STATE OF MICHIGAN
DEPARTMENT OF ENVIRONMENTAL QUALITY
LANSING

JENNIFER M. GRANHOLM
GOVERNOR

STEVEN E. CHESTER
DIRECTOR

March 2, 2006

Mr. Ben Baker
Senior Environmental Project Leader
Michigan Operations
The Dow Chemical Company
47 Building
Midland, Michigan 48667

Dear Mr. Baker:

SUBJECT: Notice of Deficiency (NOD); Tittabawassee River and Floodplain Remedial Investigation Work Plan (TR RIWP) and Midland Area Soils Remedial Investigation Work Plan (Midland RIWP); The Dow Chemical Company, Michigan Operations (Dow); MID 000 724 724

Attached are the Michigan Department of Environmental Quality's (MDEQ) "high level" deficiencies that were identified during review of the TR RIWP and the Midland RIWP (Attachment A). The TR RIWP and Midland RIWP documents were submitted by Dow to the MDEQ for review and approval on December 29, 2005.

On January 18, 2006, Dow provided a presentation on the RIWPs to the MDEQ; the U.S. Environmental Protection Agency, Region 5, (U.S. EPA); and the Natural Resource Damage Assessment (NRDA) Trustees. The MDEQ and U.S. EPA provided informal comments on the RIWPs to Dow during this presentation.

On February 10, 2006, the MDEQ provided a draft of the "high level" or fundamental deficiencies that were identified during the initial review. These deficiencies were provided by e-mail and posted to Dow's e-Project site. The February 10, 2006, e-mail also contained deficiencies, in final form, provided by the U.S. EPA. These deficiencies are provided as Attachment B to this letter. As noted in the February 10, 2006, communication, the MDEQ agrees with the deficiencies identified by the U.S. EPA on February 10, 2006, and acknowledges them to be supplemental to this NOD. The deficiencies identified in Attachments A and B are not intended to be all inclusive. It should be noted that the attached deficiencies benefited from public comment received during the February 9, 2006, Town Hall Meeting. In response to this NOD, Dow must respond to and address each of the deficiencies identified in Attachments A and B.

The February 10, 2006, documents provided the basis for meetings conducted on February 14, 15, and 16, 2006, among the MDEQ, the U.S. EPA, and Dow. The purpose of these meetings was to provide Dow with the opportunity to further explain and improve our understanding of the RIWPs in light of the high level deficiencies

identified by the MDEQ and U.S. EPA. We believe these meetings were productive and have used the results of those meetings to further clarify Attachment A of this NOD. The information requested by Dow during those meetings is provided in Attachment C.

Per Ms. Susan Carrington's February 16, 2006, request, we have also reviewed and considered the additional information provided by you on February 23, 2006. This information was provided in response to our previous meetings and the discussion regarding the MDEQ and U.S. EPA's comments on the human health risk assessment (HHRA) portions of the RIWPs. It is our understanding that Dow provided this information for discussion purposes and that this document is not intended as a revision of the formal RIWPs.

Pursuant to Condition XI.F.2 of Dow's hazardous waste management facility operating license, Dow has 60 days from the receipt of this NOD to modify and resubmit the RIWPs in accordance with, or based on, the resolution of the deficiencies identified in Attachments A and B of this NOD.

As it is our common and frequently stated goal to organize our efforts to achieve the greatest benefit with respect to sampling during the upcoming field season, we believe it is appropriate and necessary to focus at this time on revising the initial phases of the RIWP to address the field work that is to be conducted this year.

One way to achieve this goal would be to revise the RIWPs to clearly and specifically identify the remedial objectives and goals of Dow's proposed corrective action processes. The revised RIWPs would describe the iterative nature of the proposed phases of data collection and how these phases will support the remedial objectives in accordance with R 299.5528(2) of the administrative rules promulgated pursuant to Part 201, Environmental Remediation, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended. In accordance with the approved Scopes of Work, the revised RIWPs would initially propose specific data collection activities to support the HHRA processes. This HHRA work, in conjunction with the collection of additional data to further identify the nature and extent of contamination in the study areas (including reducing the uncertainty with respect to contamination levels on Priority 1 and high-use Priority 2 properties along the Tittabawassee River) and the collection of data to support Dow's proposed geospatial model, would be the focus of this year's field activities. With respect to the TR RIWP, the nature and extent of contamination work would be conducted in a manner that develops transect level information over the geographic extent of the study area. Subsequent phases of data collection would be described in a more general manner, with specific work plans to be submitted as the RIWPs progress.

In order to keep the process moving forward, on February 9, 2006, the MDEQ granted approval with modifications of the Priority 2 Mailing Package and Property Lists. This allows Dow to begin the process of pursuing property access while completing the necessary modifications to the RIWPs.

As you are aware, we will be receiving comments from the public and the NRDA Trustees until March 15, 2006. Following this date, we will be providing additional comments on the RIWPs including, but not limited to, the proposed Midland and Tittabawassee bioavailability studies, the ecological risk assessment components of the RIWPs, and the public participation components of the RIWPs.

Should you have questions regarding this NOD, please contact Mr. Allan Taylor, Hazardous Waste Section, Waste and Hazardous Materials Division, at 517-335-4799 or by e-mail at taylorab@michigan.gov, or you may contact me.

Sincerely,

George W. Bruchmann, Chief
Waste and Hazardous Materials Division
517-373-9523

Attachments
cc/att: Mr. Peter Wright, Dow
Ms. Susan Carrington, Dow
Mr. Jack Clough, Clough Consulting
Mr. Jack Bails, Public Sector Consultants
Ms. Lauri Gorton, CH2M Hill
Mr. Tom Long, The Sapphire Group
Ms. Margaret Guerriero, U.S. EPA
Mr. Gerald Phillips, U.S. EPA
Mr. John Steketee, U.S. EPA
Mr. Greg Rudloff, U.S. EPA
Mr. Jim Sygo, Deputy Director, MDEQ
Mr. Frank Ruswick, Jr., Special Assistant to the Director, MDEQ
Ms. Liane Shekter Smith, MDEQ
Mr. Steve Buda, MDEQ
Ms. De Montgomery, MDEQ
Dr. Deb MacKenzie-Taylor, MDEQ
Ms. Cheryl Howe, MDEQ
Mr. Allan Taylor, MDEQ

Attachment A
Administrative and Technical Deficiencies
Major Items and Issues for the Tittabawassee River and Midland Remedial Investigation Work Plans (TR RIWP and Midland RIWP)

1) **General.** The Remedial Investigation Work Plans (RIWPs) must be revised to contain comprehensive and detailed schedules that consolidate the major work activities proposed by the RIWPs and associated studies. The schedules need to detail the work that is proposed to be conducted under the RIWP and any associated studies proposed to support the human health risk assessments (HHRAs); the ecological risk assessments; the Midland Bioavailability Study and Potential Constituents of Interest (PCOI) Investigation; and any other studies that The Dow Chemical Company (Dow) is proposing to conduct or plans to propose to conduct in support of the overall remedial investigation (RI) process. This is necessary to provide a comprehensive picture of the RI process and to ensure coordinated sequencing of the various data gathering and data evaluation activities; and to identify the key milestones to be met in the Framework for an Agreement (Framework), the hazardous waste management facility operating license (License), the Scope of Work (SOW), and the RIWPs.

2) **General.** The RIWPs need to be revised to provide a better description of the overall remedial investigative strategy being proposed by Dow. Pursuant to R 299.5528(2) of the administrative rules promulgated pursuant to Part 201, Environmental Remediation, of Michigan's Natural Resources and Environmental Protection Act, 1994 PA 451, as amended (Part 201 Rules), the Michigan Department of Environmental Quality (MDEQ) shall approve RIWPs or reports for work done in phases if all of the following conditions are satisfied:

   (a) Anticipated subsequent phases of investigation are described in sufficient detail so that the MDEQ can determine that the phase being proposed or reported on is appropriately defined.
   (b) The RI described in the work plan (WP) or report complies with the requirements of this rule for the scope it is intended to address.
   (c) If conducting the RI in phases will not prevent the RI from being completed in a timely fashion.

   With respect to R 299.5528(2)(a), the RIWPs do not identify the remedial alternatives that are under consideration by Dow or describe how the data proposed for collection will support the evaluation of potential remedial alternatives. Therefore, it is not possible to determine that the proposed work and/or the proposed phasing of work are adequate or appropriate in the context of the overall investigations. The RIWPs need to be revised to identify reasonable, potential remedial alternatives and to describe how the proposed phasing of data collection under the RIWPs will develop the information to support remedial decision-making.

With respect to R 299.5528(2)(b), the RIWPs need to be revised to clearly identify how the proposed investigations comply with the applicable requirements of R 299.5528(3). The MDEQ has determined that all of the requirements of R 299.5528(3) are potentially applicable to these very large scale RIs. An acceptable method of addressing this requirement would be to provide tables that identify where and how the requirements of R 299.5528(3) will be addressed in the revised RIWPs.

With respect to R 299.5528(c), the proposed RIWPs are not consistent with and must be revised to be consistent with the schedules in the previously approved SOWs, which are now part of Dow's License. In particular it was noted that the Phase I RI Report for TR RIWP is scheduled in the RIWP for submission by Dow in April 2007. This conflicts with the schedule in the approved SOW, which indicates the Phase I RI Report is to be submitted in September 2006. As currently drafted, the proposed RIWP schedule will make it difficult or impossible to conduct "Phase II" work during the 2007 field season, thereby, effectively postponing any Phase II work until 2008. Such an outcome would be unacceptable.

Note also that first phases of the RIWPs do not specifically propose key exposure pathway investigation work (also required by the approved SOWs) to support the HHRA. The approved SOWs require the RIWPs provide for the collection of this information during the first phase of the RIWPs, as this information is necessary to develop cleanup criteria. Without adhering to the SOW schedule, this information would not be collected under Dow's RIWP schedule until 2007 or 2008. This would be a significant schedule deviation from the approved SOWs and is not acceptable in that it would likely prevent the RIWPs from being completed in a timely manner. The RIWPs must be revised to provide the collection of key exposure pathway information, beyond the collection of soil and sediment information, in the first phases of the RIWPs.

3) **Conceptual Site Models.** The Conceptual Site Models and Current Conditions Reports do not address or list the specific exposure pathways that are currently known to be present or identify other exposure pathways that may be present and require investigation. The RIWPs must be modified to describe the known and suspected human health exposure pathways. As noted above, the approved SOWs and the License require Dow in the initial phase of the RI to "To identify and collect exposure data to support the Human Health Risk Assessment." It is not clear in the RIWP what data Dow will propose to collect to support the HHRA or the time frame within which the data will be collected. Again, a master schedule with milestones for all of the work to be used in the RI process needs to be provided.

It should be noted that this deficiency can be corrected if Dow provides the summary tables developed by the Exposure Pathway Workgroup (EPW) in the RIWPs as initially committed to by Dow. These tables identify the known relevant exposure pathways and identified data needs to be addressed in the

initial phase of the RI. It is not clear why the summary tables were not included in the RIWPs as these tables were developed by the EPW during a six-month process and were conceptually approved by the Dow members of the EPW.

4) **Potential Constituent of Interest (PCOI) Identification.** The RIWP does not address and, therefore, must be revised to address, comments previously provided to Dow on the PCOI identification process. For example, the proposed sediment PCOI list must be revised to include contaminants that were previously detected in caged fish studies conducted adjacent to the Dow facility.

The TR RIWP must be revised to increase the proposed sediment core sampling density adjacent to the Dow facility in order to more completely evaluate a known release area (i.e., tighter PCOI sampling closer to one of the known source areas).

Additional detail must be provided in the RIWPs that comprehensively describes the chemicals and wastes produced by Dow over the history of the facility. The Revised RIWPs must show how this information was used to develop PCOI lists.

The process that Dow has proposed for the elimination of PCOIs from further consideration must be revised, especially since the initial screening process eliminated compounds from the Target Analyte List that are known to be of concern from existing environmental data. The proposal to dismiss PCOIs if they are not detected in more that five percent of the samples is not acceptable in that it has great potential to eliminate PCOIs that may be of concern of over geographic areas that may be less that one mile in areal extent. It is quite possible that smaller areas of sediment contamination could be presented adjacent to the Dow site, as suggested by contamination in the caged fish studies conducted in 1997 and 2001.

5) **Soil Sampling.** The RIWP proposes the collection of soil samples randomly distributed throughout the 8- and 100-year floodplains of the Tittabawassee River floodplain for PCOI identification and to provide data to develop a geospatial model to predict the distribution of dioxins and furans in the floodplains. Based on the review of this process, the MDEQ has the following concerns that must be directly addressed by revision of the TR RIWP:

- The first phase of the RIWP data collection must include direct investigation and the collection of detailed information on a portion of residential properties that are of highest concern, i.e., a representative population of Priority 1 Interim Response Activities (IRAs) properties and high-use areas of Priority 2 properties. These are the areas where greatest human exposure to the highest levels of contamination is expected. During the implementation of the Priority 1 IRAs, Dow chose not to collect any chemical data on the Priority 1 properties. It is necessary to determine if there are other PCOIs present at levels of concern in these areas and whether any chemical associations exist

between any identified PCOIs and/or other physical or chemical soil properties.

The RIWPs must also be revised to clearly identify the types and numbers of properties that will be sampled during the implementation of the proposed RIWPs and more clearly describe the iterative approach.

Note that the MDEQ is not opposed to the concept of developing an adequate geospatial model to predict levels of contamination in appropriate portions of the floodplain, i.e., areas where an adequate presumptive remedy is proposed or where there is less concern for human exposure. However, in the absence of a proposal for a presumptive remedy(ies) for these areas, it is not appropriate to use a model to predict concentrations on properties where there is the highest level of concern. In these areas, adequate actual soil concentration data, rather than modeled results, is necessary to ensure adequate protection of human health.

The proposed sampling density for the development of the model is not sufficient to predict the extent of contamination at the level of certainty or precision necessary to make remedial decisions for individual properties. The MDEQ notes in this review that the grid proposed by Dow to develop the model is much larger than the typical residential exposure unit. The ability to accurately model concentrations is limited by the size of the grid on which the model is based. Direct sampling on the properties of highest concern, or a representative portion of properties with validated data correlation, is necessary to reduce uncertainty in these areas and provide more technical basis to the remedial decision-making process.

Therefore, the first phases of the RIWPs must be revised to provide for the direct investigation of contaminant concentrations on a representative subset of Priority 1 and high-use Priority 2 properties. This information can then be used with the other sampling that Dow has proposed to construct the model. This work should be integrated with the U.S. Environmental Protection Agency's (U.S. EPA) preference to sample the floodplain and river on periodic transects (e.g., 1/4-mile transects at intervals of approximately 100 feet as described in the U.S. EPA's attached comments). This type of sampling will also partially satisfy the SOW requirement to collect information to support the HHRA by providing a population of sample concentrations from the areas of highest human exposure concern that adequately represents the "exposure units" (i.e., the property size for a variety of land use) with the highest contamination levels. This would represent a reasonable high-end exposure scenario for use in the HHRA.

Any meaningful random sampling approach, especially over such a large area, would require a much larger sample population than is currently proposed by the TR RIWP (i.e., about a 1,000-foot grid). Additionally, a random sampling approach over the 8- and 100-year floodplain areas with

numerous variables (e.g., land use, vegetation, soil types, elevation, etc.) at this stage of the RIWP may be too large of an undertaking without some prior transect sampling, beyond that completed in the Scoping Studies, to focus on correlating contaminant concentrations potentially to physical or chemical features throughout the study area.

The MDEQ recognizes that this will increase the number of samples to be collected during the initial phase of the RIWP. However, the MDEQ remains open to the use of screening technologies, where appropriate, to reduce costs.

- For other proposed random samples, the RIWP must provide information on the targeted locations and land uses so it can be determined whether the different land uses (e.g., residential, agricultural, etc.) are being adequately sampled and to provide a basis for the collection of more detailed information in the future. For example, farm fields with varying levels of contamination need to be identified to focus data collection on the "blowing dust" pathway.

6) **Geospatial Modeling.** If Dow proposes to conduct geospatial modeling as part of the RIWP, the following information must be directly included in the RIWPs for review and approval:

- <u>The statistical basis for the sampling grid (the point to area spatial representation) and a clear basis for proposing the sample population(s) for the study areas.</u> Dow needs to show how the proposed grid intervals are appropriate for their intended purposes. Any references and calculations need to be provided in the proposal.

- <u>The processes and equations upon which the model is built. A report documenting the development and application of the model must be presented for review.</u> The proposal should identify what type and amount of data are to be used in developing and calibrating the model and the plan for using results of all pertinent model simulations. This information needs to be included in text, table, and/or figure format.

- <u>The process by which the model will be calibrated to the n samples.</u> Model calibration consists of changing values of model input parameters, within a reasonable range, in an attempt to match observed concentrations. Calibration simulations are needed to narrow the range of variability in model input data since there may be numerous choices of model input data values that may result in similar model solutions. At a minimum, model calibration must include comparisons between model-simulated conditions and field conditions for the n samples.

- <u>Verification of the model by demonstrating that it also matches existing data.</u> This explanation would also account for the iterative process between data gathering and modeling. Any predictive aspects of the model must then be

evaluated to determine whether it can accurately estimate the concentrations in areas where there is no data. Dow must evaluate the accuracy of the modeled results by testing of the predictive capabilities and accuracy of the model by selecting locations to collect new samples and by comparing the modeled results to the actual concentrations in the soil samples. The MDEQ and U.S. EPA would collect audit samples as well to verify the results of the model.

7) **Sediment Sampling.** Dow is proposing to collect 25 sediment samples for PCOI identification (see Deficiency 4) and to test the theory that sediment levels of dioxin are "random." The RIWP needs to provide more detail to describe how the hypothesis of randomness is to be tested and at what scale this hypothesis may apply. A sampling design suitable for estimating a semivariogram at varying scales would be a more appropriate method to test for randomness (specific tests of spatial randomness are readily available). However, the spacing of data described in the RIWP is too wide to adequately identify the scale of spatial continuity within the river. The MDEQ is willing to discuss alternative approaches to determine whether there are spatially aggregated deposits of contaminants within depositional zones or whether contaminant distributions are truly random. The design proposed in the TR RIWP is not adequate for these purposes and must be revised.

For comparison purposes, the level of information used to make predesign remedial decisions on the Fox River in Wisconsin (Fox) is attached in Attachment C. Over two smaller study areas on the Fox River, nearly 16,000 samples were collected and evaluated in preremedial design investigations.

Similarly, the MDEQ's 2002 Sampling Strategies and Statistics Training Materials Document (S3TM) would indicate a random sampling grid for this long, narrow area would be an 80- to 100-foot grid. This would be the basis for a "proportioned random grid" that could then be used to provide the foundation for possibly selecting systematic and/or stratified sampling strategies to the base grid or apply to transect sampling intervals. Transect number and selection location could be based on a different strategy (see Deficiency 5).

In addition, the analysis provided by Dow in the TR RIWP is flawed in that it combines biased sampling data collected by the MDEQ in 2001 with random data collected by Dow in subsequent studies. The median concentration of the inappropriately combined data sets is about 30 parts per trillion (ppt) toxic equivalent (TEQ). When the MDEQ data, which was intentionally biased toward areas of fine grained sediment deposition, is analyzed separately from the randomly collected data, the median of the biased data set is 240 ppt TEQ. This strongly suggests that the distribution of the more highly contaminated sediments is not random and can be predicted in the field or potentially by a more comprehensive sampling approach.

As previously communicated to Dow by the MDEQ's comments on Flow and Solids Monitoring Work Plan 2003 and more recently in June and November 2005, a critical first step in this process is to determine if there are physical or chemical properties in the sediments that are controlling the distribution of dioxins and furans before designing and implementing a test to assess "randomness."

8) **Preliminary Feasibility Study Planning.** The RIWPs do not discuss or address in any detail preliminary feasibility study planning or data needs as required by Section III.F of the approved SOW, R 299.5528, or as discussed in Dow's "Performance Based Approach" proposal. The RIWPs need to be revised to provide this key component of the RIWPs.

9) **The TR RIWP does not include and needs to be specifically revised to include mapping and representative sampling of erosional areas (e.g., cut banks).** This is necessary to determine how large a continuing source these features are for remedial planning purposes.

10) **The Midland PCOI investigation strategy needs to be reevaluated.** In addition to the comments provided by the U.S. EPA on this issue, the "blind - blind" strategy proposed continues to be deficient. The MDEQ recommends a different approach using a boxed-random sampling along the proposed Phase II transects, as discussed during the meeting on February 15, 2006. Samples from multiple properties within the box would be collected, totally blinded to all parties, and a subset analyzed for the target parameters and/or physical properties. This allows for a general location reference, while protecting the identity of the property. It also provides an immediate mechanism to evaluate the occurrence of a PCOI at a level of concern; the other box samples can be analyzed without "unlocking" the code or remobilizing for sampling. If any PCOI concentrations are of concern, the concern could be limited to the geographic area of the "box."

11) **Data Quality Objectives.** These objectives will need to be revised to reflect the required modifications to the RIWPs.

The Following Items Specifically Address the Human Health Risk Assessment Work Plan (HHRA WP), Components of the RIWPs

12) Review and approval process for components of the HHRA WPs. The HHRA WPs must be revised to include a WP for each component of the HHRA to be submitted for review by the MDEQ and Independent Science Advisory Panel (ISAP) as well as requiring approval or approval with modification from the MDEQ prior to implementation pursuant to the requirements of Condition XI.B.3.(5) of Dow's License. The review and approval process for each WP must also include review by the ISAP. A review and approval process for the individual WPs for each component of the HHRA WP is necessary because the WPs represent critical decision points in the HHRA process. It is essential that such decision points get the highest level of scientific review to ensure that the best available science is used in accordance with Condition XI.B.3.(b)(iv) of the License; Section I.C.2 of the Framework; and Section III.C., Bullet 4, of the approved SOWs. As Dow has proposed in the HHRA WPs, several components do not include a review and approval process for the WP for that component.

As an example, in the introduction of the HHRA WP in the Midland RIWP, Item 5, the License language is misquoted. Condition XI.B.3.(b)(iv) of the License gives Dow "the option to propose steps [work plan] to develop site-specific cleanup criteria [SSCC]." Dow's proposed HHRA WP erroneously states that the License allows them to propose an SSCC.

13) Preliminary Conceptual Site Model (PCSM). The PSCMs must be revised to describe known and expected human and ecological exposure pathways for each land use including transport mechanisms or migration routes known or expected to occur between environmental media (e.g., soil and sediment) and receptor populations. Neither the RIWP PCSMs nor the HHRA WPs include this information. A conceptual site model is "a three-dimensional 'picture' of site conditions that illustrates contaminant distributions, release mechanisms, exposure pathways and migration routes, and potential receptors" (citation from the *U.S. EPA Superfund, Soil Screening Guidance User's Guide,* EPA/540/R-96/018, July 1996).

14) Identification of Exposure Pathways. The HHRA WPs must be revised to identify the exposure pathways by media and land use based on the concurrence of the EPW. The approved SOWs state, "The RI Work Plan will include identification of potential exposure pathways for each relevant land use" and "The RIWP will propose potential Tittabawassee floodplain exposure pathways that will need to be fully addressed in the RI. All exposure pathways evaluated will be identified and the rationale for inclusion or exclusion in the final human health risk assessment will be provided." However, the proposed RIWPs and proposed HHRA WP appendices do not identify specific exposure pathways and

media by land use that will be evaluated. Exposure pathways identified with previously concurrence with the MDEQ; the Michigan Department of Community Health; the Michigan Department of Agriculture; and the U.S. EPA, Region 5, for dioxins and furans through the EPW must be identified for the HHRA WPs and PCSM sections of the RIWPs. Exposure pathways may be different for other PCOIs. These other pathways will need to be determined after identification of other PCOIs, if present.

15) Exposure Inputs to HHRA Equations. The HHRA WPs must be revised to prioritize exposure parameters intended for development of probability distributions. The priority for exposure inputs for the development of probability distributions must consider the sensitivity of the exposure input and the type of investigation necessary to develop the distribution.

The HHRA WPs state that all inputs to the risk assessment must have probability distributions. This is not an accurate statement according to the U.S. EPA's Probabilistic Risk Assessment (PRA) guidance or an efficient use of time and/or resources. The U.S. EPA's PRA guidance recommends that PRAs start out with a preliminary evaluation of the sensitivity of each exposure assumption. This sensitivity analysis can be performed with distributions if readily available and/or by using high-end, central, and low-end tendencies. In this way, the risk assessors can determine the most important inputs for quantifying risk for each pathway. Only the more sensitive exposure inputs are recommended for the development and evaluation of representative probability density functions (PDFs) in lieu-of-point estimates.

The HHRA WPs currently show a partial list of the exposure parameter variables for which PDFs or probability mass functions (PMFs) are proposed for development prior to determining SSCC. It is not clear how the information will be obtained or developed for these probability distributions. In addition to the sensitivity analysis described above, the WPs must also indicate the type of data available, or intended to be developed, for each exposure parameter variable. The MDEQ and U.S. EPA recommend placement of each exposure variable into the following categories to clearly identify the type of investigation needed to develop a PDF or PMF for each:

(a) Parameters having a quantitative variation that is expected to be well known or of relatively low uncertainty (e.g., body weight variation) for which published data is readily available and collection of site-specific data is not needed.

(b) Parameters having a quantitative variation that is less well known or may be subject to significant uncertainty, therefore, requiring an extensive literature review; or a combination of published literature values, default values, or professional judgment.

(c) Parameters for which the quantitative variation is intended to be fully described by site-specific data or information and, therefore, will require collection of field data and a specific plan for field data collection.

To the extent possible, the WPs must place the listed exposure parameters into one of the three categories presented above. This information will give the agencies and Dow a better idea of the complexity of the impending PRA and the extent of the field data collection effort. Exposure parameters requiring field data collection must be listed in a priority order that is based on current understanding of likely influence of each parameter on HHRA. This priority order can be further refined based on the sensitivity analysis and the evaluation of data available or identified for data collection.

16) **Exposure Data Collection.** The HHRA WPs must be revised to identify specific exposure parameter data that is intended to be collected for use in the HHRA. The specific preliminary data and/or approaches to identify the exposure data that will be evaluated for collection must also be included. The SOW states that "the initial phase of the RI is anticipated to include collection of data to…identify and collect exposure data to support the human health risk assessment (HHRA)." The proposed RIWPs or HHRA WPs do not identify any specific preliminary exposure data needs or specific approaches to evaluate these exposure data needs. Consideration of exposure units and adequate representation of media concentrations for each exposure unit is also necessary for development of sampling plans to collect environmental media concentration data for the HHRA. Collection of data must be initiated to begin addressing known pathways in a prioritized manner. Priority must be set for exposure data collection.

17) **Missing Relevant Exposures.** The HHRA WPs must be revised to include typical dietary exposures and breast milk exposures. Further identification or description of culturally relevant exposures (e.g., culturally related Native American exposures) must also be included.

The HHRA WPs specifically state it will not include background dietary exposures. Dow claims that the HHRA process in practice does not address risks from other sources. An example of a soil cleanup criterion developed with consideration of other sources of exposure, including typical diet, is provided in the justification for the current generic residential direct contact criterion for lead (see Attachment C). There was concurrence by the EPW that typical diet was relevant as part of the exposure necessary to be included for noncancer risk assessment for dioxins and furans. Part 201 specifically includes the consideration of nonrelease sources in evaluation on noncancer risk using a relative source contribution factor other than the default value of 1.0 when "compound and site-specific data are available to demonstrate that a different source contribution is appropriate," Michigan Compiled Laws (MCL) 324.20120a(4). R 299.5703(d) of the Part 201 Rules states: "Relative source contribution factor" or "RSC" means that portion of a person's total daily intake of a noncarcinogenic hazardous substance that comes from the medium

being addressed by the cleanup criterion." The RSC is included in R 299.5710(3), Equation for Noncarcinogens, and R 299.5720(1) and (2), Equation for Noncarcinogens, of the Part 201 Rules. The RSC is included to account for other sources of exposure (predominantly considered for dietary exposure).

The HHRA WPs do not include breast milk exposure accounted for in the text or algorithms. This exposure pathway is important for evaluation of the risk posed for developmental effects, which is a sensitive effect of dioxins and furans. Breast milk exposure has been demonstrated to be a major component of total exposure for infants and young children, who are sensitive subpopulations both for exposure to and noncancer effects of dioxins and furans.

The HHRA WPs do not include the Native American related exposure pathways identified as part of the EPW consensus with help from a representative of the Saginaw Chippewa Tribe. The HHRA WPs must be revised to include these exposure pathways for evaluation during the HHRA process.

18) **Toxicity Values.** The Identification and Derivation of Toxicity Values section of the HHRA WPs must be revised to eliminate the use of PDFs for the development of toxicity values. The MDEQ concurs with the U.S. EPA's, Region 5, position that it is not acceptable to develop PDFs for toxicity values. Combining of data from multiple studies typically is carefully done using meta-analysis, not a Monte Carlo approach, and ensuring only studies appropriate for combining in a meta-analysis are used. Dow's proposal is also contrary to Part 201 requirements, which require the use of 95 percent upper bound on cancer risk and those criteria be based on most sensitive effect. MCL 324.20120a(4) specifically requires 95 percent upper bound estimate of cancer risk not "most likely" or maximum likelihood estimate and that criteria must be based on the most sensitive effect. Dow's proposed approach does not comply with these requirements.

As noted in Deficiency 26, it is not necessary or appropriate to focus limited resources on obtaining agreement on the appropriate toxicity value(s) at this time. This work can be done while field work is being conducted to fill the site-specific data needs of the HHRA process. Delaying the identification of the toxicity criteria will also ensure that the most current science is used at the time of criteria development. For example, the U.S. EPA may have completed their reevaluation of the toxicity of dioxin-like chemicals by the time the site-specific data collection process is completed. The MDEQ is willing to work with Dow on identifying appropriate toxicity criteria at the appropriate time in the HHRA process. If necessary, reevaluation of the process and sequence can be done as new information relevant to toxicity criteria becomes available.

It must also be pointed out that some developmental adverse effects (e.g., developmental reproductive effects in males) from dioxins and furans appear to be more sensitive than other noncancer adverse effects including other

reproductive effects. Combining studies, even with an appropriate approach such as meta-analysis, is not an acceptable approach to the development of toxicity values if it includes those studies evaluating less sensitive adverse effects and is contrary to the requirements of Part 201.

19) **Toxic Equivalency Factors (TEFs).** The HHRA WPs must be revised to identify the World Health Organization's (WHO's) TEFs for use in the HHRA. The HHRA can adopt updated WHO's TEFs when available. The MDEQ considers the WHO international consensus TEF values as "best available science" for use in HHRA. The HHRA WPs propose to develop or use TEFs and/or relative potency factors (RPFs) different from WHO international expert consensus values. These alternate values would be developed using probability distributions or other separate studies. Dow's justification for proposing this approach cites U.S. EPA ecological risk assessment guidance. Citation from a draft U.S. EPA Eco Risk Guidance document also states: "In most cases, it is reasonable to use the TEFs (WHO). They reflect careful scientific judgment following expert review of the existing database. Other RPFs can be derived for a particular species" (consider ecological risk basis of language). A different RPF would only be considered if all of the following applied: (1) the RPF is specific to most sensitive endpoint for that congener, (2) the RPF is demonstrated to account for human toxicity for that congener than the WHO's TEF, and (3) the use of the RPF incorporates the additively requirements of Part 201.

The MDEQ will consider updated WHO's TEFs, which are expected to be released soon, to represent "best available science." The updated WHO's TEFs are expected to incorporate evaluation of new data, including the recent National Toxicology Program bioassay for 2,3,4,7,8-pentachlorodibenzofuran.

20) **Screening Level Risk Assessment (SLRA).** The HHRA WPs must be revised to ensure that exposure pathways and/or PCOIs will not be eliminated if their elimination could result in representative environmental media concentrations from exposure units with the highest levels of contamination that would exceed cleanup criteria for those exposure pathways or PCOIs developed pursuant to the requirements of Part 201. The revisions must include using maximum media concentrations or concentrations that represent the 95 percent upper confidence level (UCL) for the highest contaminated exposure units in the study area for that exposure pathway and land use. The risk assessment requirements from Part 201 for developing cleanup criteria must also be included in the revised HHRA WPs.

Dow proposes to use SLRA to eliminate exposure pathways that will not exceed Part 201 cleanup criteria and associated requirements. This approach makes sense to the MDEQ, but the SLRA should be moved to the beginning of the process for all PCOIs (see Deficiency 26a.). However, the proposed approach for conducting the SLRA is unacceptable because it is likely to eliminate exposure pathways and PCOIs that may have representative environmental media concentrations that exceed Part 201 cleanup criteria as described below.

MCL 324.20120a(4) requires the use of 95 percent upper bound on cancer risk and all criteria based on most sensitive effect. Dow's proposal for the SLRA proposes to use maximum likelihood cancer and noncancer toxicity values. This proposal is contrary to Part 201 requirements and not an acceptable approach to assure that PCOIs concentrations and exposures will not exceed the requirements of Part 201. Noncancer distributions are proposed to include multiple endpoints, although it is not clear if these would include both sensitive and insensitive effects. This may not meet the requirements of Part 201 that the most sensitive endpoint be the basis for cleanup criteria and by extension HHRA. In addition, the SLRA, as proposed by Dow, allows use of any values from the distribution, which could include less conservative exposure inputs from the distributions, resulting in underestimating risk and the exceedance of cleanup criteria.

The U.S. EPA typically uses maximum exposure media concentrations for screening level risk assessments in order to determine the critical exposure pathways and PCOIs. Dow's SLRA proposes using a 95 percent UCL from environmental media concentrations. This approach could be acceptable if there was representative sampling of each exposure unit available (i.e., each property or MDEQ-approved representative subset of properties in the contaminated areas, especially the Priority 1 properties). Without having this data available, using the maximum media concentration helps to ensure that exposure pathways are not eliminated inappropriately. Evaluation of appropriate representative sampling by exposure unit is necessary prior to use in an exposure medium probability distribution or 95 percent UCL concentration calculation. Sampling to represent exposure units should be done only after the critical exposure pathways and PCOIs are identified. This will also ensure data collection is focused on critical exposure pathways to efficiently conserve time and limited resources.

21) **Forward-looking Probabilistic Risk Assessment.** The HHRA WPs must be revised to indicate that sensitive subpopulations will be evaluated separately with appropriate exposure inputs for each sensitive subpopulation. The PRA is titled as population-based and individual. However, the content describes a population-based approach and states the approach can provide a central tendency and reasonable maximum exposure from the general population distribution, but does not include evaluation of an individual with reasonable maximum exposure. The algorithms portion of the HHRA WPs proposes to use age-adjusted average values as inputs for the equations. This approach is appropriate for some adverse effects. However, the age-adjusted approach does not account for susceptible subpopulations (e.g., fetuses and children) when the most sensitive noncancer effects of the hazardous substance is developmental. Exposure assumptions specific for sensitive subpopulations are necessary, when the adverse effect(s) occur in those sensitive subpopulations that are not adequately protected by generic exposure assumptions (R 299.5734[3][a] of the Part 201 Rules). A list of chemicals that have cleanup criteria based on

developmental effects and the associated exposure inputs for the appropriate sensitive subpopulation is provided in Attachment C. Also, the approach described in the HHRA WPs is not likely to adequately account for high-end exposures (e.g., families using local fish as a major protein source).

22) **Area Wide Cleanup Criteria (AWCC) and SSCC.** The HHRA WPs must be revised to eliminate the use of the term AWCC or clearly state that the term is a subset of SSCCs as authorized under Part 201. AWCC is not a concept contemplated or authorized under Part 201. Any criterion developed under the proposed HHRA would be considered a site-specific criterion as defined by Part 201. Part 201 does contemplate a concept of an area-wide zone encompassing more than one facility to be covered by a single remedial action plan. However, the study areas included in Dow's proposed RIWPs are all one facility as defined by Part 201.

SSCC are necessary for the Tittabawassee River and floodplain. Contaminant levels found in various biota (e.g., chicken eggs, wild game, fish, etc.) indicate that other injuries have occurred that are not accounted for by generic criteria and need to be considered in the development of SSCC in order to protect public health, safety, welfare, and the environment pursuant to MCL 324.20120a(17) and R 299.5728 of the Part 201 Rules. In addition, SSCC will need to be established for surface water sediments pursuant to MCL 324.20120a(17) and R 299.5730 of the Part 201 Rules. The MDEQ is invoking R 299.5728 at this time to assure that adequate information is provided in the HHRA for the MDEQ to satisfy its obligation under MCL 324.20118(1) and (2)(a) to determine that the corrective action will be protective. The additional response activity being required now under R 299.5728 is evaluation of the exposure pathways where other injury has been documented. The necessity for actual additional remediation (i.e., beyond the response activity of evaluating risk in the affected pathways) will be determined by the MDEQ. The MDEQ's evaluation will be based on whether response activity that satisfies SSCC for Soil Direct Contact and Sediment is likely to also result in sufficient decrease in the availability of and exposure to dioxins that are currently producing injury in the other exposure pathways, such as the human food chain, so that the overall response is protective.

23) **Soil and Sediment Concentrations related to food-chain pathways.** The HHRA WPs must be revised to include algorithms that are based on exposure media that can be remediated (e.g., soil and sediment) or a process by which such algorithms will be identified or developed. The HHRA WPs include some major category exposure equations, but only for intermediate exposure media (e.g., fish, vegetable, meat concentrations). The HHRA WPs must include equations for determining critical exposure media concentrations (e.g., soil, sediment) necessary for determining cleanup levels.

24) Identification of other PCOIs. This section of the HHRA WPs must be revised to address the following deficiencies to ensure that PCOIs that may be significant are not screened out without adequate justification:

(a) The HHRA WPs propose to use generic human benchmark values as a threshold to eliminate PCOIs from further consideration. This is not appropriate if another benchmark (e.g., surface water protection, ecological protection, agricultural protection, etc.) is more applicable and restrictive. This proposed process must be revised to utilize the most appropriate benchmark value for the compound of concern for making decisions about retaining or eliminating it as a PCOI.

(b) The HHRA WPs propose to use trend analysis and mapping as a methodology to evaluate potential PCOIs and to determine if they are related to releases from Dow. These types of analyses will need to be proposed and evaluated on a case-by-case basis as the level of information being proposed for collection during the RIWPs may not be sufficient to conduct meaningful trend or spatial analyses.

(c) The HHRA WPs proposes using background threshold values (i.e., 95 percent upper prediction limit) to compare contaminants identified in the study areas to natural and anthropogenic concentrations of PCOIs in reference areas. The results of the comparison would be used to eliminate potential PCOIs. Part 201 allows the use of "background" in place of a generic cleanup criterion (R 299.5706a[5][b] and R 299.5707 of the Part 201 Rules). "Background" is defined in R 299.5701(b) of the Part 201 Rules as "the concentration or level of a hazardous substance which exists in the environment at or regionally proximate to a site that is not attributable to any release at or regionally proximate to the site." Again, these types of proposals will need to be evaluated on a case-by-case basis as in some cases the background areas proposed by Dow may have been affected by releases from Dow. For example, there is the potential for airborne releases of contaminants from Dow to affect soil and sediment quality in one of the proposed reference areas upstream of Dow (i.e., Emerson Park). It would not be appropriate to use areas for "background" that have been affected by releases from Dow or other sources to eliminate PCOIs from further consideration.

(d) The HHRA WPs propose to substituting benchmark risk values with practical quantitation levels (PQLs). This may not be appropriate as the PQLs may exceed the applicable benchmark values. R 299.5706a(5)(a) and R 299.5707 allow the use of a target detection level (TDL) that is set at, or as close as feasible to, the method detection limit as a default for a cleanup criterion that is below a TDL (R 299.5103[l] of the Part 201 Rules). A PQL is typically much higher that the TDL. Bioaccumulative PCOIs may not be detectable in sediments at a PQL or TDL but may be detectable in other media such as caged fish.

(e) Excludes analytes present in fewer than five percent of samples (regardless of concentration in samples that analyte is detected). As noted in previous deficiencies, this practice is not acceptable.

25) Citations and references. The HHRA WPs must be revised to correct the citations and references for Part 201 requirements and applicable U.S. EPA guidance documents. Several citations and references are provided in the HHRA WPs that are incomplete, are out of context, do not include all the applicable Part 201 regulatory requirements, or do not cite applicable U.S. EPA guidance.

For example, the HHRA WPs cite U.S. EPA's *Risk Principles and Guidance* (U.S. EPA, 2004) for developing toxicity criteria. The correct title of the U.S. EPA document is: "An Examination of EPA Risk Assessment Principles and Practices." The cited document is a staff paper and clearly states it "does not establish new Agency policy or guidance or amend any existing Agency policy or guidance. Nor does the document attempt to present binding prospective requirements, necessarily applicable to future agency actions." For the Dow HHRA WPs, this document may only be cited to describe typical U.S. EPA risk assessment practices.

In another example, the HHRA WPs state: "The development of an SSCC would be consistent with Part 201 [MCL 324.20120a(2)] and Rule 299.5732." This citation is incomplete in that additional portions of Part 201 and the associated administrative rules also set requirements for the development and implementation of SSCCs (e.g., R 299.5706, R 299.5706a[9], R 299.5734, R 299.5736, and R 299.5738 of the Part 201 Rules).

Corrections must be made to these and other citations and references in the HHRA WPs. For reference to Part 201, it would be acceptable to generically reference the statute and rules, in total, rather than specific subsections.

26) Sequence of proposed HHRA WP components. The HHRA WPs must be revised to incorporate a sequence and schedule as described below:

The sequence of components in the proposed HHRA does not appear to be structured in an efficient order and does not follow the U.S. EPA PRA guidance. The proposed HHRA must be revised to address and prioritize the most critical pathways, exposure parameters, and PCOIs. The approach and sequence proposed in the HHRA WPs is time and resource intensive and does not prioritize the collection of RI data for use in the HHRA early in the risk assessment process. Emphasis on the most critical aspects of the risk assessment should allow the HHRA to proceed more expeditiously. The HHRAs need to be revised to incorporate the following general sequence of activities:

(a) The critical exposure pathways and PCOIs should be determined prior to development of the exposure pathway inputs and toxicity criteria, instead of the sequence proposed in Dow's HHRA WPs. This can be done by conducting the SLRA first (with the revisions to the SLRA process described in Deficiency 20). Conducting the SLRA first will allow time and resources to be focused on critical exposure pathways and PCOIs instead of using time and resources on exposure pathways that will not be risk drivers. As mentioned previously, to determine the critical exposure pathways and PCOIs, the maximum or otherwise appropriate exposure unit based environmental media concentrations should be evaluated with generic cleanup criteria for the applicable land use. For relevant exposure pathways identified without generic criteria or PCOIs without generic criteria, an SLRA should be performed using point estimates for exposure and toxicity inputs. This is necessary to determine exposure pathways and PCOIs that should be subject to further risk assessment. This process needs to be separated as the SLRA can be conducted first for dioxins and furans while Dow begins to identify the PCOIs for risk assessment from sampling in the study areas. The HHRA process for additional PCOIs, without generic cleanup criteria, can follow this process after collection of data to identify or eliminate additional PCOIs.

(b) Once an SLRA is conducted, a sensitivity analysis can be used for the remaining exposure pathways and PCOIs to determine exposure assumptions that are critical for the development of probability distributions. It is also critical for this to be done early in order to determine the exposure data that needs to be collected as part of the RI.

(c) Based on the SLRA, a determination of any additional exposure data and other data that will be collected during the RI for use in the HHRA will be made next. A clear understanding and prioritization of the data to be collected for use in the HHRA is critical (as described in HHRA WPs Deficiencies 15 and 16). As the HHRA WPs have stated, it may take over a year to collect data of sufficient quality and quantity to be used in the HHRA, therefore, WPs for the collection of this data need to be submitted early in the HHRA process.

(d) Because the toxicity values are not dependent on the collection of site-specific data, this component may be deferred until after the determination of exposure inputs has been substantially completed. This will also allow for the toxicity values to benefit from the most current information available prior to completion of the HHRA process as identified in Deficiency 18.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGIONS 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

REPLY TO THE ATTENTION OF:

FEB 10 2006

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RETURN RECEIPT REQUESTED

DW-8J

Waste & Hazardous
Materials Division

FEB 14 2006

Mr. James Sygo
Associate Director
Michigan Department of Environmental Quality
P.O. Box 30241
Lansing, Michigan 48909

Re: *U.S. EPA Comments on the Tittabawassee River and Floodplain Remedial Investigation Work Plan and Midland Area Soils Remedial Investigation Work Plan submitted to the State of Michigan on December 29, 2005 by the Dow Chemical Company, Midland, Michigan*

Dear Jim:

In accordance with EPA's oversight role under the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6901 et seq., the United States Environmental Protection Agency, Region 5 (EPA or the Agency) has conducted a preliminary review of the Tittabawassee River and Floodplain Remedial Investigation Work Plan (T-RIWP) and the Midland Area Soils Remedial Investigation Work Plan (M-RIWP) submitted to Michigan Department of Environmental Quality (MDEQ) by the Dow Chemical Company, Midland, Michigan (Dow) on December 29, 2005. As detailed in the attached comments, the Agency has determined that the T-RIWP and M-RIWP (RIWPs) are critically deficient.

Prior to the submission of the Agency's comments, EPA and MDEQ staff conferred and agreed that the RIWP deficiencies set forth in EPA's comments need to be addressed by Dow prior to initiation of a more comprehensive review of these documents. Of particular note, Dow's Human Health Risk Assessment Work Plans are fundamentally flawed, and it would not be a wise or efficient use of either agency's resources to attempt to approve them with modifications in their current form. As a result, EPA requests that MDEQ require Dow to promptly address the deficiencies detailed in the attached comments and then require Dow to resubmit amended RIWPs to the State of Michigan no later than sixty (60) days from the date that Dow is provided written notice of the subject deficiencies. EPA also requests that MDEQ not approve either RIWP, in full or in part, until all of the requested changes are made by Dow and such changes have been reviewed and approved by MDEQ.

I want to thank you again for all of the hard work you and your staff have devoted to this matter and MDEQ's continuing efforts to protect human health and the environment throughout the State of Michigan. EPA considers MDEQ to be a valuable partner in protecting the environment and the

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Agency will continue to work closely with the State of Michigan in its oversight capacity in order to ensure that Dow timely complies with its RCRA license and all applicable federal laws

Please contact me at (312) 886-0399 if you have any questions concerning this letter or the attached comments

Sincerely,

Margaret M. Guerriero, Director
Waste, Pesticides and Toxics Division

cc: George Bruchmann, MDEQ
Frank Ruswick, MDEQ

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

CRITICAL DEFICIENCY COMMENTS

On

The Tittabawassee River and Floodplain Remedial Investigation Work Plan and Midland Area Soils Remedial Investigation Work Plan Midland, Michigan (December 2005) Submitted to MDEQ by the Dow Chemical Company, Midland, Michigan (MID 000 724 724)

February 10, 2006

The United States Environmental Protection Agency, Region 5 (EPA) has identified the following critical deficiencies in the Tittabawassee River and Floodplain Remedial Investigation Work Plan (T-RIWP) and the Midland Area Soils Remedial Investigation Work Plan (M-RIWP) submitted by the Dow Chemical Company, Midland, Michigan (Dow) to the Michigan Department of Environmental Quality (MDEQ) on December 29, 2005.

After a preliminary review of the T-RIWP and the M-RIWP (RIWPs), EPA has determined that the RIWPs are critically deficient and must be amended by Dow and resubmitted to MDEQ prior to the initiation of a detailed and complete review of the documents by MDEQ and EPA. Accordingly, EPA believes that MDEQ must require Dow to promptly remedy the deficiencies set forth below and resubmit amended RIWPs to MDEQ by no later than sixty (60) days from the date that Dow is provided written notice of the deficiencies. In addition, EPA requests that MDEQ not approve either RIWP, in full or in part, until the following changes are made by Dow and reviewed and approved by MDEQ.

TITTABAWASSEE RIVER AND FLOODPLAIN REMEDIAL INVESTIGATION WORK PLAN

Tittabawassee River Sediments

1. The sampling protocol set forth in the T-RIWP by Dow to determine the nature and extent of hazardous constituent contamination in the Tittabawassee River (TR) sediments is severely inadequate. Dow's current proposal to use approximately one sample to characterize each mile of river (25 samples per 22 miles of river) is unacceptable. Because EPA believes that Dow's proposal underestimates a technically supportable sampling density by several orders-of-magnitude, EPA requests that MDEQ require Dow to propose a significantly and substantially more intensive and comprehensive sampling program in the T-RIWP in order to adequately and properly characterize the nature and extent of Principal Contaminants of Interest (PCOIs) within the TR sediments. In addition, Dow's proposal in the T-RIWP to analyze only a surface sediment composite

and one randomly-selected underlying sediment composite is not acceptable. Dow's proposed approach will not define the vertical extent of the PCOIs within the TR sediments. As a result, EPA requests that MDEQ require Dow to analyze all of the soft sediment vertical composites for all the PCOIs.

2. Existing data is insufficient to support Dow's conclusion that sediment contaminant concentrations in the TR are random and that no consistently elevated areas of contamination exist within the TR sediments. Dow's proposal of one sediment sampling location per mile is very likely to be orders-of-magnitude greater than the actual distance of spatial correlation. Consequently, analytical results obtained from sampling locations with a separation of one mile would have a strong tendency to exhibit the unpredictability postulated by Dow. Because spatial correlations between sediment samples in the TR sediments no doubt exist, EPA requests that MDEQ require Dow to submit a sampling protocol to properly define empirically, the parallel and perpendicular correlation distances for the PCOIs in the TR sediments.

Tittabawassee River Floodplain

3. EPA does not consider geospatial modeling as an acceptable substitute to an empirical characterization of the nature and extent of contamination. Dow's proposed characterization protocol for the TR floodplain predominantly relying upon geospatial modeling to establish the nature and extent of the PCOIs in flood plain soils, as set forth in the T-RIWP is, therefore, not acceptable. Because the process of determining the nature and extent of the contamination in the TR floodplain must be essentially empirical, as well as technically supportable, EPA recommends that MDEQ require Dow to implement a significantly more comprehensive and intensive sampling program that will establish the nature and extent of the PCOIs within the TR floodplain.

Tittabawassee River Water Column Sampling

4. Dow's proposal for three surface water sample locations in the TR to be sampled during a base flow and flood event is inadequate. EPA requests that MDEQ require Dow to conduct a more frequent and comprehensive water sampling program in order to determine how, and under what conditions, the PCOIs are migrating within the TR watershed. In addition, water sampling locations should be increased to include, at a minimum, one location immediately downstream from an actively eroding source area within or along the TR that is associated with elevated PCOI concentrations. Further, EPA requests that Dow be required to conduct significant additional sampling during high-flow events, since much of the erosional and sediment transport activities occur during these events. All samples should be separated into a dissolved and suspended-solids phases. Each phase should be analyzed for all of the PCOIs.

Acceptable Preliminary Approach for Tittabawassee Rivers Sediments and Floodplain Soil

5. EPA requests that MDEQ require Dow to undertake the following four sequential steps in order to properly characterize the TR and Floodplain: 1) completion of a thorough PCOI

study; 2) completion of a thorough geochemical study on all of the identified PCOIs (or all PCOI chemical groupings) of interest; 3) completion of a pilot characterization study to determine horizontal sampling grid interval for both the River sediments and the floodplain soils (recommended vertical compositing intervals are provided below); and 4) completion of a full characterization study including the preparation of depth-based contaminant-concentration contour maps for all identified PCOIs. As all characterization activities tend to be iterative, EPA proposes that an acceptable preliminary (first iteration) approach to characterize the nature and extent of the hazardous constituents in the TR sediments and floodplain soils would include, at a minimum, the following activities:

- **PCOI Investigation**

  - All documents and information reviewed in creating the Target Analyte List (TAL) proposed by Dow in the TR-RIWP (Figure 4.3) should be included, with cross references to the appropriate sections, in a new appendix to the T-RIWP. It is necessary for MDEQ and EPA to review all such documents and information in order to verify that the conclusions drawn by Dow in formulating the proposed TAL are accurate and appropriate.

  - The proposed sediment, floodplain soil and surface water sampling may be adequate for the purposes of a PCOI investigation, however, PCOI sediment sampling frequency should be increased close to the Midland Plant site. This increased sampling density is necessary due to: 1) the additional (beyond dioxins and furans) PCOIs that have been detected in caged fish studies; 2) the known presence of NAPL at or near Dow's facility; and, 3) the fact that there are likely areas on or adjacent to Dow's facility which potentially serve as continuing sources of contaminants. At all sample locations, the sediment and soil samples collected for PCOI analysis should consist: 1) a surface composite extending from the surface to a depth of six inches (0-6 inches); and, 2) composite samples collected over one foot intervals thereafter until unimpacted material is reached. In addition, the PCOI study should include the analysis of groundwater outside the RGIS system, and free-nonaqueous phase liquid samples from the on-site RGIS.

- **Pilot Characterization and Geochemistry Study**

  - EPA believes that the limited nature of the existing site characterization information currently precludes establishing a statistical basis for the Pilot Characterization and Geochemical Studies outlined below. These limitations include: the lack of a completed PCOI investigation; the low density of sampling locations; and inconsistencies within Dow's current site conceptual model. While EPA's proposed Pilot Characterization and Geochemistry studies are not statistically-based, all site characterization activities are iterative in nature. The information these studies will provide will form a firm foundation for either a technically defensible statistical analysis on the nature and extent of PCOI contamination, or will form the basis for the collection of additional information

needed to meet the RI objectives, including statistical defensibility. In addition, the proposed approach is consistent with long-standing precedents established by EPA approvals of similar site characterization investigations. Sampling for both PCOIs and geochemistry should be performed on transects across the river at a minimum of 1/4 mile intervals (approximately 100 transects). Core soil and sediment sample spacing along each transect should be at one hundred (100) foot intervals. At all sample locations, the sediment and soil samples collected for PCOI analysis should consist: 1) a surface composite extending from the surface to a depth of six inches (0-6 inches); and, 2) composite samples collected over one foot intervals thereafter until unimpacted material is reached. A minimum of three river sediment samples should be collected per transect. The selection of transect locations should be conducted so that the various land uses and geomorphological characteristics of the River are properly represented. Samples to be analyzed for the geochemistry study should be selected to provide a range of characteristics (e.g. grain size, TOC, mineralogy, contaminant concentration, surface coating on mineral grains, etc.) so as to define parameters which control the fate and transport of the PCOIs.

- Additional grid sampling should be conducted at a significantly higher density at the three scoping areas used by Dow during its preremedial investigation scoping studies in 2003, 2004 & 2005. EPA recommends that the sampling locations be gridded on a one hundred (100) foot interval throughout both the floodplain and the River, extending from one side of the one hundred (100) year floodplain to the other. At a minimum, three river sediment samples should be collected per grid transect; e.g. for every one thousand (1,000) feet of river reach, sediments will be collected from at least 30 locations. Grid locations where only surface sampling was conducted, should be resampled with the core sampling methodology described above.

- **Full Characterization Study**

  - A final sample methodology, reviewed and approved by MDEQ, shall be based upon the results of the Pilot Characterization and Geochemistry study, unless MDEQ determines further data are required to finalize the sampling methodology. As with the preliminary characterization study, and for consistency and comparability, EPA recommends that the compositing methodology described above be used for the full characterization study.

- **End Products**

EPA recommends that, at a minimum, the final work products of the T-RIWP characterization process include the following:

- 90 ppt TEQ boundary line map (vertical and horizontal).
- Depth based concentration contour maps with a 100 ppt TEQ contour line.
  - 0-6 inch surface TEQ concentration contour map.

    - TEQ concentration contour maps for all underlying 1-foot vertical compositing intervals.
  - Comparable boundary lines and maps should be produced for all other PCOIs.

MIDLAND AREA SOILS REMEDIAL INVESTIGATION WORK PLAN (M-RIWP)

6. Dow's proposal in the M-RIWP to delay Phase II sampling until 2008 is not acceptable to EPA. Rather, to avoid this unnecessary delay in the remedial investigation and to minimize any ongoing exposure and associated risks, EPA requests that MDEQ require Dow to initiate the Phase II sampling, described within the M-RIWP, no later than Spring of 2006. This recommended change to the M-RIWP would eliminate the need for the duplicative Preliminary PCOI Investigation component of the Midland Area Representative Soils Sampling and Analysis Plan in Support of the Bioavailability Study.

7. While the January 20, 2005 Framework Agreement between Dow and the State of Michigan does not require Dow to conduct additional off-site D/F nature and extent sampling until risk-based site-specific and/or area-wide cleanup criteria (AWCC) have been developed by Dow and a final determination on such criteria has been made by the State, this multi-year process of developing, reviewing and approving these risk-based and/or area-wide criteria will preclude a thorough evaluation of the extent and intensity of the D/F contamination within the City of Midland. Such a delay in not acceptable or appropriate in light of the significant potential risks posed by the known hazardous constituent contamination in the City of Midland. Rather, EPA recommends a substantially more proactive assessment of such risks, i.e. comprehensive characterization of the contamination starting in 2006 and, if necessary, the implementation of prompt remedial measures to address such contamination and reduce the potential for exposure.

8. EPA requests that MDEQ require Dow to include in the M-RIWP's proposed Phase II sampling plan, soil sampling at the Dow Midland facility. The primary purpose of this on-site sampling would be to evaluate the presence or absence of other PCOIs which have been released from the facility. A complete PCOI list is a prerequisite to a full characterization of the nature and extent of both the on-site and off-site contamination. On-site sampling at Dow's facility is an simple and efficient way to evaluate the presence or absence of PCOIs.

9. EPA recommends that, at a minimum, the final work products of the M-RIWP characterization process include the following:

    - 90 ppt TEQ boundary line map (vertical and horizontal).
    - Depth based concentration contour maps with a 100 ppt TEQ contour line.
      - 0-6 inch surface TEQ concentration contour map.
      - TEQ concentration contour maps for all underlying 1-foot vertical compositing intervals.
    - Comparable boundary lines and maps should be produced for all other PCOIs.

HUMAN HEALTH RISK ASSESSMENT WORK PLANS

The Human Health Risk Assessment Work Plans (HHRAWPs), as proposed by Dow in the RIWPs, do not comply with EPA risk assessment policy and guidance and, therefore, cannot be approved by EPA. As a result, EPA requests that MDEQ require Dow to substantially amend and revise the HHRAWPs prior to the initiation of a detailed and complete review of these work plans in accordance with the comments provided below.

10. EPA requests that MDEQ require Dow to identify in the RIWPs the likely and potential specific pathways of human exposure to PCOIs in the Midland soils and TR soils and sediments. Such exposure pathways will likely include direct contact to PCOIs and indirect exposure to PCOIs after fate and transport processes have occurred, e.g. consumption of contaminated fish and/or wildlife. In addition, Dow must identify appropriate high-end receptor populations, such as subsistence fish and wildlife consumers and native American populations. MDEQ should also require Dow to include these specific exposure pathways and relevant transport processes in each Site Conceptual Model via appropriate tables and diagrams.

11. EPA requests that MDEQ require Dow to describe in specific detail in the RIWPs how the proposed field data collection and field sampling results will be used in the HHRAWPs. Dow should be required to identify the specific data which will be collected and used to support the exposure assessment portion of the HHRAWPs. In addition, Dow should be required to explain how the PCOI concentrations will be incorporated into the HHRAWPs to determine levels of risk and used for comparison to Cleanup Criteria.

12. EPA policy does not allow probabilistic methods to be used for deriving dose-response parameters. Rather EPA policy requires the long-standing and scientifically supportable method of developing chemical-specific toxicity factors (e.g., cancer slope factors, Reference Doses, TEFs, etc.) based on an analysis of the most sensitive endpoints relevant to human exposure. Dow's proposal, in the HHRAWPs, to use probabilistic methods for deriving dose-response parameters for the PCOIs is unacceptable. In addition, Dow has not identified the criteria by which the dose-response risk-assessment parameters currently in use by EPA and MDEQ will be determined to be "unreliable." Dow implies that the methodology for applying probabilistic risk assessment (PRA) to dose-response data in HHRAWPs would be straightforward, but this is far from the case. For example, Dow does not explain whether the PRA analysis will use human studies in addition to animal bioassay studies. If data from one animal species were to show a clearly defined (and human related) dose-response effect (positive), but the data from another species did not (negative), it is not clear in the HHRAWPs whether Dow would give the data from the positive species more weight than the data from the negative species, in accordance with EPA policy and guidance. The same questions arise in regard to the use of human data versus animal data, i.e. if the human data were to show a clear or suggestive dose-response effect, it is not clear whether Dow would give more weight to the human data over animal data.

In accordance with the comments above, EPA does not believe that Dow has proposed an adequate or widely accepted methodology for constructing Probability Distribution Functions (PDFs) for dose-response data. Because the establishment of dose-response data and toxicity factors for chemicals has national implications, EPA cannot approve requested deviations on a site-specific basis. National standards are based upon scientific consensus and are established by EPA Headquarters in Washington, D.C. Recognition and use of these standards are a necessary prerequisite to national consistency. As a result, EPA, Region 5 cannot approve a PRA which includes probabilistic methods for deriving dose-response parameters. Specifically, OSWER's program guidance on PRAs states:

"This guidance does not develop or evaluate probabilistic approaches for dose-response in human health assessment and, further, discourages undertaking such activities on a site-by-site basis. Such activities require contaminant specific national consensus development and national policy development. Parties wishing to undertake such activities should contact the OERR to explore ways in which they might contribute to a national process for the contaminant of interest to them." (RAGS Volume 3 Part A - "Process For Conducting Probabilistic Risk Assessment"; December 31, 2001).

As a result, inquiries on the use of alternative toxicity factors are typically referred to the appropriate EPA Headquarters program (e.g., OSWER, ORD, OPPT) for a national expert review in which the Region would participate.

EPA conducts independent external peer reviews of the dose-response data evaluations and provides for public comment on the draft evaluations via several forums, e.g., Federal Register notices, technical workshops, FACA committees, draft RED notices, etc. Hence, there is, has been and will continue to be ample opportunity for Dow to participate in these national review processes.

EPA believes that Dow's proposal to generate a complex PRA as a first attempt to determine cleanup criteria, is inappropriate and unnecessary given the limited nature of the characterization data for the soils and sediments within the proposed study areas. Rather, EPA believes Dow should be required by MDEQ to develop a base-line risk evaluation which is simple and deterministic, e.g. similar to a CERCLA point estimate risk assessment. This simplified risk assessment approach would be more than sufficient to derive any supplemental cleanup criteria for exposure pathways and/or land use not currently included in MDEQ Part 201. In addition, such cleanup criteria could be used during RIWP sampling to assist Dow in development of the Data Quality Objectives. Also, this base-line deterministic risk assessment approach is capable of identifying a chemical contaminant(s) which is (are) present in environmental media: 1) at a concentration level exceeding the existing Part 201 Generic Cleanup Criteria; or 2) at a concentration level exceeding the Part 201 residual risk goals, i.e. cancer risk not above 1E-05; toxic hazard not above 1.0 for an exposure pathway that does not have an existing Part 201 Generic Cleanup Criteria. In summary, Dow's PRA should focus only on the contaminant(s) which exceeds Part 201 Generic Cleanup Criteria or the Part 201 residual risk goals.

13. EPA requests that MDEQ require Dow to follow the guidelines and recommendations set forth in the EPA document titled "Risk Assessment Guidance for Superfund: Volume III - Part A, Process for Conducting Probabilistic Risk Assessment" (U.S. EPA, 2001) in amending its revised HHRAWPs. At a minimum, EPA believes that the following concepts should be incorporated into the HHRAWPs:

- Dow should use a tiered approach to incorporating PRA into the site risk assessment.

- Dow should perform a point estimate/deterministic risk assessment prior to developing a PRA.

- After Dow's deterministic assessment is complete, Dow will need to perform a streamlined sensitivity analysis to identify the key parameters whose variability/uncertainty could significantly affect the calculated results of the deterministic assessment. Next, Dow should be required to focus its efforts on using statistical or probabilistic methods to describe quantitative variability/uncertainty only on these key parameters.

- After Dow's deterministic risk assessment and the streamlined sensitivity analysis are completed, any inferred potential value (benefit(s)) that would accrue to the risk management decision process through generation of a multi-tiered PRA, must be justified. This justification will need to be evaluated by MDEQ and EPA for scientific/technical appropriateness and supportability.

- It seems neither appropriate or scientifically necessary for every parameter, e.g., exposure factor, fate-transport factor, chemical-specific constant, etc. in the PRA to be described by a PDF. Some parameters will probably need to be entered as point estimates due to the lack of sufficient quantitative data to generate a valid PDF or because the preliminary sensitivity analysis indicated that certain parameters have a limited variability and therefore ability to affect the calculated risk estimate. As a result, such PDF parameter estimates should only be used with the approval and at the discretion of MDEQ.

COMPREHENSIVE SCHEDULE

14. A single comprehensive schedule is needed for all activities including: all workplan submittals, all field work, all deliverables, human health risk assessment activities and supporting studies, ecological risk assessment activities and supporting studies, and all deliverables. EPA understands that exact dates cannot be stated for all activities, but it is important for MDEQ and EPA to understand the sequencing and interdependencies of the activities to allow for work planning.

MICHIGAN DEPARTMENT OF NATURAL RESOURCES

INTEROFFICE COMMUNICATION

October 26, 1993

JUSTIFICATION

TYPE B CLEANUP CRITERIA

FOR LEAD

This justification supports the soil and groundwater Type B cleanup criteria for lead. The direct contact soil criterion and groundwater criterion are 400 ppm and 4 ppb (or local background if shown to be higher), respectively. The direct contact soil criterion of 400 ppm was derived assuming a drinking water concentration of 4 ppb, however, if local background for groundwater can be shown to be higher, background can be used as a cleanup goal. There may be a few unique situations where a groundwater criterion greater than 4 ppb (up to 15 ppb) is acceptable, but it will be necessary to demonstrate that off-site migration of the groundwater will not result in unacceptable exposures. Further information on this exceptional situation can be obtained from an ERD toxicologist.

The lead criteria were developed using the Integrated Uptake Biokinetic Model (hereafter referred to as the Lead Model) developed by EPA. Following is a discussion of the lead model and the assumptions used with the model. Any questions pertaining to this justification can be directed to Christine Flaga, Michigan Department of Natural Resources, Environmental Response Division (517-373-0160).

The lead criteria presented in this justification represent the current state of the art on the subject. As the model is updated and as new data on lead are generated, changes to the criteria may be warranted.

<u>The Lead Model</u>

The Lead Model was originally developed by Harley and Kneip (1985) and was first used by U.S. EPA in their Office of Air Quality Planning and Standards to set the National Ambient Air Quality Standard for lead. The model has since been updated and improved through five computer versions (versions 0.1 through 0.5) and EPA is currently in the process of completing the first final version (version 1.0). The model has gone through an extensive review and validation process which indicates that the model is a reliable predictor of mean blood lead (PbB) levels associated with multimedia exposures in children. The model is distributed by the Environmental Criteria and Assessment Office (ECAO) as a method for predicting the distribution of blood lead levels in children aged 0 to 7 years exposed to multimedia lead sources.

The Lead Model combines site-specific or default values for lead in air, water, soil and food with assumed behavioral and physiologic parameters that determine intake and absorption of lead from each medium to yield estimated rates of uptake into the blood of

children. The model is specifically designed for children since they are considered to be the most sensitive subgroup within the population. The model then computes age-specific blood lead levels based on a five compartment biokinetic model of tissue distribution and excretion. It incorporates default assumptions regarding rate constants for transfer between blood and four physiologic compartments: bone, kidney, liver and gastrointestinal tract (GI). Transfer of lead from blood to urine and mother to fetus is also considered. Output from the model displays the predicted distribution of PbB levels within the exposed population. The model also predicts the percentages of the population which are above and below a PbB level of 10 ug/dl which the Center for Disease Control (CDC) has defined as the threshold for lead poisoning prevention activities. Use of this type of model to predict responses to chemical exposure is unique. Traditional methods of assessing risks are not possible for lead. Although lead is classified by EPA as a probable human carcinogen, data are insufficient to calculate a cancer slope factor. The absence of a clearly defined threshold precludes the development of a reference dose (RfD). Lead is also unique in that most of the reported data associates an effect with a PbB level (ug lead/dl blood) rather than with an administered dose which is usually presented in units of mg lead/kg of body weight.

Use of the lead model requires the selection of site-specific media concentrations (concentrations of lead in air, water, food and soil) or the model default values. The default values within the model represent national averages (USEPA, 1990). The model's default values for food and water are reasonable assumptions for Michigan. Michigan-specific air data were used to determine an average air concentration of 0.04 ug/cubic meter (cu m) which replaces the model default value of 0.2 ug/cu m. Reported below are the media concentrations that were used to develop the Type B soil criterion for lead:

Outdoor Air Lead Concentration	0.04 ug/cu m
Drinking Water Lead Concentration	4 ug/1
Lead Intake From Food	6.8 ug/day

Lead in Soil and Dust: this is the parameter that was varied to determine the most appropriate (i.e. protective of an adequate percentage of the population) soil criterion. For other purposes, the lead model assumes soil/dust lead concentrations of 200 ppm.

The lead model also uses many behavioral and physiologic values which, in conjunction with the media concentrations, result in uptake values of lead from food, drinking water, air and soil/dust. Some of the default values that are pertinent to the development of a soil criterion are: 1) soil ingestion rate of 100 mg/day; 2) 30% lead absorption from soil/dust (from the gastrointestinal tract); 3) an outdoor soil/indoor dust weighting factor of .45/.55 which represents the amount of time spent outdoors and indoors and the activity patterns within each environment. These values represent the most recent information for these parameters, however, research is continuing and new data may result in future changes.

Two of the major variables which significantly impact the resulting soil criterion are the geometric standard deviation and exposure to indoor lead-based paint. Each is discussed separately below.

Geometric Standard Deviation (GSD)

The distribution of PbB levels is approximately log normal and, thus, is defined by its geometric mean and GSD. The GSD represents the variability of PbB levels within a population. The observed differences in PbB levels within a population may be due to biological variability (differences in lead tissue distribution and elimination of lead); uptake variability (differences in lead absorption and chemical/physical differences in the type of lead present); exposure variability (differences in quantity of intake due to behavioral factors, sociodemographic factors, climate, etc.); sampling variability (differences in the sample analyzed and the actual concentration of lead to which lead exposure occurred); and, analytical variability (measurement and analysis errors). Use of different GSDs within the model can result in significant differences in the acceptable soil criterion for lead.

PbB levels throughout the U.S. were measured during the Second National Health and Nutrition Examination Survey (NHANES II) which was conducted from 1976 to 1980. From these data, a PbB GSD of 1.42 was estimated for young children after removing the variance in PbB levels attributable to air lead exposure (by adjusting every individual PbB level to what it would be at zero air lead). Also excluded from the analyses were children with PbB levels greater than 40 ug/dl. Since these data were obtained from a very large population with relatively few instances of excessive exposures, this GSD is probably as low as will be found. It pertains to fairly homogeneous populations (with respect to behavioral and pharmacokinetic factors) exposed to similar mean levels of lead from the same sources. GSDs are expected to be larger in small populations exposed to high lead levels. The lead model assumes a GSD of 1.42 as a default value.

Estimated PbB level GSDs for children in some smelter and mining towns range from 1.30 to 1.63. These values represent adjusted GSDs. Unadjusted or raw values range from 1.67 to 1.79. The raw GSD is based on the variability of the whole data set and includes differences in environmental lead variables. The adjusted GSD represents the residual deviations in blood lead after statistical adjustment for all known exposures. As a result, the adjusted GSD is a minimal estimate of variability.

The EPA Guidance Manual for the Lead Model recommends using a GSD of 1.66 which is intermediate between the raw and adjusted GSDs indicated above (USEPA, 1991). Based on the adjusted and raw GSDs reported from mining and smelter sites, the Science Advisory Board (SAB) which reviewed the Lead Model and its companion Guidance Manual states: “This suggests that for such areas a sliding scale of GSDs from 1.8 for minimal data to 1.6 for adequate data would be appropriate”. The recommendation from the SAB appears to be for areas similar to the western mining sites. No guidance is given by either EPA or the SAB on what GSD should be used when generating a statewide soil cleanup criterion or for assessing the risks at other types of contaminated sites (i.e., sites other than mining or smelting sites).

The environmental media concentrations used in the model (lead concentrations in air, water and food) for development of a statewide lead soil criterion represent reasonable or average exposures in Michigan. The goal of the state-wide Type B soil criterion is to protect the average Michigan child from exposure to elevated levels of lead in soil. The ideal GSD to be used in developing this soil criterion is one representative of PbB levels in Michigan. However, data are not available to allow us to identify an appropriate PbB GSD for Michigan children. Such information may become available later. At this time, the best supporting data are from NHANES II, although these data are not without problems. Data from NHANES II are 12 to 16 years old (blood samples were collected between 1976 and 1980) and were adjusted to remove any effects from air exposure. In addition, children with PbB levels greater than 40 ug/dl were removed from the data set. These factors may make the resulting GSD lower than what is most appropriate for our purposes.

Personal communication with Allen Marcus (Marcus, 1992b), who is the primary author of the recent versions of the model, indicated that NHANES III has been conducted and data compilation is underway; results should be available soon. Preliminary evaluation indicates that PbB levels are lower than what was reported in NHANES II and the associated GSD is higher. Other data pertinent to establishing a GSD for our purposes are from a PbB study done in Baltimore which reports a GSD of 1.7 (Harris, 1992). Such data from an urban study are expected to be comparable and applicable to urban areas in Michigan. Considering the adjustments made to the NHANES II data, indications that the GSD from NHANES III will be higher and the GSD of 1.7 from the Baltimore study, we have chosen a GSD of 1.55 which is halfway between 1.42 and 1.7. When Michigan-specific data and/or the NHANES III data are available, an adjustment to the GSD may be required.

Exposure to Interior Lead-based Paint

A strong relationship exists between lead-based paint in the home and childhood lead intake. Lead-based paint in poor condition (i.e., cracked, peeling, flaking paint) presents the greatest concern, resulting in the highest dust lead concentrations. The actual ingestion of flakes or chips of paint will result in the highest PbB levels. Children who ingest paint chips cannot be protected through a soil remediation program due to their excessively high intake of lead from paint. The following discussion refers only to lead-based paint in housedust.

The Guidance Manual recommends using the following contributions from lead paint to house dust: a dust lead concentration of 2200 ppm as a plausible high-risk value for older houses with deteriorating lead paint; and, 1200 ppm as a plausible low-risk scenario for lead-based paint in fair to poor condition. For situations, where the lead paint is in good condition, 200 ppm is recommended as a dust lead concentration. If we were to assume 2200 ppm or 1200 ppm lead in housedust from lead paint, a soil remediation level of even 50 ppm would not protect an adequate percentage of the exposed population (64.28% and 22.99% of the population, respectively, would exceed a PbB level of 10 ug/dl). If we assumed that children are exposed to lead-based paint in their home, no more than a minimal exposure (i.e. 200 ppm lead in housedust from paint) to lead paint could be assumed to generate a reasonable soil cleanup criterion.

Although there are some sources which suggest that the average American child is potentially exposed to at least minimal levels of lead in housedust, Michigan-specific data are not available. In addition, it is clear that outdoor soil remediation programs cannot adequately mitigate total lead exposure and address the issue of deteriorating lead-based paint. The problem of lead-based paint must be addressed through interior lead paint abatement programs and community education programs. For these reasons, a joint policy decision was made by the MDNR and MDPH to assume that the average Michigan child is **not** exposed to interior lead-based paint for the purpose of developing a soil cleanup standard. This is the assumption we have made in developing the Type B criteria for lead.

Seasonal Exposure to Outdoor Soil

The Type B direct contact algorithm in the 307 Rules assumes exposure to outdoor soils occurs six out of twelve months in Michigan due to snow cover and frozen soil. This assumption was considered for use with the lead model, however, Allen Marcus (Marcus, 1992a) and EPA staff members recommended that we assume year round exposure to outdoor soils for the following reasons. The model does not currently present options for seasonal exposure to outdoor soil and, as a result, no one was able to provide specific guidance on how this assumption should be incorporated. If the assumption was to be incorporated, it was suggested that adjustments be made to the soil ingestion rate or to the outdoor soil/indoor dust weighting factor (Marcus, 1992a). Adjustments should not be made to the soil concentration itself. In addition to the lack of guidance on how to make the adjustment, caution was indicated due to a child's year-round exposure to outdoor soil present in household dust. Work is currently ongoing at EPA to further address the issue of seasonal exposure. Until further data and guidance are available, exposure to outdoor soil is assumed to occur throughout the year.

Groundwater Criterion

The groundwater criterion was developed assuming that groundwater serves as a drinking water source and soil lead concentrations are at 400 ppm. A concentration of 4 ppb in groundwater is the default value for the lead model and represents a nation-wide average of lead in drinking water. Lead data obtained from the MDPH for community water supplies and private wells indicates that most exposure to lead in drinking water in Michigan is below analytical detection (3 ppb). As a result, the 4 ppb default value is a reasonable, and generally, a conservative assumption for Michigan. In combination with the other multimedia exposures considered in the lead model, a drinking water lead concentration of 4 ppb and a soil concentration of 400 ppm results in an acceptable PbB level.

Under certain circumstances, groundwater lead concentrations up to 15 ppb may be acceptable where soil concentrations are less than 400 ppm. In order to allow a groundwater lead concentration higher than 4 ppb (or local background), the soil lead concentrations must be sufficiently lower than 400 ppm to still result in an acceptable, predicted blood lead level given the higher groundwater concentration (contact an ERD toxicologist for details). In addition, the hydrogeologic conditions must be such that groundwater lead concentrations higher than 4 ppb will not migrate to other properties potentially resulting in unacceptable exposures.

Soil Criterion Protective of Groundwater

The Type B direct contact criterion does not address potential impacts to groundwater. Since the 20X groundwater criterion is less than what is expected for background levels, background is the default soil concentration which is protective of groundwater. Any soil concentration exceeding background levels must be shown not to leach above the Type B groundwater criterion. This can be demonstrated through an appropriate leachate test.

Cleanup of Lead-contaminated sites

Before lead-contaminated soils at a site can be remedied, it must first be determined if the lead concentrations in the samples are spatially correlated with each other. That is, are the sample concentrations at a given location related to concentrations of nearby sample locations? If the contamination is randomly spread across the site, as may be the case when the contamination is the result of the presence of certain historical fill material, the sample concentrations may not be spatially correlated. However, if the contamination is the result of a specific release, as in an underground tank leak, the sample results are expected to be spatially correlated.

If concentrations are spatially correlated, as in a specific release, the lead soil criterion should be used as a “not to exceed number” on a sample-by-sample basis. Those sites with contamination spread randomly across the site (i.e., no spatial correlation) can be evaluated and remediated on the basis of lead concentrations represented as an arithmetic mean within a Type B exposure unit. These latter types of sites are addressed below.

Sites with lead sample results which do not correlate spatially can be addressed on the basis of a Type B exposure unit. A Type B exposure unit represents an area which a resident is expected to frequent and come into contact with soil. The average size of an urban yard will define the typical residential exposure unit. A quarter acre is considered a reasonable area for a residential yard, so an exposure unit approximately 10,890 square feet would be acceptable (i.e., 100’ X 100’, 60 X 180, 80 X130, etc.). The purpose of dividing a site into Type B exposure units and evaluating each of those units is to insure that the site can be used for residential development in the future and remain protective of public health. This exposure unit method is intended to prevent the dilution or masking of areas containing excessively elevated lead concentrations by averaging a large number of lead samples across a large site.

Once the site has been divided into appropriate Type B exposure units, data from each unit must be compiled and evaluated for lead. If the samples have already been taken, the site can be divided into Type B exposure units beginning with the southwest corner of the site. Since the Lead Model was designed to use arithmetic means as input values, the lead concentration for an exposure area can be represented as an arithmetic mean for remediation purposes. However, the exposure unit method may require the use of statistics to evaluate the sample results within an exposure unit for the presence of outliers before the exposure unit mean is calculated (see the Soil Verification Document for further guidance). The arithmetic mean for an exposure unit can be calculated after outliers have been addressed. If the analytical data from an exposure unit indicate a mean greater than 400 ppm, that unit would need to be remedied. If the

data indicate a mean less than 400 ppm, that area is considered to be protective of public health from the perspective of direct contact hazards. Remediation of that area (lead less than 400 ppm) would not be necessary of it can be demonstrated that the residual lead in the soil will not leach at a concentration greater than the Type B groundwater criterion. One of several leach tests could be used to perform this demonstration (see Operational Memorandum #12). The above described procedure would need to be performed for each of the Type B exposure units identified on a site.

REFERENCES

ATSDR. 1988. The nature and extent of lead poisoning in children in the United States: A report to Congress.

Harris, Reginald. 1992. Personal Communication, January 27, 1992. USEPA, Region 3.

Marcus, Allen. 1992a. Personal Communication, February 11, 1992. Battelle Applied Statistics.

Marcus, Allen. 1992b. Personal Communication, May 1, 1992. Battelle Applied Statistics.

USEPA. 1990. Technical Support Document on Lead. ECAO-CIN-757, September, 1990.

USEPA, 1991. Guidance manual for site-specific use of the USEPA Lead Model. Draft report. September, 1991.

USEPA, 1992. An SAB Report: Review of the uptake biokinetic (UBK) model for lead. Review of the OSWER model to assess total lead exposure and to aid in developing soil lead cleanup levels at residential CERCLA/RCRA sites by the Indoor Air Quality and Total Human Exposure Committee. First Review Draft – January 6, 1992.

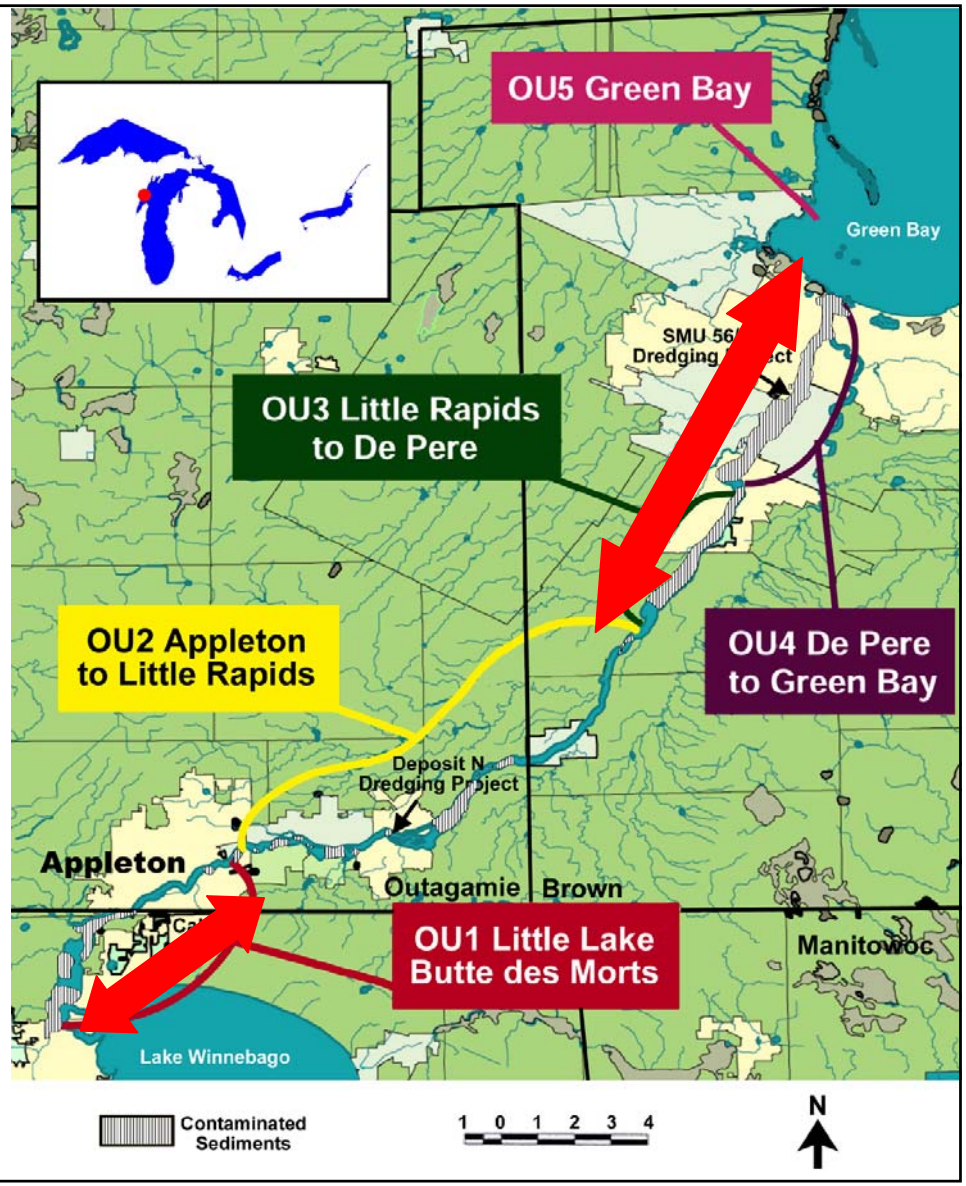
Chemicals with Cleanup Criteria based on Developmental Effects

The following list is chemicals with Part 201 generic cleanup criteria based on developmental endpoints and corresponding child and/or pregnant female exposure inputs.

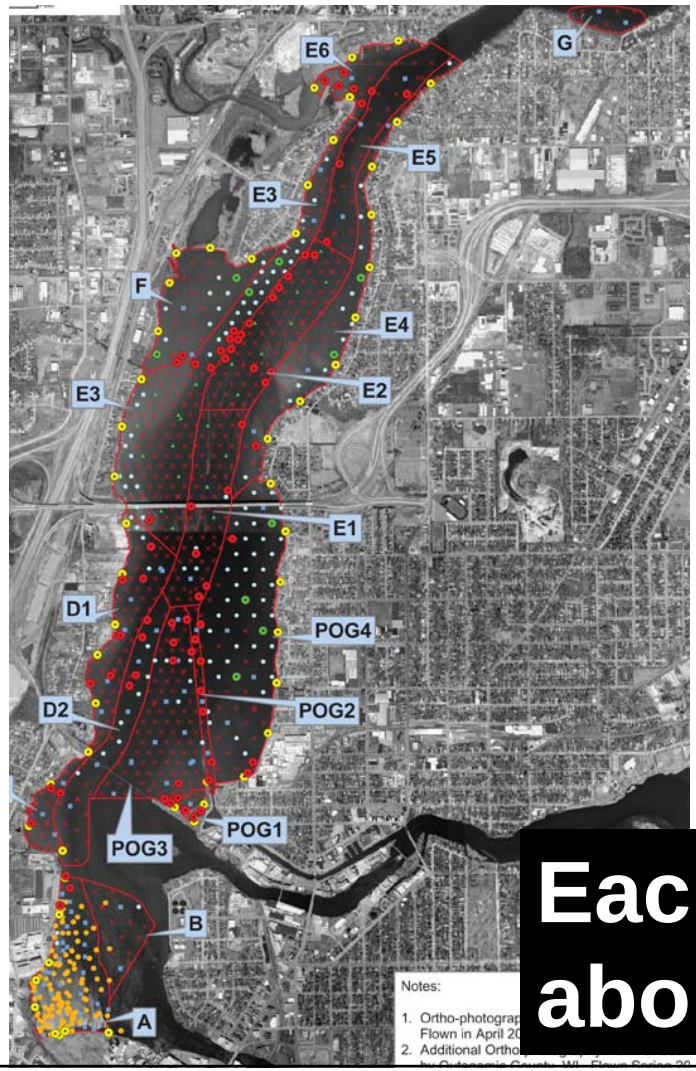
Chemical	CAS #
Acrylic acid	79-10-7
Aluminum	7429-90-5
Atrazine	1912-24-9
Boron	7440-42-8
2-Butanone (MEK)	78-93-3
Caprolactam	105-60-2
Carbon disulfide	75-15-0
Di(2-ethylhexyl) adipate	103-23-1
Diazinon	333-41-5
Dicamba	1918-00-9
2,4-Dichlorophenol	120-83-2
Dinoseb	88-85-7
Ethanol	64-17-5
Fluorine (soluble fluoride)	7782-41-4
Glyphosate	1071-83-6
Lead	7439-92-1
Lithium	7439-93-2
Metolachlor	51218-45-2
Phenol	108-95-2
Propyl alcohol	71-23-8
Tebuthiuron	34014-18-1
1,2,4-Trichlorobenzene	120-82-1
Trichloroethylene	79-01-6
Triethylene glycol	112-27-6
3-Trifluoromethyl-4-nitrophenol	88-30-2
Vanadium	7440-62-2
Vinyl acetate	108-05-4
White phosphorus	12185-10-3

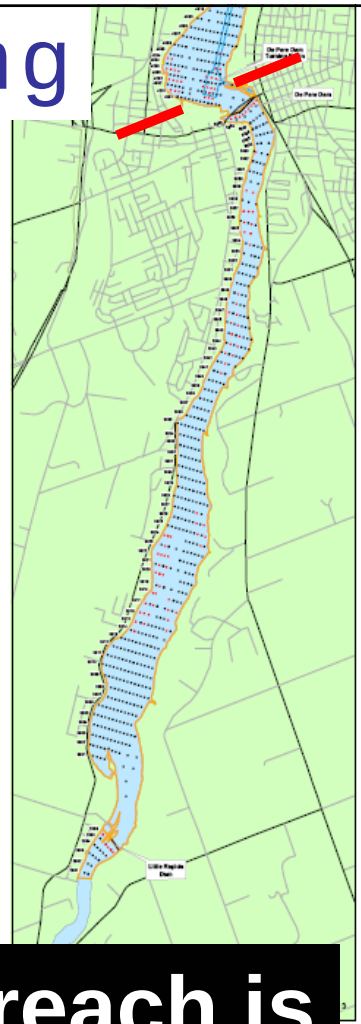
Fox River

Fox River recent sampling



Fox River sampling





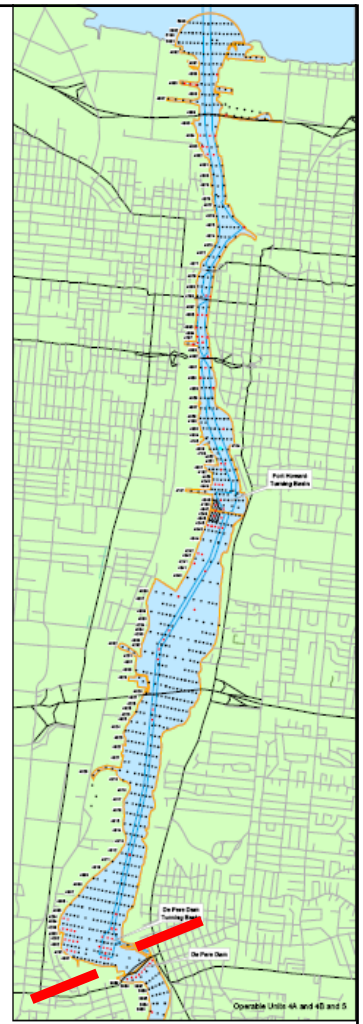


Figure 2-1
Remedial Design Sediment
Core Location Map
Operable Units 2 to 5
Lower Fox River

ANCHOR
Shaw

Each reach is about 6 miles

Pre-design sampling

		OU 1 (upstream)	OU 2- 5 (downstream)
River length (miles)		6	12
Horizontal sample density		1 sample every 1 – 2 acres	1 sample every 1.5 – 6 acres
Vertical interval		every 6 inches	
Number of samples	PCBs	5800*	9700*
	Geotechnical	550	780

***Total samples for 18 miles of river: 15,500**