the contractor is engaged until the end of FY 09, following which there is an internal effort at ATSDR to review and analyze the data.

Tom noted that this survey is a large data set which will arrive coincident with other Camp Lejeune studies that are supposed to be completed, and that it may be appropriate to consider engaging a subcontractor to perform some of the data analysis.

Richard asked about the nature of the contract; Carol replied that it is a time and materials contract. Brian asked what the assumptions are for the costs of administering the survey. Perri replied that the assumption is 300,000 surveys with a 65% response rate. The largest cost associated with the contract is the assumption that 100,000 patient files would need to be located. Caroline McDonald noted that dealing with subcontractors for this scale of survey effort is not something that ATSDR has a great deal of experience with. Richard suggested that the Navy may be able to provide cost estimate support, or evaluate whether a contract vehicle with another Navy subcontractor would be more cost effective. Frank noted that one consideration when evaluating other subcontractors is the perception of agency independence from the CAP. Tom noted that much of the cost estimate is based on having the highest participation rate. The development of unit cost budgets was requested by Brian Harrison. ATSDR agreed to provide.

Brian asked whether all of the costs needed to be funded in FY 09, or whether tasks could be broken into separate contracts. One suggestion was to fund the initial, smaller study under a separate contract, while estimates for the actual registrant pool are still being refined. Tom asked if there was a driver to complete the survey in one fiscal year; or if the survey could be phased, with one contract issued not to exceed a certain number of respondents in a fiscal year. Frank noted that the survey is already planned for phased implementation. Richard stated that while tasks for additional research and collecting medical records could be spread over two fiscal years, the survey itself should be conducted more quickly to engage individuals who are registered. *Action Item - Brian and Carol to review health study acquisition strategy*

Perri noted that it is important for ATSDR to receive initial comments from the Navy on the survey and protocol by September 2008; Kim replied that the Navy anticipates supplying comments hopefully in July 2008.

VIII. Future Health Studies III: Mortality Study, IV: Cancer Incidence Study

Frank, Perri

Frank explained that much of total population being considered is from DMDC. The DMDC sometimes has incomplete records, but virtually all of these records have date of birth and social security numbers associated with them. With this information, the linkage study is able to check with the National Death Index, the Social Security Administration, and the Veterans Administration to determine whether an individual has died. The state of death, date of death can be determined, a death certificate can be recovered, and sometimes next of kin can be located as well.

Brian asked how the mortality study would be structured to determine the causal link with exposure. Frank explained that more complete information on a subgroup (i.e., those who complete the health survey) can be used to inform the analysis of a larger group (i.e., the total population included in the mortality study). Kim asked if conducting studies on smaller and larger groups result in a duplication of effort. Frank responded that the mortality study simply links personnel data from the DMDC with vital status and mortality databases and therefore has no information on smoking and other possible confounders. To address the possible bias from a confounder such as smoking, one of two approaches can be taken. If the health survey is successful, then information from the survey can give an indication of the relationship between exposures to the drinking water contamination and smoking habits. If the survey indicates that there is no relationship between drinking water exposure and smoking habits, then smoking would not be a confounder. If there is a relationship, then this information can be applied to the analyses of the mortality study. On the other hand, if the survey is not successful, then a nested case control study could be conducted in which next of kin would be interviewed about smoking habits and other possible confounders.

Tom noted that the purpose of the mortality survey is to determine if there is a significant difference in cause-specific deaths. The problem is that there are illnesses that do not ultimately cause death. A mortality survey alone does not identify all the potential outcomes of interest, and ATSDR was tasked by congress with considering more than just a mortality study; a cancer incidence study is being proposed as well. Frank noted that a table in the feasibility assessment shows that many more cancers could be evaluated in a cancer incidence study versus a mortality study.

Uzo Chukwama asked whether information could be collected for the cancer incidence study from the health survey. Frank replied that if the health survey has a poor participation rate, the cancer incidence data linkage approach is necessary. The data linkage approach is time consuming, but the epidemiological expert panel recommended it, because health surveys often do not have a high participation rate. Brian asked if it is prudent to begin the data linkage effort until the survey participation rate is known. Frank stated that the process would start with meeting individual state cancer registry representatives, which isn't a significant effort. Brian noted that the timeline and budget summaries seem to show much of the cancer incidence and

data linkage study being completed in FY 09, before the results of the health survey are known, and questioned if the survey needs to be completed before commencing the cancer study. Tom acknowledged that the cancer study start date should probably be adjusted to accommodate a decision point. He said ATSDR will reevaluate the timetables for these efforts and revise accordingly. Brian noted that FY09/FY10 costs may need to be adjusted to reflect assessing the results of the health survey first. Frank noted that the effort to gain the cooperation of state cancer registries is still important to confirm the results of the health survey. **Action Item - A decision point for proceeding with the cancer incidence data linkage study based on the results of the health survey is to be inserted into a revised timeline.**

Wanda Holmes asked how the questions for the health survey are being developed to feed into the cancer incidence study. Frank explained that the feasibility assessment outlines the data linkage effort as an alternative to the health survey alone, if it does not provide enough data.

Wanda asked if only cancer specific to TCE is being considered. Frank responded that most of the existing data is from occupational exposure which isn't the same as drinking water exposure, and as a result wider cancers are being considered. Wanda's concern is the potential perception by an individual completing the survey that all of the diseases listed are a result of exposure at Camp Lejeune. Uzo asked if the list should be limited to what is biologically plausible; Frank responded that for some diseases biological plausibility isn't known, and very few cancers have been ruled out from being potentially linked to TCE and PCE.

Tom responded that there are standard rates for causes of mortality in a large population, and that observed and expected rates would be compared in this analysis. For specific occupational groups, there is generally a lower observed mortality rate than a general population, because the general population would include individuals who are not healthy enough to work, and don't have as high of a survival rate. When studying cancer in an occupational scenario, generally there isn't an elevation in total incidence of cancer, but an increase in a specific target organ cancer. Examining a number of different mortality factors gives greater confidence in the accuracy of the methods.

Richard asked how important it is to have the same population for the health survey as the cancer incidence, data linkage study. Frank explained that if the bias that links one group to the next is known, the comparison can be made. Richard explained that it could be difficult to explain these different populations to the general public. Frank stated that it has been communicated well to the CAP thus far.

Mary Ann Simmons asked if it was possible that both the health survey and the cancer incidence study might be completed without yielding conclusive results which could be presented to the public. Frank noted that this possibility was noted in the feasibility assessment. Tom noted that the cancer incidence study would not proceed if cooperation cannot be achieved from all or most of the state cancer registries. There is also a possibility that the Institutional Review Board process for individual states might prohibit carrying the cancer incidence study forward as well, and that there is a meeting with the CDC board that funds state cancer registries.

There was further discussion about the revised presentation of budget and the level of effort, and planning for resources throughout the year. Tom suggested that intramural and extramural costs by major category task can be presented within the timeline on a quarterly basis. **Action**

Item - ASTDR will submit revised budgets and timelines prior to finalization of the meeting minutes.

IX. Communication Approaches/Next Steps

Tom, Richard

Tom noted that there are vulnerabilities in communication between the agencies, and the media. Carol noted that a Questions & Answers (Q&A) sheet should be developed, and that a communication strategy should be part of future planning and budgeting efforts. Kim noted that both the Marine Corps and Navy are addressing communications, and a Q&A sheet has been developed in the past. Mary Ann noted there is a public affairs officer (PAO) relationship between the agencies that has been used in the past. Morris noted that there is a CAP meeting next Wednesday, the existing Q&A should be revised prior to the CAP meeting. **Action Item - Morris will develop a Q&A relating to groundwater modeling, and send to Scott to distribute to DOD personnel.**

X. Closing Comments

Richard

Richard thanked all of the meeting participants for their open communication at the meeting. Good information was shared which will support both DON and ATSDR working together more closely and meeting our common goals to get the most scientifically valid information regarding this site and effectively communicating those results to the stakeholders. Richard concluded that he felt the meeting was very productive, and looked forward to future regular meetings. **Action Item - Richard agreed to develop a statement relating to the general proceedings of today's meeting. Here is what was agreed to the following day: "ATSDR and DON leadership and staff met from 0900-1500 on July 8, 2008. There were several purposes and goals for this meeting. Most importantly, both agencies wanted to ensure we are working together in an efficient and effective manner and that we communicate in a consistent, open, and transparent way with all stakeholders. The meeting included technical discussions regarding ongoing and planned groundwater modeling efforts, notifications, and health studies. Results of these discussions will support reaching agreement on the specific requirements and associated funding for FY-09, over the next 3 months. In summary, both agencies felt this was a very productive meeting. There will be many action items and follow up meetings to ensure these efforts continue to proceed in a timely manner. Detailed minutes of this meeting will be generated and shared openly with all interested stakeholders, when completed."**

Action Items

- *Distribute meeting minutes to the CAP.*
- *Add an expert panel to the Hadnot Point timeline; revise any of the schedule items that need to be adjusted, and add financial information to the timeline.*
- *Scott will address whether the email registrations that Perri forwarded from registrants who made contact through ATSDR's website have been addressed.*
- *September 2008 - Evaluate the registration results to date and determine whether more outreach efforts are needed; Scott will need results from the IRS survey, the timeline should be revised to show the decision point.*

- *Brian and Carol to review health study acquisition strategy*
- *ASTDR will submit revised budgets and timelines prior to finalization of the meeting minutes.*
- *Morris will develop a Q&A relating to groundwater modeling, and send to Scott to distribute to DOD personnel.*
- *Morris and Dan will discuss uncertainty associated with the water modeling efforts ATSDR and DOD will meet quarterly to discuss progress and plans for Camp Lejeune.*

Parking Lot

****Congressional Briefings**

****Potential Contracting Mechanisms**

****Streamlining data discovery between Camp Lejeune and ATSDR**

****Determine whether an additional expert panel review of health studies is appropriate**

****Procedure to provide correspondence and other documents to stakeholders**Develop process to address future or changing project requirements and funding needs**