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Camp Lejeune 2011 APOW Meeting Summary

2 September 2010

10:12 to 12:48

In attendance:

<u>Participant</u>	<u>Representing</u>
Aloisio, Carol	NCEH/ATSDR
Bove, Frank	ATSDR
Brown, Kim Parker	NAVFAC HQ
Don, Joe	ATSDR
Fleetwood-Williams, Sharon	ATSDR
Harris, Carolyn	ATSDR
Harrison, Brian	NAVFAC HQ
Helbling, Mike	NAVFAC HQ
Maslia, Morris	ATSDR
Masone, Jim	NCEH/ATSDR
Peeples, Beverly	NCEH/ATSDR
Rennix, Chris	USMC HQ
Ruckart, Perri	ATSDR
Sinks, Tom	ATSDR
Waddill, Dan	DoN
Williams, Scott R.	USMC HQ

- The meeting commenced at 10:12. Tom Sinks welcomed all participants and everyone introduced themselves. Dr. Sinks reminded all that there will be a Congressional briefing on Camp Lejeune on 16 Sep 10. He hoped that the issues could be resolved and the APOW signed prior to that event.
- Brian Harrison expressed some concerns regarding the FY 2011 APOW. He cited as examples:
 1. The APOW did not include a budget for the out-years. Response: At the time ATSDR developed the draft FY 2011 APOW (May 2010) there were two known significant events that would influence the out year projection. These were the data discovery activities and the final award of the health survey contract. In May it was decided that the out year projections should be revised after more was known about the impact of these two issues. ATSDR will revise the out year projections based factual information the week of September 13th. This information will not be a formal part of the FY 2011 APOW, but will be provided as a courtesy to DON for their planning purposes.
 2. DON stated the budget needed more detailed information: Response: ATSDR stated that the level of detail provided in the draft APOW

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meets the requirements of the Memorandum of Understanding and is consistent with what has been provided with the APOW previously. ASTDR agreed to include brief descriptors of the work to be accomplished through contracts and grants in the APOW appendices. 2011

- Since the meeting was going off agenda, all agreed to enumerate Major Issues that needed to be addressed during the meeting. It was agreed that the presentations would be shortened. The Major Issues could be addressed at the end of the meeting to ensure that they were sufficiently covered. The Major Issues were:
 - Cost breakdowns by deliverables across activities.
 - Changes in schedules that will impact costs.
 - Costs for on-site data mining activities.
 - Early, hard deadlines affecting budget. i.e. CAP Meeting, USGS IAA, Extension of travel.
 - Decision points.
- DHAC briefed on water modeling activities and plans for 2011 activities.
- DON made a technical presentation entitled “DON’s Perspective on Water Modeling”. ATSDR invited the DON to participate in more in-depth technical discussions at a later date to address their concerns.
- DON asked how ATSDR can complete epidemiological studies when the water modeling activities have not yet been completed. ATSDR stated that while the timeline for water modeling extends into 2012, the information will be available for the epi studies several months earlier. The additional time included report writing and documentation of the study. DHAC’s final water modeling report will not be available until long after the results are provided to DHS to commence epi studies.
- All present expressed concern about how much time the water modeling is taking. Dr. Portier (ATSDR Director) had recently inquired into the matter. He expressed strong support for the approach that the research is taking and was satisfied that it would be done by mid-2011 and reporting by December, 2011. DON reminded that the Water Modeling constituted, by far, the largest portion of the 2011 APOW. It is for this reason that DON requests greater clarity regarding what the spending is for OCs 25 (procurement) and 41 (grants and cooperative agreements).
- DHS briefed on CAP activities and the health studies.
- The DHS is waiting for water modeling data to complete the case control study on birth defects and childhood cancers and to reanalyze the 1998 adverse reproductive outcome study. The epidemiologic datasets have already been edited.
- The mortality study is only using DMDC data. Because it is a data linkage study and participants will not be interviewed, response rates are not an issue. The study is progressing on schedule.
- DON asked who the contractor was on the mortality study. Answer: Westat.
- ATSDR is in the final stages of awarding the Health Survey/Morbidity Study. It should be awarded in by September 10, 2010. ATSDR is still awaiting OMB approval of the protocol. ATSDR expected to receive OMB approval in August.

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- OMB approvals for all such projects were held up until the 2010 census hold is complete; however, the hold period is over now. There is likely a backlog. Anticipate September. ACTION ITEM: ATSDR to follow up with OMB.
- The health survey proposes to include two signed letters from the highest ranking USMC officials: a pre-notice letter letting participants know that a survey is coming and the survey invitation letter. The two letters have been jointly drafted by ATSDR and USMC staff. However, because of recent changes in USMC leadership, the two letters need to be discussed with General Payne's replacement and the new Commandant to obtain their signatures.
 - Discussion of the scheduling of the signing and issuance of the letters. The survey is due to start on 1 Dec 10. The contractor needs the signed letters no later than 1 Nov 10 in order to avoid delay in the survey... ATSDR suggested taking the current, mutually agreed upon letters and asking the Commandant if he will be willing to sign. ACTION ITEM: ATSDR to get latest version of letter to DON. ACTION ITEM: DON to get clarity and commitment to get the letter signed by 1 Nov.
 - The expert panel will make a determination regarding whether to confirm self-reported diseases from the survey. Prior to receiving completed surveys, the panel will develop criteria for judging the effectiveness for the survey. As surveys are returned, the panel will apply the criteria to determine if the survey is successful and make a recommendation to ATSDR. ATSDR may need to move quickly in the latter part of FY11 to prepare IRB documents and establish formal relationships with the state cancer registries in preparation for confirming the self-reported cancers. This may require funding in FY 2011.
 - The planned timeline for the health survey/morbidity study as it stands right now:
 - December 2010 to June 2011: Send survey out and use the Dillman method to increase response rates.
 - By March 2011, the Expert Panel will meet to develop the criteria for judging survey effectiveness.
 - Final survey results in July 2011; panel will apply criteria and make recommendation to ATSDR.
 - If the panel recommends confirming self-reported diseases and the Agency concurs, then the option period of the health survey contract will need to be awarded, however some funds may be needed in late FY11 to obtain IRB approvals and establish agreements with state cancer registries.
 - As soon as the contractor and contract amount for the health survey/morbidity study award is determined, the price of the option phase (morbidity study) will be known since it is a fixed price option. ATSDR will need the funds by no later than March 2012.
 - Discussion occurred about how long it will take to start the mailing of the survey, send reminders, and receive all the completed surveys. More likely time frame will be six months.
 - DON briefed on water modeling activities. Several points:
 - All water modeling to date has been first rate;
 - The need for water modeling is undisputed;
 - DON respects the NRC's findings;

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- Overarching concern about how uncertainties regarding water modeling is communicated to the public;
- Discussed the differences between accuracy and precision of a model;
- Presented data relative to the results of the water modeling to date
- Question was raised regarding why the data did not show actual field data. Point was made that the modeling captures field data (known data points) with a high degree of accuracy.
- Discussion that the reason why water modeling had to be done was because actual data had been unavailable. As sample data of finished water at the treatment plants became available in the early 1980s it aligned closely to the results of the modeling.
- Point was raised that DON is concerned with how the water modeling is portrayed, not the quality or accuracy of the water modeling.
- Meeting was redirected to the mission of the gathering: To address the APOW.
- DON indicated that the discussion was germane because:
 - Different ways of water modeling had been proposed. This would necessarily impact the cost of the work to be done;
 - Modeling is a valid tool that DON uses but it must be understood by all stakeholders (including the general public) that it is not perfect;
 - NRC makes useful recommendations. DON would like for ATSDR to consider the recommendations but the request to consider it is not direction to use it or to change ATSDR's water modeling activities.
- All agreed that good science is based on careful, critical, and constructive thinking and non-adversarial communication.
- ATSDR has no desire or intent to exclude DON or NRC out of the scientific process; however, ATSDR is an independent agency – not a contractor for DON. ATSDR, in order to be recognized as being impartial by the public, and true to its scientific integrity, must retain its independence from the funding agency. Transparency is paramount.
- Discussion about regular technical meetings to discuss such issues. There used to be regular technical meetings but apparently they ceased at some point. These need to resume. ACTION ITEM: Confirm status of meetings and resume contact if necessary.
- Discussion about transparency of the technical meeting. One proposal was to have a member of the CAP present. ATSDR will defer the matter and the discussion to the technical staff who will actually participate in the meeting.
- Talked about the communications plan. Concerns that both parties abide by the fundamental practice of informing one another about external communications and giving one another an opportunity to comment prior to issuance. Issue rose regarding the status of the communication plan. ACTION ITEM: Check with Jana and Maryann to find out where we are with this. All concurred that communication can and should be improved.
- DON specifically requested that they receive the agendas for future meetings sooner. ATSDR confirmed that the items that DON requested were on the agenda; however, the final approval was not received and the agenda was not issued until late on Wednesday.

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- Review of the Major Issues:
 - DON asked how ATSDR arrived at such precise numbers on the out year projections. Answer: Agency makes estimates and then factors in overhead. They are still estimates.
 - DON stated that they do not have enough information to know what ATSDR is going to spend OC 25 and 41 costs on.\There currently is no SOW other than the one already supplied to DON to provide more details on the OC work.\. DON requested a short description of these expenses, rather than a detailed budget breakdown.
 - ACTION ITEM: Masone will provide a brief (one or two lines) description of proposed OC 25 and 41 awards in the APOW.
 - DON prefers the format that out-year cost projections were provided in previous years. They would like the numbers reformatted as presented last year.
 - ACTION ITEM: By 15 Sep, Masone would reformat out-year information in the form and format that DON requested. Will include YTD 2010 information as soon as the precise number for the HS/MS contract is known.
 - ACTION ITEM: Revise the 2011 budget to include more known cost factors such as
 - Cost of 2011 option on HS/MS contract;
 - NDI data for DHS;
 - Change in contract amounts for DHAC;
 - Changes in labor.
 - ACTION ITEM: Adjust narrative related to the HS/MS option in case data becomes available early enough.
 - ACTION ITEM: Identify obligations that will have to happen early in the year.
 - **Changes in schedules that will impact costs.**
 - Morbidity Study. There is a chance that a decision will be made to confirm the self-reported diseases from the health survey before the end of FY 2011. In that event, it would be preferable to start the study in 2011 rather than waiting for 2012 funding. DON indicated that they would strongly prefer that ATSDR not come in later in the year with a request for more funds. Agreed that the morbidity study should be requested for 2011 because it is easier to return funds than it is to obtain additional funds.
 - **Costs for on-site data mining activities.**
 - ATSDR confirmed that costs for data mining resource are covered for the balance of 2010. For 2011, the costs should be included through the first quarter. These will be included on the revised 2011 APOW budget.

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- **Early, hard deadlines i.e. CAP Meeting, USGS IAA, and Extension of travel.**
 - Identified the costs that will come early in FY 2011 that must be funded immediately:
 - CAP meeting
 - USGS IAA
 - Extension of travel
- **Decision points.**
 - ACTION ITEM: Expert Panel to set criteria for what constitutes a need for the Morbidity Study.
 - ACTION ITEM: Finalizing Communication Plan.
 - ACTION ITEM: Find out who will sign the pre-notice and survey invitation letters. Review draft with the CAP. The letter must be finalized and signed by 1 Nov.