DEFENSE HEALTH BOARD
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JUN 2 6 2008

DHB

MEMORANDUM FOR: The Honorable S. Ward Casscells, Assistant Secretary of Defense for Health Affairs

SUBJECT: Defense Health Board Findings Pertaining to Health Risk Assessment, Burn Pit Exposures, Balad Air Base, Iraq

REFERENCES

a. Memorandum, DASD (FHP&R), 29 February 2008, Request for the Defense Health Board Pertaining to Draft Health Risk Assessment, Burn Pit Exposures, Balad Air Base, Iraq.

b. National Research Council (1983) *Risk Assessment in the Federal Government: Managing the Process (Red Book)*, National Academy Press: Washington, D.C.

c. Institute of Medicine Quality of Health Care in America Committee (2000) *To Err Is Human: Building a Safer Health System*, National Academy Press: Washington, D.C.

BACKGROUND

The Deputy Assistant Secretary of Defense for Force Health Protection and Readiness Ms. Ellen P. Embrey in her memorandum dated 29 February 2008, requested the Defense Health Board to review and comment on the "Draft Health Risk Assessment, Burn Pit Exposures, Balad Air Base, Iraq." The Board's findings regarding the Balad risk assessment are listed below. In addition, the Board was asked to comment generally on the risk assessment process, including quality control measures employed in combat environments, and to offer recommendations, if any, for future assessments. The Board's general recommendation will follow in a subsequent report.

In the spring of 2007, a screening environmental health risk assessment was conducted at Balad Air Base, Iraq, in response to concerns from Service members. Air sampling characterizing burn pit emissions were initially found to have high levels of dioxins exceeding established military exposure guidelines (MEG). Risk modeling based on exposure measures led to concerns regarding calculated elevated cancer risks for those stationed at Balad Air Base greater than four months. To help confirm the air sampling measures, paired (pre- and post-deployment) sera from a small number of randomly selected service personnel previously assigned to Balad Air Base were analyzed for dioxin. Serum results were interpreted as "negative" with no perceptible post-deployment increase in dioxin levels.

Upon further review, the calculations used to obtain airborne concentrations of dioxins were found to be erroneous, overestimating the dioxin exposure and subsequent cancer risk calculation. As a result, the Army Center for Health Promotion and Preventive Medicine and the Air Force Institute for Operational Health issued a revised draft report, "Draft Health Risk Assessment, Burn Pit Exposures, Balad Air Base, Iraq." The comments below reflect the Board's review of the revised draft document.

SPECIFIC FINDINGS

Inherent Limitations of Screening Risk Assessment

The report as reviewed by the DHB subcommittee did not clearly state that a **screening** risk assessment was conducted. Apparently in Department of Defense (DoD) parlance, screening risk assessments differ from comprehensive assessments in that they typically attempt to quantify the level of various environmental exposures and compare the results to established permissible standards. Screening assessments may also collect data on health outcomes and biological exposure markers to compare with standards or background levels, but do not typically attempt to establish multivariate correlations. It is essential that the final version of the government's risk assessment report clearly state a screening risk assessment was conducted, and explain the distinction used by DoD between a screening and comprehensive risk assessment.

The report recognized the small number of environmental samples collected in relation to the estimated length of exposure and the number of sites under study. According to DoD, typical of most screening risk assessments, a determination as to whether any samples should be rejected for quality control reasons was not made due to the paucity of data. In addition, the report acknowledged that actual locations and activities of study subjects while stationed at Balad Air Base were unknown. Therefore, the relationship between locations and personnel-level exposure is not defined. In contrast, even in this screening risk assessment, the locations of environmental samples were known but not fully used to differentiate potential exposures by area.

The screening risk assessment did not clearly state that dioxin body burden measures (pre- and post-deployment serum specimens) were obtained from randomly selected anonymous service members, leading the reader to wonder why no attempt was made to determine level of environmental exposure and dioxin body burdens based on workplace location or job category (personnel maintaining burn pit fires). If a more definitive risk assessment were conducted, person-level data such as proximity to the burn pit fires and other covariates would be valuable.

While the report indicated a comprehensive ambient air sampling effort was conducted, it also reports a relatively large level of uncertainty regarding actual personnel exposure levels and health risks. It is important that the report clearly define "comprehensive" in that the obtained samples were analyzed for a large number of environmental agents, but the actual number of samples was relatively small. The report acknowledged high variability of both the meteorological conditions at Balad Air Base and the quantity and composition of material burned. These factors would indicate a high level of heterogeneity with respect to airborne exposures. In addition, the multiple 24-hour sample collection process used to account for any

meteorological or operational variability in exposure levels, had the potential to dilute exposure peaks by averaging the exposure levels within each sampling period. To counter this problem, this screening assessment used risk calculation methodologies depicting "worst case" exposures. Such methodologies include the calculation of exposure point concentrations for every compound of potential concern at the 95th upper confidence limit of the average, with a conservative exposure duration estimate of 24 hours a day for seven days a week. While these methods may over-represent actual human exposure if the time and locations samples as taken produced accurate exposure estimates, they are preferable to methods that do not take "worst case" scenarios into account. The final report should clearly detail the "worst case" methodology used and the reasons it was employed. Due to the nature of burn pit activities, it would be preferable to acquire samples at shorter time intervals in the future. Furthermore, the serum samples of the pilot study were de-identified and obtained at random from the Department of Defense Serum Repository (DoDSR); as a result, personal information was not linked to the samples tested. Consequently, the random samples screened may not be representative of actual human exposure, if the time and location characteristics of the samples chosen were not conducive for the accurate ascertainment of actual exposure.

The geographic analysis of respiratory illness was presented as incidence of respiratory illness at various bases. However, the data were limited to a single syndromic entity (respiratory illness) and did not include detailed information regarding whether other contributory factors (such as smoking) were associated with respiratory illness. For purposes of comparison between bases, this analysis is of limited value, particularly given the paucity of base-specific environmental sampling and the lack of information on person-level risk correlates for respiratory disease. While it is somewhat reassuring to find no substantive differences in respiratory illness between the bases, these finding add little to the overall assessment.

Uncertainties

While the report provided an adequate account regarding uncertainties and their impact on assumptions required for data interpretation and analysis, the report offered limited data examination and information on the potential effects of Service member burn pit combustion product exposures, the exposure variance, and the relation of exposures to the Military Exposure Guideline (MEG) benchmark.

Although comparisons to the MEG value occurred frequently in the report, insufficient information and discussion precluded determinations as to whether it was derived or used appropriately, since exposure was not limited to a traditional work week.

Since the amount and type of material disposed in the burn pits are not well controlled, burn pit emissions were not fully characterized. To help counter this uncertainty, the investigators employed a broad list of analytes in their sampling efforts. While this represents a reasonable approach, an inventory of disposed materials would have improved the sampling process and helped assure no contaminant was overlooked.

The report did not indicate whether the activities on Balad Air Base, including aircraft and their attendant auxiliary equipment, were considered in calculations regarding air pollutants, particularly with respect to particulate matter and polycyclic aromatic hydrocarbons. These pollutants could impact health and may impact the assessment. While it may be assumed that aircraft operations were ongoing and any contribution from aircraft engine combustion would be included in the results, the report should clearly state this information, as well as that such operations are typically not known to generate dioxins.

Although 50 of the 163 samples surpassed the one-year MEG for particulate matter PM_{10}, the report stated the PM_{10} levels are characteristic for this region. Burn pit combustion products typically contain elevated levels of particulate matter in the ultra fine and fine range. Uncertainty in the risk assessment could be reduced if characterization of the size distribution of particulate matter, including $PM_{2.5}$ and $PM_{0.1}$ associated with the burn pit environment were conducted and compared to normal background levels outside this environment, in addition to particle composition and associated potential health risks.

While dioxin levels did not exceed the 1-year MEG among the 32 air samples analyzed, characterization of these samples by particulate size would have provided information regarding exposure to the burn plume. Particulates should have been used to sort the air samples into strata in order to determine whether the 32 samples analyzed for dioxin levels were derived from high or low particulate samples.

Prevention of Error

The report did not provide a clear explanation regarding the source of the initial erroneous risk assessment. Errors can occur by miscalculation, in transcription or the use of the wrong unit of measurement and inaccurate programming of automated systems, among other ways. Various methods can be employed which ensure quality control, including peer-review, adequate staff training or field-testing of systems to ensure accuracy, and automatic alerts which indicate when data exceeds a pre-determined range. It is not clear whether quality control approaches were employed in this risk assessment.

GENERAL FINDINGS

The Board concludes that, given the data available, the screening risk assessment provides an accurate determination of airborne dioxin exposure levels for service members deployed to Balad Air Base. Based on the information provided, no dioxin-associated significant short- or long-term health risks or no elevated cancer risks are anticipated among the personnel deployed to Balad, Iraq.

While the Board respects the distinction drawn by DoD between a "screening risk assessment" and a "comprehensive risk assessment," the Board recommends that the general use of this distinction be reconsidered. Our concern is in two areas. First, the analysis of the distribution and determinants of exposure and health outcomes if limited to univariate analysis may lead to conclusions that may not be sustained when more thorough analysis is conducted.

The Board suggests that analysis should fully exploit the level of detail of the information that was collected. Second, limiting data collected in a "screening risk assessment" may lead to a regrettable situation in which a "do-over" of data collection necessary for a "comprehensive risk assessment" is not feasible. This may lead to situations in which screening risk assessments cause appropriate concern but there is no opportunity to later collect more useful information that may well lead to a resolution of concerns.

As depicted in the report issued by the Institute of Medicine *To Err Is Human: Building a Safer Health System,* preventable errors which transpire in the clinical setting can have severe and substantial repercussions, while exacting significant costs. Lessons learned from the clinical setting can also be applicable in the public health arena. Upon review of the revised report, the Board found the systems in place for error prevention and detection in the Draft Health Risk Assessment should be reviewed. This should include an analysis into the source of the error which occurred in the initial Draft Risk Assessment report, so that necessary and appropriate steps are taken in the attempt to prevent errors, as well as any resulting adverse consequences, from occurring in the future.

The Board also identified several areas where further clarification, analysis or investigation was needed. Overall, the report provided adequate descriptions of the screening risk assessment methodologies employed, as well as concepts related to uncertainties and subsequent assumptions that followed with regard to the risk assessment process.

CONCLUSIONS

In addition to the findings and recommendations detailed above, the Board recommends:

1. **The screening assessment report further detail the source of the mathematical error in the original report, with the goal of identifying systematic opportunities for their prevention in the future.**

2. **There is a need to develop, implement, and deploy in a timely fashion effective risk communication plans, particularly since misinformation regarding dioxin risk at Balad abounds within the military community.**

3. **The Board also agrees with the recommendations in the revised final Draft Health Risk Assessment, which include actions to minimize open bit burning of potentially toxic solid wastes, the further development and enforcement of policies concerning the use of burn pits within combat environments, and the continuation of exposure assessments at Balad AB following the installation of incinerators.**

4. **The Board recommends appropriate quality control measures be put in place with regard to future risk assessments, particularly those conducted in contingency or combat environments. The Board plans to engage with DoD medical agencies to characterize gaps in quality control procedures and determine risk assessment best**

practices which can be effectively employed in austere and hostile environments. A follow-up report will be issued on completion of the Board's activities.

The above conclusions were unanimously approved.

FOR THE DEFENSE HEALTH BOARD:

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cc:

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