Health Consultation

Review of Picatinny Arsenal PCB Health Risk Assessment Assumptions

PICATINNY ARSENAL

DOVER, MORRIS COUNTY, NEW JERSEY

CERCLIS NO. NJ3210020704

JANUARY 21, 1999

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Agency for Toxic Substances and Disease Registry
Division of Health Assessment and Consultation
Atlanta, Georgia 30333

Health Consultation: A Note of Explanation

An ATSDR health consultation is a verbal or written response from ATSDR to a specific request for information about health risks related to a specific site, a chemical release, or the presence of hazardous material. In order to prevent or mitigate exposures, a consultation may lead to specific actions, such as restricting use of or replacing water supplies; intensifying environmental sampling; restricting site access; or removing the contaminated material.

In addition, consultations may recommend additional public health actions, such as conducting health surveillance activities to evaluate exposure or trends in adverse health outcomes; conducting biological indicators of exposure studies to assess exposure; and providing health education for health care providers and community members. This concludes the health consultation process for this site, unless additional information is obtained by ATSDR which, in the Agency's opinion, indicates a need to revise or append the conclusions previously issued.

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Prepared by:

Federal Facilities Assessment Branch
Division of Health Assessment and Consultation
Agency for Toxic Substances and Disease Registry

BACKGROUND AND STATEMENT OF ISSUES

Revisions to exposure and toxicity assumptions which affected a remedial decision were made in an Addendum to the Phase I Remedial Investigation Human Health Assessment (hereafter referred to as "Addendum") for the Picatinny Arsenal prepared under contract to the U.S. Army. The areas affected by the Addendum are referred to as Site 20 and Site 24 of the larger area covered in the Phase I Remedial Investigation for Picatinny Arsenal (RI). The revised assumptions affected estimates of doses and risks for soil pathways (ingestion, inhalation, and dermal). The risk management decision prior to the revision was that soils containing PCBs would be removed. Based on the revisions, a decision of no further action has been proposed.

The restoration advisory board for Picatinny Arsenal asked ATSDR to review the health risk assessment done in the RI, with respect to the revisions in the Addendum and the future use anticipated for the site. In particular, it is our understanding that the following statements express the request by the restoration advisory board.

(1) Does ATSDR concur that the "Addendum to the Phase I Remedial Investigation Human Health Risk Assessment" considers the appropriate factors in evaluating potential human health impacts at Site 20/24?

(2) Considering the anticipated future use of Site 20/24, do surface soil sampling data (from the RI and additional sampling event) indicate that "no further action" is appropriate?

(3) If ATSDR believes the risk assessment is conservative, provide some explanation as to why.

DISCUSSION

A no further action decision was based on the revised analysis presented in the Addendum that estimated that soil exposure pathways (i.e., dermal absorption from contaminants in soil and inhalation and ingestion of contaminants in soil) would not result in greater than 1E-4 excess individual cancer risk. Excess individual cancer risk was defined as a summation of estimated excess individual cancer risk for each contaminant found in the soil pathways.

The future-use scenario anticipated by DoD and accepted by EPA for this site was commercial/industrial. Three potentially exposed populations were described in the RI for this future use scenario. The populations were:

- Current outdoor maintenance workers,
- Future industry or research workers, and
- Future construction workers.

The excess individual cancer risk estimates for only one of the three populations (future industry or research workers) was above the decision criterion in the RI. Risk estimates as revised in the Addendum for all three populations were below the criterion. The former and revised values for exposure and dose-response variables used for the future industry or research worker population are described in Table 1.

Table 1. Exposure and dose-response assumptions that were revised by the Addendum.

Assumptions	Values used in the RI	Values used in the Addendum
Exposure point concentration (EPC).	In the RI, maximum detected values are used for areas 20 and 24. The EPC used for area 20 was 33.1 ppm and for area 24 the value used was 23 ppm.	136 new samples were used in the Addendum, and an upper confidence level estimate of all samples was used instead of maxima. The upper confidence level estimate used for EPC for both areas was 11.3 ppm
Exposure Frequency	250 days per year	250 or 100 days per year
Cancer Slope Factor	7.7/(mg/kg-d)	2/(mg/kg-d)
Averaging area	Sites 20 and 24 were averaged and assessed separately.	Sites 20 and 24 were averaged and assessed together.

Exposure point concentration – Does the upper confidence estimate of mean of the samples represent the EPC for the upper percentile individual modeled in the addendum?
The exposure point concentration term used in the Addendum was the upper bound of a 95% confidence interval for a mean derived from the aggregate of several sampling efforts (156 samples from four separate sampling efforts). Sampling points are shown in the map provided as Appendix A to this consultation. Samples were 0-1 foot composites. The distribution of means from which the exposure point concentration was chosen is heavily influenced by 136[1] samples taken in the winter of 1997. These 136 sampling points were taken in a grid pattern from the northwest corner of the map in Appendix A, covering approximately one quarter of area 20 and the northwest half of area 24. Of these 136 samples, 60 were reported as no detect, with the average of the levels reported as no detect being approximately 0.6 ppm. The range of 76 detected values was 0.71 to 296 ppm, with 29 sample values above 10 ppm. The numerical distribution of the 76 detections approximates a lognormal shape (determination made by ATSDR

[1]The Addendum states in text that 137 samples were taken; however, results for 136 samples are presented in the Addendum. This analysis in this consultation uses the 136 sample values provided in the Addendum. The Addendum also reports in text that the highest value reported was 246 ppm for total PCBs; however, the values reported for individual samples range up to 296 ppm.

using BestFit on the values presented in the Addendum). The spatial distribution of the 136 sample values is shown in Figures 1 and presented as a contour in Figure 2.

The rationale for choosing the mean of an area heavily weighted by the 136 sample grid is unclear from the information provided in the RI and Addendum. The best estimate of averaged exposure point concentration (EPC) for a particular pathway would be derived from a sampling coverage that approximates the overall activity pattern of the individual over the exposure duration being modeled in the exposure-dose equations. The sampling grid location and the choice of mean for the area as the EPC appears to assume that receptor is expected to spend most of his time while onsite in the grid area (and to randomly sample from that area over the 25 years he spends working in that area). The basis for this assumption should be made clear, because activity patterns will influence averaged exposure point concentration. For example, if more than 5% of receptors would choose to spend most of any particular period of time in the areas of higher concentration within Site 20/24, then the mean would tend to not represent an EPC that is high on the distribution of likely EPCs across all individuals. Alternatively, if all receptors tend to visit more of Site 20/24 than is represented by the grid sampling, then the mean would be overly conservative (since the highest concentrations for Site 20/24 are apparently found within the grid area).

Exposure point concentration – Does the sample depth influence our uncertainty about the EPC?

Sample depth for the samples taken prior to the 1997 sampling round were 0-6 inches. Samples taken in 1997 were apparently 0-1 foot, although documentation of the depth of the samples has not been received by ATSDR.[1] The source of the PCB contamination is unknown; however, it is possible that it was through surface spills. Due to the binding of PCBs to soils and the relatively low water solubility of PCBs, surface spills would be expected to distribute so that higher PCB concentrations are found in more superficial soils than in deeper soils (ATSDR 1997). For these reasons, it is likely that a 0-1 foot composite sample would tend to under-represent the contamination present in the upper 0-6 or the upper 0-3 inches of soil available to receptors. A conservative way of addressing this uncertainty would be to multiply the observed PCB concentrations in 0-1 foot samples by a factor of 2 to 4 to account for dilution of contamination in surficial soil by cleaner subsurface soil.

[1] ATSDR asked USA CHPPM for clarification on the depth of samples during a phone conference and in written communication on 11/19/98. USA CHPPM indicated in subsequent communications that they were unable to verify the depth of the samples. No documentation of the depth of the samples was received as of 12/31/98.

Figure 1. Total PCB values and relative sample locations for the 136 samples presented in the addendum and taken in the winter of 1997 (the location of this grid in areas 20 and 24 of Picatinny Arsenal can be seen by referring to northwest corner of the map in Appendix A).

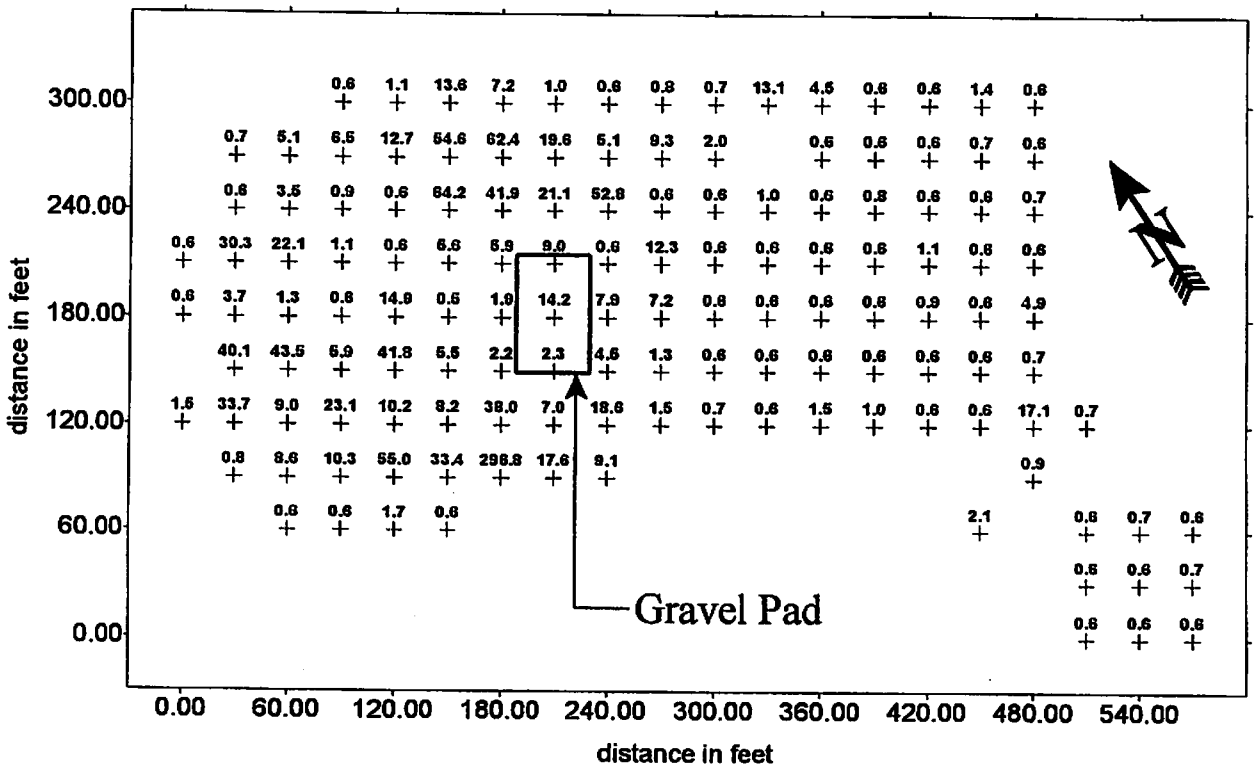
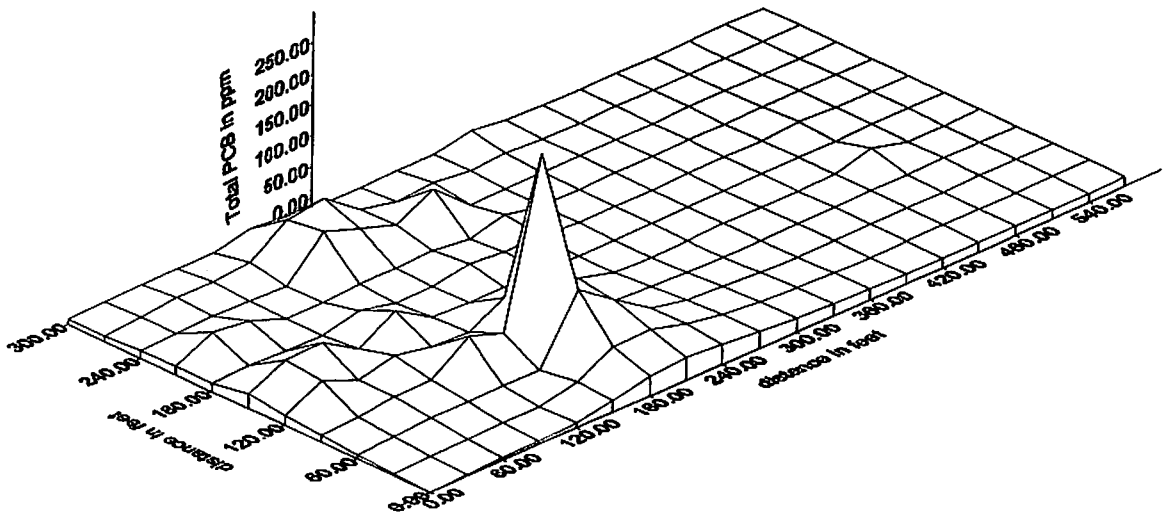


Figure 2. Contour representing total PCB values for samples within the grid area sampled in winter of 1997 (refer to Figure 1 for values underlying this representation).



Exposure frequency.
The Addendum presents estimated dose and risk for an upper-end exposure individual who would spend 250 days per year at the site (i.e., every working day of the year) and an individual who would spend 100 days per year at the site. Risk estimates for both individuals result in lifetime doses for 25 years of exposure that are below the stated decision criterion for the site. Furthermore, the estimated risks do not indicate that a public health hazard exists for chronic exposure and cancer under either exposure frequency assumption.

Although somewhat vague, the first paragraph of page 4 of the Addendum appears to suggest that exposure frequency could be confirmed through analysis of the administrative record (i.e., presumably referring to documentation of the actual work practices of current or future workers). This seems a reasonable suggestion and should be considered if members of the RAB are concerned about the protectiveness of this exposure assumption despite arguments made in the Addendum and in this consultation. However, it should be noted that evaluation of each assumption should be done in light of the other assumptions for exposure to arrive at an understanding of how likely it is that the described individual would be likely to exist (e.g., for the 250 day assumption, would an individual spend every working day receiving dermal and ingestion exposures as assumed, and would that individual work there for 25 years).

Cancer slope factors.
The cancer slope factors used in the Addendum and the RI were both taken directly from EPA. EPA revised the cancer slope factor for PCBs downward in 1996, and it is appropriate and protectively conservative to use the new cancer slope factor as done in the Addendum. EPA's cancer slope factor is an upper bound estimate of the slope of the relationship between liver tumor incidence and dose for mixtures of PCBs, based on careful and exhaustive dose-response analysis for PCB mixtures performed and described by EPA (EPA 1996; Cogliano 1998). It should be noted that (a) the slope used is an upper bound estimate of slope and (b) the dose-response analysis done by EPA assumes that there is no threshold for cancer from PCBs. There is some evidence that PCBs would in fact act through a mechanism that has a threshold for at least some forms of cancer (i.e., the slope is likely to be a protectively conservative overestimate of the true slope for the risks considered by the Addendum). The central value (that is, EPA's best estimate) for the slope is 1/(mg/kg-day). EPA's upper bound estimate of slope of 2/(mg/kg-day) was used in the Addendum (a greater slope will result in a greater estimate of risk).

Averaging area.
The choice of what area to average is a difficult one for Picatinny, because the choice varies depending on how the site is expected to be used by future workers, and it also depends on whether short term or long term exposures are being considered. The choice of averaging area should be made on the basis of the expected activity pattern over the exposure duration for the individual who is being modeled in the exposure analysis. For example, if you drew a line on a map that followed every step made by the individual being modeled over the 25 years assumed

under the analysis in the Addendum, then the density of the overlapping lines at the end of the 25 years would tell you how you would need to sample in order to estimate that individual's exposure point concentration. The samples used in the Addendum are taken mostly from the area in the northwest third of Site 24, and the northwest half of Site 20. The choice to use these samples makes the assumption that the reasonably maximally exposed (RME) individual would spend most of their time in the area of the grid (in the northwest half of Site 20 and the northwest third of Site 24) and that they would equally sample this grid area over the 25 year exposure duration. Given that sampling and past land-use patterns indicate that the PCB contamination is largely contained within the grid, the assumption to average over all available samples is conservatively protective of health with respect to chronic cancer risk.

However, with regard to exposures of less than 25 years, the choice of using the entire grid is less conservative because individual activity patterns for shorter periods of time are more likely to focus on smaller areas of the site. For example, if a job required an individual to work in the areas with highest contamination over a summer (for example, the areas north and southwest of the gravel pad in the western half of the grid area), then an average of those areas would apply to that individual's exposure for that period of time.

Conservatism in the approach.
Exposures are estimated in the Addendum using conservative values for the more sensitive exposure variables (i.e., soil adherence, PCB absorption, soil ingestion rate, and inhalation rate), which will result in description of an individual at the high end of the distribution of all exposed individuals. Based on review of the values chosen in relation to data presented in the EPA Exposure Factors Handbook (EPA 1997), it is likely that the values chosen will result in estimation of an individual above the 95th percentile of all exposed individuals. Furthermore, conservative estimates of the EPC (i.e., 95% UCL means of the more highly contaminated areas were used) and cancer slope were used, which provide a further level of conservatism to the analysis for chronic cancer risk.

A large part of the reduction of the risk estimate seen between the RI and the Addendum is due to the change in the slope factor. This change was based on more thorough analysis of the dose-response for PCBs and cancer by EPA, and so the estimate in the Addendum is likely to be more accurate as a result. It is unlikely that cancer risk to the RME individual was underestimated in the Addendum; rather, it is likely that cancer risk was overestimated for the RME individual.

Consideration of acute or intermediate duration exposure potential.
Recalculated risk characterizations for chronic noncancer risk to a high-end exposure individual are presented in Table 3 of the Addendum using the 95% UCL means estimated for all of Sites 20 and 24. These risk characterizations describe an individual who equally samples all areas of Sites 20 and 24 over the 25 years he visits the site. The doses presented in the Addendum for this individual are below levels of concern using the estimated 95% UCL means. However, the

pattern of contamination (i.e., Figures 1 and 2) suggests that noncancer health effects from exposure to the relatively high contamination in the north west corner of Site 24 for shorter periods of time should be considered. Contamination is not evenly distributed across Sites 20 and 24. Depending on

> The area contacted (e.g., the areas north and southwest of the gravel pad in the western half of the grid area),
>
> Dilution of surficial concentration that may have occurred through use of 0-1 foot samples, and
>
> The type of contact (e.g., dermal and ingestion exposure, exposure during work that involves disturbing the soil),

it is reasonably likely that an individual could receive doses within a factor of 10 to 30 of the lowest observed adverse effect levels (LOAELs - the lowest PCB exposure levels at which a study has shown adverse effects) for immune and dermal effects in rhesus monkeys for exposure to PCBs (5 µg/kg-d).

The long biological half-times of PCBs affect the likelihood that toxic effects would occur for exposures of several months. The durations of exposure observed to cause effects in animals are 1 to 3 years for developmental, immune, and dermal effects in monkeys (Arnold et al 1993a, b; Barsotti and Van Miller 1984; Tryphonas et al 1989, 1991a, b). Furthermore, neurobehavioral effects have been observed at similar exposure levels (7.5 µg/kg-d) for exposure durations as short as 20 weeks in nursing infants (Rice 1997, 1998). Because of the very long biological half-times of PCBs (ATSDR 1997), exposures over several months can affect the body for durations equivalent to the longer exposure periods in test animals. Therefore, consideration of LOAELs for effects that occurred in monkeys after 1 to 3 years of exposure is appropriate for this site.

Furthermore, it should be noted that the evidence for developmental effects in animals is limited, but sufficient hazard information in human populations and animals (e.g., Barsotti and Van Miller 1984; Levin et al 1988; Rice 1997, 1998) exists so that protective conservatism is warranted with respect to women of childbearing age on the basis of this potential effect where costs of remedial action are known and minimal.

If dilution of surficial PCB concentration has occurred through use of 0-1 foot soil samples, then concentrations in excess of 100 to 200 ppm would be likely for areas north and southwest of the gravel pad in the western half of the grid area. Furthermore, averages for the areas north and southwest of the gravel pad in the western half of the grid area could range from 25 to 100 ppm.

Information regarding patterns of use of the land received by ATSDR from USA CHPPM

indicates that land usage by future industry or research workers performing the tasks that are currently performed at the site would involve at most one or two weeks of exposure in a given month (USA CHPPM 1998). Given this exposure pattern and considering uncertainty about exposure point concentration as discussed above, it does not appear likely that doses would reach within 30 fold of the LOAELs for any given month for current workers. If future work patterns are similar to past work patterns (that is, if the area continues to be used as it has been used), then the site would pose no apparent health hazard for these workers. If work patterns change so that more work is done in the areas north and southwest of the gravel pad in the western half of the grid area over a period of months, then the site would pose a health hazard for these workers. Institutional controls were not identified that would prevent activity patterns that would result in use of areas north and southwest of the gravel pad in the western half of the grid area over a period of months.

Using assumptions for exposure as presented in the RI, it appears likely that future construction workers would receive doses within 10 to 30 fold of the LOAELs for PCBs for months at a time, if work occurred in the area of the sampling grid. Therefore, a health hazard would exist for future construction workers for this site.

Uncertainty in the analysis presented in this consultation.
The uncertainty with regard to a conclusion that cancer effects are not expected is estimated to be low, given that excess individual cancer risk estimates would exceed screening criteria only when the assumption is made that individuals would spend a majority of time over 25 years on site working on the areas of highest contamination. Furthermore, the conservative nature of other assumptions made in the dose equations used in the RI and addendum add to the certainty that cancer effects are not likely at this site.

Uncertainty with regard to a conclusion that noncancer effects are not expected for future research or industrial workers is moderate. It is not known whether someone would work in the areas of higher concentration over a few months; however, past practices indicate that this will not happen.

Uncertainty with regard to the conclusion that noncancer effects are possible for future construction workers working in the area of the known PCB contamination is low to moderate.

The majority of the uncertainty regarding noncancer effects for the considered exposures is expected to lie within the following three areas.

1. The estimate of behavior patterns (regarding whether an individual would work predominantly in areas north and southwest of the gravel pad in the western half of the grid area over a period of months).

2. The estimate of soil concentration in the top 3 inches of soil (data are only available for a mixture of the top 1 foot – a measure which is likely to dilute what is found in the top 3 inches).

3. The toxicity of PCBs, particularly with regard to the developmental toxicity of PCBs.

ATSDR CHILD HEALTH INITIATIVE

ATSDR's Child Health Initiative recognizes that the unique vulnerabilities of infants and children demand special emphasis in communities faced with contamination of environmental media. ATSDR did not identify any situations in the past, current, or future which would involve children directly exposed to chemical contaminants at Picatinny Arsenal Sites 20/24. However, as indicated above, developmental effects of PCBs (i.e., relevant to women of childbearing age) are reasonably likely for the exposures considered.

CONCLUSIONS

(1) Does ATSDR concur that the "Addendum to the Phase I Remedial Investigation Human Health Risk Assessment" considers the appropriate factors in evaluating potential human health impacts at Site 20/24?

ATSDR ***does concur*** with the assumptions made for exposure and risk variables in the Addendum and in the full RI with respect to chronic exposure and the risk for cancer. The Addendum and the RI combined consider appropriate factors in evaluating potential human health impacts at Site 20/24 with respect to chronic exposures and cancer.

ATSDR ***does not concur*** with the assumptions made when intermediate or acute exposures and noncancer health risks are considered. ***The PCBs in soil north and southwest of the gravel pad in the western half of the grid area pose a potential public health hazard*** on the basis of risk for immune and developmental effects. This conclusion is based largely on uncertainty in expected behavior patterns for construction workers and research/industrial workers at this site over periods of months, and uncertainty regarding PCB concentration of the uppermost layer of soil. It should be noted that the evidence for developmental effects is limited, but sufficient hazard information in human populations and dose response in animal studies exists so that protective conservatism is warranted where costs of remedial action are known and minimal.

(2) Considering the anticipated future use of Site 20/24, do surface soil sampling data (from the RI and additional sampling event) indicate that "no further action" is appropriate?

No, the conclusion of "no further action" is not appropriate. The PCBs in soil north and southwest of the gravel pad in the western half of the grid area pose a potential public health hazard on the basis of risk for immune and developmental effects.

(3) If ATSDR believes the risk assessment is conservative, provide some explanation as to why.

With respect to chronic cancer risk, ATSDR does find the risk assessment to be conservative. This finding is related primarily to the expectation that over 25 years an individual is not very likely to spend most of their time only on the areas of higher contamination, but rather would average the concentrations over a larger area. The risk assessment estimated doses and risks using high end estimates for most exposure variables, (i.e., exposure to an RME individual was estimated) and the resulting estimates of excess individual cancer risks were well within acceptable ranges. Therefore the estimates are protectively conservative with respect to cancer assessment

for the populations that might be exposed to the PCBs and other contaminants at Site 20/24.

(4) The conclusion that a potential public health hazard exists for future industry or research workers is based on the premise that institutional controls were not identified that would prevent activity patterns that would result in use of areas north and southwest of the gravel pad in the western half of the grid area over a period of months.

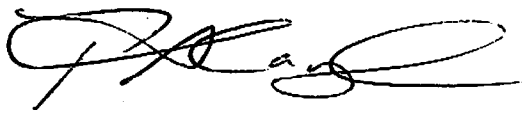
RECOMMENDATIONS

1. Remediate or restrict access to soils containing PCBs north and southwest of the gravel pad in the western half of the grid area (the area corresponding to rows 6 through 13 December 1997 sampling) prior to any future construction activities.

PUBLIC HEALTH ACTION PLAN

1. Follow up by regional representative to determine whether stakeholders (e.g., the RAB for Picatinny Arsenal, DoD, EPA) are satisfied with the analysis presented in this consultation.

2. Regional representative will determine whether cleanup will be conducted as recommended in this consultation.



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Documents reviewed:

Picatinny Arsenal Installation Restoration Program. Addendum to the Phase I Remedial Investigation Human Health Assessment for Site 20/24. Prepared by Dames & Moore 7101 Wisconsin Avenue, Suite 700, Bethesda MD for Army Total Environmental Program Support under contract DAAA15-90-0015. July 1998.

Picatinny Arsenal Installation Restoration Program. Phase I Remedial Investigation Human Health Assessment for Site 20/24. Prepared by Dames & Moore 7101 Wisconsin Avenue, Suite 700, Bethesda MD for Army Total Environmental Program Support under contract DAAA15-90-0015. May 1988.

Letter from Doug Schicho, ICF Kaiser International Inc. to William Roach, U.S. EPA Region 2 and attachments, including map of winter 1997 sampling locations.

REFERENCES

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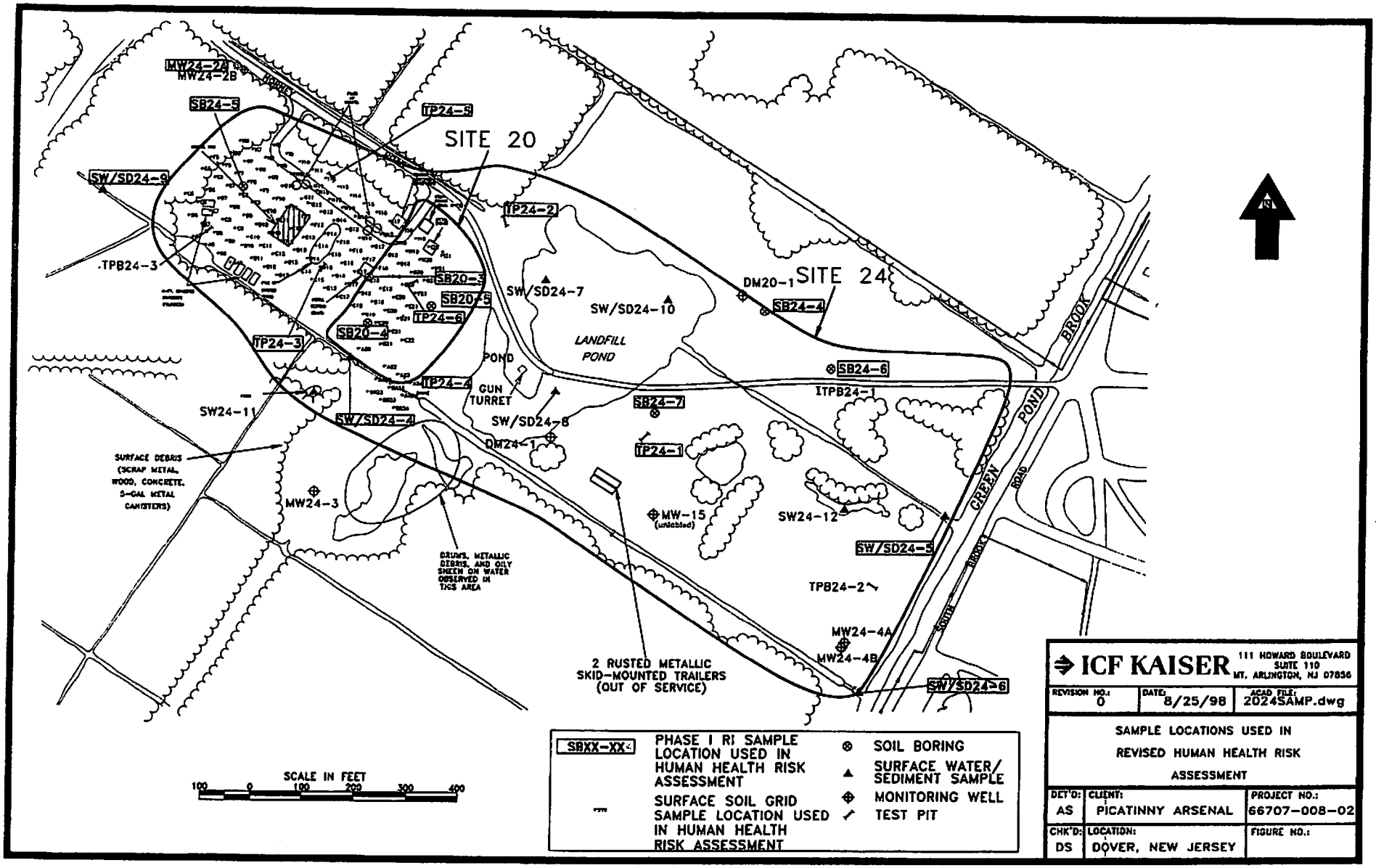
Tryphonas H, Luster MI, White Jr KL, et al. 1991a. Effects of PCB (Aroclor 1254) on non-specific immune parameters in rhesus (Macaca mulatta) monkeys. Int J Immmunopharmacol 13:639-648.

USA CHPPM 1998. Email titled "Picatinny site 20/24 exposure patterns" and attachment "Pik5" received by Richard Canady of ATSDR from Mike White of USA CHPPM 12:01 PM December 30, 1998.

Appendix A
Map of sampling locations used in the Addendum.



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REVISION NO.:	DATE:	ACAD FILE:
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SAMPLE LOCATIONS USED IN REVISED HUMAN HEALTH RISK ASSESSMENT

DET'D:	CLIENT:	PROJECT NO.:
AS	PICATINNY ARSENAL	66707-008-02
CHK'D:	LOCATION:	FIGURE NO.:
DS	DOVER, NEW JERSEY	