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REPORT ON THE DRAKE CHEMICAL SITE INCINERATOR RISK ASSESSMENT PEER REVIEW WORKSHOP

Prepared for:

U.S. Environmental Protection Agency
Risk Assessment Forum
Washington, DC 20460

EPA Contract No: 68-D5-0028
Work Assignment No: 98-08

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March 1998

NOTICE

Mention of trade names or commercial products does not constitute endorsement or recommendation for use. Statements are the individual views of each workshop participant; none of the statements in this report represent analyses or positions of the Risk Assessment Forum or the Environmental Protection Agency (EPA).

This report was prepared by Eastern Research Group, Inc. (ERG), an EPA contractor, as a general record of discussions during the Drake Chemical Site Incinerator Risk Assessment Peer Review Workshop. As requested by EPA, this report captures the main points and highlights of discussions held during plenary sessions and includes brief summaries of the breakout sessions. The report is not a complete record of all details discussed nor does it embellish, interpret, or enlarge upon matters that were incomplete or unclear. In particular, each of the breakout session summaries was prepared at the workshop by individual session leaders based on discussions during the workshop. Thus, there may be slight differences between the five groups' statements. ERG did not attempt to harmonize the statements.

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SECTION ONE

BACKGROUND

GENERAL SUMMARY

Timothy Fields, Acting Assistant Administrator for the U.S. Environmental Protection Agency's (EPA) Office of Solid Waste and Emergency Response, asked the Risk Assessment Forum (RAF), as an independent body with subject expertise, to organize a peer review of the Drake Chemical Site Incinerator Risk Assessment. The RAF undertook this task, evaluating a pool of nominees provided by local, regional, and Federal stakeholders. Forum members conducted this evaluation without correlation of stakeholders to nominees. The EPA requested that the reviewers independently evaluate the scientific and technical merits of the draft final report. A 2-day peer review workshop held on January 15-16, 1998, in Williamsport, Pennsylvania, provided a forum for the expert reviewers to discuss the findings of their individual reviews.

At the workshop, reviewers were organized into the following five topic areas:

- Combustion engineering
- Air dispersion modeling/deposition modeling
- Exposure assessment
- Human health
- Ecological risk assessment

Prior to the meeting, each reviewer provided written comments describing their evaluation of one of these aspects, depending on their expertise. In addition, all reviewers were asked to comment on the executive summary, introduction, risk characterization, and uncertainty and sensitivity analyses sections of the draft final risk assessment. During the workshop, reviewers met in breakout sessions to discuss their findings.

Other workshop activities included a tour of the Drake Chemical site and plenary sessions, during which time general discussions were held. During designated times during the plenary sessions, workshop observers provided input and asked questions.

This report presents a brief history of risk assessment activities at the Drake Chemical site (Section One); opening remarks made by EPA and the workshop chairperson (Section Two); a description of site visit activities (Section Three); the workshop chairperson's summary (Section Four); workgroup summaries (Section Five); and a summary of premeeting comments and observer comments and questions (Section Six).

Seven appendices also are included in this report, containing the following information:

- Expert reviewer list (Appendix A)
- Breakout session assignments (Appendix B)
- Charge to peer reviewers (Appendix C)
- Premeeting comments (Appendix D)
- Agenda (Appendix E)
- Peer reviewers' and observers' handouts/overheads (Appendix F)
- List of observers (Appendix G)

HISTORY OF RISK ASSESSMENT ACTIVITIES AT THE DRAKE CHEMICAL SITE

From 1948 through 1982 the Drake Chemical Company produced chemical intermediates for the dye, textile, pharmaceutical, and pesticide industries at its facility in Lock Haven, Clinton County, Pennsylvania. The company was cited numerous times by state and federal agencies for violating environmental, health, and safety regulations. When EPA began removal and remediation activities, the Drake Chemical Superfund site contained demolition debris, chemical tanks and reactors, unlined lagoons containing sludge, and several thousand rusted and leaking drums.

In 1982, in response to the company's noncompliance with environmental regulations, EPA Region III began emergency removal actions, including removal and disposal of surface drums, surface sludges, and liquids contained in process and storage tanks, and placement of fences around the border of the site. Remediation actions have continued. Phase I activities included the remediation of a leachate stream

draining into Bald Creek. Phases II and III included draining and removal of materials from lagoons, and demolition and removal of the buildings.

Studies conducted at the site indicate that soil contamination presents a serious threat to human health and the environment. The 1988 ROD prescribed that the contaminated soil should be excavated and treated on site in a high temperature incinerator.

Construction of the incinerator, ash handling buildings, feed building, and wastewater treatment facility was completed in 1996. Soil has been excavated from the northern and southern portions of the site, and the excavated soils have been stockpiled within the area yet to be excavated and in the feed preparation building.

Risk assessments were conducted prior to the trial burn process to evaluate the potential human health risks. EPA published a 3-volume risk assessment of the trial burn process in June, 1996. This risk assessment report was based on emissions predicted from known site soil chemical concentration data, anticipated soil feed rates, incinerator design parameters, and emissions data from other incinerators. The June risk assessment was supplemented by a February, 1997, report (referred to as "Volume 4" of the June 1996 report). Volume 4 examined the potential effects of snowfall on contaminant fate and transport.

Trial burns, including stack testing, occurred in January and February, 1997. The purpose of the trial burns was to demonstrate compliance with regulatory performance standards and emission limits and to generate data to allow EPA to evaluate if operation of the incinerator would be protective of human health and the environment. The trial burns were conducted under the range of conditions expected to be maintained during the full scale operation. Extensive chemical analyses were conducted of the stack gas and waste feed stream.

The draft "Drake Chemical Site, Incinerator Full Burn Integrated Risk Assessment," dated November 24, 1997, was prepared based on the stack test data collected during the trial burn and previous air dispersion modeling data. This is the document reviewed by the 14 expert reviewers. Each reviewer was provided with this 2-volume document as well as air dispersion modeling documentation (Volume III of the June, 1996, risk assessment).

SECTION TWO

OPENING REMARKS

Dr. William Wood, EPA

Dr. William Wood, Director of EPA's RAF, opened the plenary session of the workshop. He described the RAF as a group of 30 senior scientists from various program offices throughout EPA and emphasized that the RAF is regulatory-neutral.

Dr. Wood described the process used to identify the peer reviewers evaluating the draft risk assessment document for the Drake Chemical site. On July 16, 1997, Mr. Timothy Fields, Acting Assistant Administrator for the Office of Solid Waste and Emergency Response, requested that EPA's Risk Assessment Forum organize an external peer review of the risk assessment being prepared for Region III. In response to his request Dr. Wood wrote to stakeholder organizations representing EPA Region III, state and local government, and citizens groups seeking nominations for potential peer reviewers. The call for nominations specified that candidates must be independent of the project, having no previous involvement in Drake site activities. A total of 49 nominations was submitted for consideration. All except two nominees met the independence criteria specified. After receiving the nominations, a subcommittee of the Risk Assessment Forum was convened to review and select the peer reviewers and to develop the scientific charge to the reviewers. The Risk Assessment Forum members were provided with the curriculum vitae (CV) but were not provided with information as to which stakeholder group made the nomination. The Risk Assessment Forum members emphasized technical expertise and independence in selecting the peer reviewers from the stakeholder nominations. After careful review of the CVs, 14 highly qualified expert reviewers were selected. Each peer reviewer selected to participate in the Drake incinerator review was contacted and presented proposed workshop dates. The 14 reviewers who ultimately participated in the workshop all expressed a willingness and availability to participate in the peer review. Each reviewer attested to the fact that he/she had not been involved with previous risk assessment or litigation activities for the site. The 14 reviewers represent a balance across the scientific disciplines of combustion engineering, dispersion modeling, exposure, and human and ecological toxicology.

Gregg Crystall, EPA Region III

Mr. Gregg Crystall, EPA Region III, provided a summary of risk assessment activities for the Drake Chemical site assessment. Following EPA's Record of Decision (ROD), which called for remediating site soils using onsite incineration, EPA produced separate direct and indirect risk assessments in 1995, each conducted by a separate contractor. A more comprehensive risk assessment was conducted prior to the trial burn. Worst-case stack emissions were estimated based on feed material analyses and data from similar incinerators. The trial burn project was a combined effort of the EPA's Office of Research and Development (ORD), Agency for Toxic Substances and Disease Registry (ATSDR), EPA's Environmental Response Team (ERT), USACE, and the Pennsylvania Department of Environmental Protection (PADEP), with support from Roy F. Weston, Inc., and OHM Remediation Services (OHM). This risk assessment was comprehensive, evaluating both direct and indirect exposures, and suitable to present in District Court. The case was dismissed before trial. Using this second risk assessment, EPA determined that it was safe to conduct the trial burn. The trial burns took place in early 1997. A supplemental winter burn scenario testing was conducted, assuming that two months of snowy weather would be likely during the full burn. Validated data from the trial burn and the risk burn were entered in models and projections to prepare the full burn risk assessment.

The EPA Region III team and the team at the Drake Chemical site believe that the risk assessment is comprehensive and conservative, and demonstrates that it is safe to continue with the full burn.

Dr. Yoram Cohen, Workshop Chairperson

Dr. Yoram Cohen, Professor of Chemical Engineering and Director of the Center for Risk Reduction at the University of California at Los Angeles, emphasized that the participating expert peer reviewers are personally and professionally committed to solving environmental problems. He noted that each peer reviewer reviewed the risk assessment document independently. Dr. Cohen explained that the purpose of the review and workshop was to enable the experts to discuss the science and present their independent evaluation of the risk assessment. He described the seven steps in the peer review process:

- Initial review of the risk assessment documents
- Site visit
- Presentation of premeeting comments by breakout session discussion leaders
- Observer comments
- Review of risk assessment by breakout session discussion leaders
- Work on review team report
- Final report of review team comments

Appendix F includes slides prepared but not presented by Dr. Cohen due to time restrictions.

SECTION THREE

PEER REVIEWERS' VISIT TO THE DRAKE CHEMICAL SITE

At the Drake Chemical site, Dave Modricker, United States Army Corps of Engineers (USACE), presented a description of the site including its operational, regulatory, and legal history, and site remediation strategies. He also presented an overview of the incinerator and operating parameters. (See Appendix F for copies of the slides.) During the presentation and tour, peer reviewers frequently asked questions.

Mr. Modricker's presentation and responses to reviewers' questions are summarized below:

- Cleanup of the Drake Chemical site is a coordinated effort involving the EPA, Pennsylvania Department of Environmental Protection (PADEP), USACE, and OHM Remediation Services (OHM).
- Drake Chemical produced chemical intermediates for the dye, textile, pharmaceutical, and pesticide industries.
- Soil contaminants include volatile and semi-volatile chemicals, β-naphthylamine, fenac, and pesticides.
- Briefly stated, the remediation plan is to excavate, treat, test, and backfill 200,000 cubic yards of contaminated soil (10 acres x 12.5 feet). The ultimate goal of the project is groundwater treatment and protection. The onsite incineration of site soils is considered "source removal" to prevent further contamination of the groundwater. The Drake facility is under a consent decree with the adjacent American Color and Chemical facility for groundwater remediation.
- The Drake Chemical site is in bankruptcy. Ownership of the site will likely revert to the Commonwealth of Pennsylvania and eventually to the City of Lock Haven. Proposed use is as a parking lot or maintenance facility.
- Only contaminated soil from the Drake site will be burned in the incinerator. The incinerator will not be used to burn any materials from off the Drake site. These limitations are specifically stated in the Superfund permit. When the Drake remediation project is complete, the incinerator will be dismantled and removed from the site.
- All drums discovered during soil excavation will be analyzed to identify the contents and then shipped to the appropriate offsite remediation facility.
- The onsite wastewater treatment plant treats lagoon water, stormwater, de-watering water, and process water.

- Four air monitoring stations are located at the perimeter of the site. Real time ambient air data are collected (hourly during incinerator operation) for total non-methane organic hydrocarbons (NMOCs). Detected levels greater than 1 part per million (ppm) automatically initiate analysis for three hydrocarbons. Averaged-time sampling is also conducted for semi-volatiles, metals, and particulates.

- Four air monitoring stations are located in the community, each approximately one mile from the site. Averaged-time sampling is conducted for volatiles, semivolatiles, metals, particulates, and polychlorinated dibenzo dioxins and polychlorinated dibenzo furans (PCDD/PCDF).

- EPA, USACE, and Pennsylvania State University are working together on a moss bag study to attempt to determine the background levels of PCDD/PCDF and metals. This effort will continue throughout the duration of the remediation project.

Peer reviewers toured the site and were shown the layout of the site, the location of the soil pre-treatment ash handling facility, wastewater treatment buildings, an onsite ambient monitoring station, and an onsite gas chromatography laboratory for analysis of ambient samples. Mr. Modricker described the incinerator in detail and key components were pointed out to the reviewers, including the soil feed, feed conveyor, feed screw, rotary kiln, bottom ash handling system, hot gas cyclone, secondary combustion chamber, evaporative cooler, baghouse, fly ash handling system, induced draft fan, acid gas scrubber, stack, and continuous emissions monitoring system.

SECTION FOUR

CHAIRPERSON'S SUMMARY OF THE WORKSHOP

The 1988 ROD for the Drake Chemical Superfund site selected incineration of soils excavated from the site as the preferred treatment method. Accordingly, risk assessment was conducted by Roy F. Weston, Inc., for EPA to assess the potential human health and ecological risk from full-scale operation of the incinerator site.

In order to evaluate the scientific adequacy of the risk assessment and its accuracy, EPA gathered 14 experts to review the risk assessment as described in a series of documents prepared by Roy F. Weston, Inc. The 14 expert peer reviewers (Appendix A) were presented with general and specific review tasks (Appendix C). The review process consisted of a preliminary review by the individual reviewers, a two-day workshop held on January 15-16, 1998, in Williamsport, Pennsylvania, and preparation of summary reports by reviewers in each of the individual breakout sessions. The preliminary review comments, as submitted by the individual peer reviewers, were compiled and published by EPA prior to the January 15-16 workshop (Appendix D).

The activities of the workshop included a tour of the Drake Chemical site, plenary sessions that were open to the public, and working breakout sessions during which expert reviewers met to discuss specific sections of the draft risk assessment report (Appendix E). Reviewers meeting in breakout sessions examined five aspects of the draft report: combustion engineering, air dispersion modeling/deposition modeling, exposure assessment, ecological risk assessment, and human health (Appendix B). Several observers who had registered in advance of the meeting, provided input during designated times throughout the workshop (Appendix G). Following the two scheduled observer comment periods, question and answer periods were held. During these periods, observers (e.g., community members) who had not signed up in advance to speak made comments or asked the peer reviewers questions. In addition, during the breakout sessions, observers were permitted to make comments or ask questions, rather than the standard approach of observers not actively participating in the breakout session discussions.

The workshop provided a forum for 14 expert peer reviewers to discuss the scientific and technical aspects of the draft risk assessment report for the Drake Chemical site incinerator. The reviewers evaluated

the scientific and technical merits of the draft report, with the understanding that their review comments may be utilized by the EPA to evaluate site-specific site remediation issues for the Drake Chemical site incinerator. The detailed review comments of the five breakout sessions are provided in Section Five, and a brief summary of the major components of the risk assessment process and issues raised by the peer reviewers is presented below.

The risk assessment was based on four trial burns under a range of conditions. During the trial burns, extensive sampling and analyses were conducted of the stack gas emissions and soil feed. Emissions were estimated from direct monitoring studies with about 200 organic and inorganic chemicals identified for risk analysis based on monitoring of stack emissions, soil monitoring, and predictions of products of incomplete combustion. In order to estimate concentrations in the environment surrounding the incinerator, emission estimates were coupled with dispersion modeling to estimate concentrations of the target chemicals in various receptor locations.

The risk assessment included a detailed quantitative human health risk assessment and a qualitative and less rigorous ecological screening assessment. The health risk assessment consisted of four major components: (a) estimation of concentration levels at the location of target receptor sites; (b) estimation of chemical intake by the human receptor via various pathways (e.g., inhalation, water drinking, and fish, meat, milk and crop ingestion); (c) compilation and estimation of toxicological information to obtain dose-response parameters; and (d) combination of the information in (a) through (c) to determine cancer health risk as well the level of expected exposures, relative to the recommended safe levels, for non-carcinogens.

The draft risk assessment is a commendable and credible study that represents a detailed evaluation of potential risks and accounts for many of the uncertainties which exist in any project of such complexity. The risk assessment study was well-conceived and executed, designed to account for the critical pathways and to arrive at conservative health risk estimates (i.e., upper limit estimates of plausible exposure scenarios). The reviewers concurred, however, that there are a number of areas of concern that are worth addressing in order to better quantify the potential risks that may be imposed by the operation of the incinerator at the Drake Chemical Superfund site. A summary of the major issues of concern regarding the health and ecological risk assessments is provided below.

Health Risk Assessment

The health risk analysis followed standard procedures for most of the chemicals identified for the analysis. However, in the case of polyaromatic hydrocarbons (PAHs), the approach used to determine health risk relied on a method that, at present, is believed to be inappropriate for this class of compounds. Likewise, the risk assessment for dioxin-like compounds did not follow the current common approaches and the rationale for the approach was not clearly documented in the risk assessment document. Another issue of concern is that, due to the different methodology used to estimate risks for lead and dioxin, these compounds have not been incorporated into the "total risk" associated with exposure to chemicals originating from the Drake Incinerator site.

Risk assessment requires extensive data and parameters, many of which are known only approximately or are best estimates. Thus, an inherent uncertainty is associated with risk analysis and knowledge of the uncertainty is important to decision makers. Although the risk assessment document provided a qualitative discussion of uncertainty, a quantitative assessment of the uncertainty in the analysis for the chemicals with the highest contribution to the overall risk was not provided.

Additional uncertainties in the risk assessment are due to a number of areas that were not considered, such as:

- Additional potential risks associated with the volatilization of organic vapors during handling and storage of feedstock soil and deposition of fugitive dust.
- Impact of stagnation on dispersion and resulting exposures.
- Potential risks associated with certain combustion by products (e.g., benzoquinone).
- Emissions due to leaks from seals in the incinerator facility.

Although the health risk assessment was confined to emissions from the incinerator, it failed to recognize that there may be background exposure levels that, combined with the additional risk from the incinerator, may result in a greater total risk for sensitive sectors of the population. Thus, one may argue that in a complete risk assessment there is merit in considering existing background exposure in relation to

baseline data for human health (particularly childhood asthma and pulmonary diseases), ecological receptors, and air quality.

Ecological Risk Assessment

Ecological risk assessment was attempted at a screening level in order to assess the potential impact on wildlife and other ecological receptors. As noted by the reviewers, the ecological risk assessment was less rigorous than the health risk assessment. Specific recommendations on how one could revise the ecological risk assessment, as presented in the draft risk assessment document, are presented in Section Five. Briefly, the reviewers identified the following major concerns:

- The ecological screening did not follow EPA guidance or good environmental assessment practice.
- The ecological risk assessment did not include an analysis of potential risk to wildlife, other than fish-eating birds and mammals.
- Given the prominence of mercury in the ecological risk assessment, the reviewers noted that a careful reevaluation of exposure to mercury is warranted with more realistic site-specific scenarios.

The complete set of review comments prepared by each of the five breakout session discussion leaders is presented in Section Five. These reports identify both the strengths and weaknesses of the risk assessment and areas of the report that may require revision. It is important to recognize that the charge to the expert reviewers was to review the scientific basis of the risk assessment and the accuracy and validity of the approaches, and to identify areas where the risk assessment process is incomplete and improvements are warranted. The scientific review process was not intended to provide a risk management decision regarding the operation of the incinerator. The review of the risk assessment document identified issues of concern and the need to improve both the risk assessment and the risk assessment document.

SECTION FIVE

BREAKOUT SESSION SUMMARIES

This section presents summary reports that highlight the discussions of the breakout sessions. These reports supplement the premeeting comments included in Appendix D and therefore are not intended to replace or diminish those comments already made by individual peer reviewers.

COMBUSTION ENGINEERING

Dr. Elmar Altwicker, Discussion Leader
Professor, Chemical Engineering
Rensselaer Polytechnic Institute
Troy, New York

Dr. JoAnn Slama Lightly
Associate Professor, Chemical Engineering
University of Utah
Salt Lake City, Utah

Dr. Francis (Bill) Holm
Private Consultant
Placitas, New Mexico

The comments of the Combustion Engineering expert reviewers regarding emission characterization are detailed in the following subsections:

- Incineration System
- Development of Emission Rates
- Process Upsets
- Fugitive Emissions
- Long-range Research Recommendation

In general, the sections in the risk assessment regarding the emission characterization follow a logical format; however, the presentation of the material is not always clear, concise, or easy to follow. The group also recommends the inclusion or acquisition of certain additional information.

Incineration System

The description of the incinerator system is not adequate. For example, the text did not mention that the kiln was fed pure oxygen, yet this is shown in Figure 1.2-3. This figure should be replaced with a more informative one, including the thermal relief valve (TRV) location. It is not clear whether pure oxygen (as indicated) or oxygen-enriched air is fed. Also, the fuel type is not given. Are oxygen and air fed to the secondary chamber? If so, how are conditions changed depending upon the burn in question? These and other details should be included; otherwise, the entire discussion of the system should be removed and the reader should be referred to the corresponding EPA references for all engineering design and operational aspects. In addition, the descriptions of the incinerator conditions during the various trial burns and risk burns are not complete. If information regarding these conditions is to be included, other aspects such as sampling locations, temperature and pressure measurement points, and oxygen concentration should be added. The temperatures given should be referenced as ranges (not simply as a single value) or a standard deviation should be reported. Table 5-1 lists suggested parameters. Figure 2-3 of the MRI-Report (Trial Burn Plan for the Drake Chemical Superfund Site's Mobile Hazardous Waste Incinerator, Volume 1, Trial Burn Plan, MRI Project No. 3620-09-021, Revised September 20,1996) would be an improvement over Figure 1.2-3 of the November 1997 Risk Assessment Report.

The terminology throughout the document should be checked for consistency. Several times mini burn, risk burn, trial burn, etc., were used and it was not clear which conditions were actually applicable. It should also be stated that each burn consisted of several (give exact number) of test runs of 3 hours duration (which required x hours of startup time) and that emission rates are reported with respect to each test run. The text states that trial burn data were not going to be used because the soils were spiked (the nature of the spikes, 1,4-dichlorobenzene and naphthalene alone, and various metals, as well as their spiking rates, should be mentioned together with the trial burn characterization, not elsewhere in the report). However, the development of the predicted emission rates (Appendix 2C of the draft assessment report) relies on the

Table 5-1

Suggested Incineration System Parameters

Parameters that should be reported for each burn, in addition to soil feed rate, kiln T (i.e., exit T), SCC T (i.e., exit T):

- Natural gas rates (to kiln and SCC)
- Oxygen feed rates and % excess oxygen
- Air flow rates (to SCC)
- Gas volumetric flow rates (kiln, SCC)
- Gas residence times (kiln & SCC, τ_g)
- Solids residence time (kiln, τ_s)

destruction and removal efficiencies (DREs) of the spiked principal organic hazardous constituents (POHCs). This needs to be clarified.

The cyclone is a useful design feature that reduces the solids load on the secondary combustion chamber (SCC) and the downstream air pollution control device (APCD), primarily the bag house. From an operational point of view, it would be highly desirable (though apparently not required by regulation) to know the efficiency of the cyclone. Then, combining this bottom ash with that from the kiln breech, the load to the SCC could be monitored successfully.

Development of Emission Rates

This section was not particularly easy to follow. The reader should be told up front what will be reported in terms of quantitative emission rates. The designations of X1 through X4, M, J, and the like used as data qualifiers were confusing, compounded by inclusion of all these in the already large data tables (2.2-1 and 2.2-2). The M designation, which was used only for the risk assessor, should be removed and the X1 through X4 designations should be simplified. The X designations per se cannot be removed because

they are referenced and used in Appendix 2C. Useful information on the above-referenced tables should include the methodology followed to obtain emission rates (numbers 1 through 8 on pages 2.2-3 and 2.2-4). The use of this information further exemplifies the conservative nature of the estimates. For example, in Section Seven of the risk assessment, several compounds were stated as major contributors to the risk assessment for different scenarios. If one looks at these data and the method by which the emissions were obtained, one sees that dibenzo (a,h) anthracene, indeno (1,2,3-cd) pyrene, 4,4'-DDE, endrin aldehyde, and benzo (a) pyrene were not detected in any test run but were predicted to be emitted in a revised analysis. The lower of the predicted value or one-half the detection limit was used. The others, namely benzene, 2,3,7,8-TCDD, 2,3,7,8-TCDF, inorganic mercury, and mercury, were evaluated using the average of the emissions for the test runs. For these runs no mean and standard deviation was given; it is difficult to assess the relative accuracy of these numbers. Also, 2-butanol was only tentatively identified. If 2-butanol is so important from an inhalation risk perspective, shouldn't more of an effort be made to identify it positively? For details on the analytical methodologies used, consult the MRI report Project Number 3620-09-21, September 20, 1996, Trial Burn Plan for the Drake Chemical Superfund Site's Mobile Hazardous Waste Incinerator. (A table was furnished by Roy F. Weston, Inc., during the peer review breakout session; it is recommended that these tables be included in a revised risk assessment. The top page from the table for risk burn No. 1 conditions is enclosed as Table 5-2 of this workshop summary report.)

Finally, the absence of a couple of compounds in the emissions was surprising. Naphthalene and several of its derivatives were in the feed, yet naphthoquinone was not cited; benzoquinone was cited. A similar comment applies to anthraquinone. In laboratory studies, anthraquinone compounds can lead to PCDD/F (Olie and Addink, Environ. Sci. Technol. 29, 1425 [1995]). The inclusion of some compounds only on the basis of having observed them under certain limited laboratory conditions (thereby excluding others that were not observed) needs to be reviewed (perhaps by conducting a broad-based literature search).

The discussion on the metal emissions was difficult to follow and the reviewers agreed that the measured emission rates were used based on the table handed out at the review by Roy F. Weston, Inc. Again, mean or standard deviation was not reported. The particulate matter emission rates reported should be compared to the regulatory limit and relatively large amounts of sodium emitted should be clarified.

Table 5-2.
Approach for Development of Emission Estimates for Drake Chemical Site
Risk Burn 1 Conditions

Chemicals of Concern		Risk Burn 1 Selected Emissions Approach				Risk Assessment Emissions Approach
		Run 1	Run 2	Run 3	Run 4	
Organics						
Acetone		5	5	5	5	5
Acetonitrile		5	5	5	5	5
Acrylonitrile		5	5	5	5	5
Aldrin		4-PRED	4-PRED	4-PRED		4
Aniline		5	5	5	5	5
Benzaldehyde		3-TIC	3-TIC	3-TIC		3
Benzene		1	1	1		1
Benzoic acid		1	1	1		1
Benzonitrile		3-TIC	3-TIC	3-TIC	3-TIC	3
Benzoyl chloride		6	6	6	6	6
Benzyl chloride		5	5	5	5	5
Biphenyl		3-TIC	3-TIC	3-TIC	3-TIC	3
Bis(2-chloroethoxy)methane		4-1/2 DL	4-1/2 DL	4-1/2 DL		4
Bis(2-ethylhexyl)phthalate		1	1	1		1
Bromochloromethane		5	5	5	5	5
Bromodichloromethane		1	1	1		1
Bromoform		1	1	1		1
Bromomethane		2-MEAS	2-DL	2-DL		2
2-Butanone (MEK)		1	1	1		1
Butyl benzyl phthalate		1	1	1		1
Carbazole		4-1/2 DL	4-1/2 DL	4-1/2 DL		4
Carbon disulfide		1	1	1		1
Carbon tetrachloride		1	1	1		1
alpha-Chlordane		4-PRED	4-PRED	4-PRED		4
gamma-Chlordane		4-PRED	4-PRED	4-PRED		4
4-Chloroaniline		4-1/2 DL	4-1/2 DL	4-1/2 DL		4
Chlorobenzene		1	1	1		1
Chloroethane		1	1	1		1
2-Chloroethyl vinyl ether		5	5	5	5	5
Chloroform		1	1	1		1
Chloromethane		5	5	5	5	5
4-Chloro-3-methylphenol		4-1/2 DL	4-1/2 DL	4-1/2 DL		4
beta-Chloronaphthalene		4-1/2 DL	4-1/2 DL	4-1/2 DL		4
2-Chlorophenol		4-1/2 DL	4-1/2 DL	4-1/2 DL		4
4,4'-DDD		4-PRED	4-PRED	4-PRED		4
2,4'-DDE		7	7	7		7
4,4'-DDE		4-PRED	4-PRED	4-PRED		4
4,4'-DDT		4-PRED	4-PRED	4-PRED		4
Dibenzofuran		4-1/2 DL	4-1/2 DL	4-1/2 DL		4
Dibromochloromethane		1	1	1		1
1,4-Dichlorobenzene		1	1	1		1
1,2-Dichlorobenzene		1	1	1		1
1,3-Dichlorobenzene		4-1/2 DL	4-1/2 DL	4-1/2 DL		4
3,3'-Dichlorobenzidine		4-1/2 DL	4-1/2 DL	4-1/2 DL		4
1,2-Dichloroethane		4-1/2 DL	4-1/2 DL	4-1/2 DL		4
1,1-Dichloroethene		1	1	1		1
trans-1,2-Dichloroethene		1	1	1		1
2,4-Dichlorophenol		1	1	1		1
Diethyl phthalate		1	1	1		1
2,4-Dimethylphenol		4-1/2 DL	4-1/2 DL	4-1/2 DL		4
Dimethyl phthalate		1	1	1		1
Di-n-butyl phthalate		1	1	1		1
2,4-Dinitrophenol		4-1/2 DL	4-1/2 DL	4-1/2 DL		4
Di-n-octyl phthalate		1	1	1		1
Dioctadecyl ester phosphonic acid		6	6	6	6	6
Dioxin/Furans						
2,3,7,8-Tetrachlorodibenzo(p)dioxin		1	1	1		1
1,2,3,7,8-Pentachlorodibenzo(p)dioxin		1	1	1		1
1,2,3,4,7,8-Hexachlorodibenzo(p)dioxin		1	1	1		1
1,2,3,7,8,9-Hexachlorodibenzo(p)dioxin		1	1	1		1
1,2,3,6,7,8-Hexachlorodibenzo(p)dioxin		1	1	1		1
1,2,3,4,6,7,8-Heptachlorodibenzo(p)dioxin		1	1	1		1

Data on PCDD/F emissions from both risk and trial burns were furnished by OHM-Corporation during the peer review breakout session. If one takes PCDD/F from these tables in terms of total 2,3,7,8-TCDD-equivalents (corrected to 7% O_2), the average for risk burn No. 1 is 0.0520 ng/dscm; for trial burn No. 1 is 0.0262 ng/dscm (the trial burn was the one spiked with POHC). For risk burn No. 2, the value is 0.0140 ng/dscm; for trial burn No. 2 the value is 0.0273 ng/dscm. The implications of these findings for the proposed burn should be discussed. For example, they suggest that toxic equivalent emissions are not very sensitive to burn conditions within the proposed range and are unlikely to be affected by changes in total organics loading (due to differences in soil concentrations). Since these compounds also drive risk (i.e., are major contributors to the overall risk), the high versus low value effect on results should be discussed.

Process Upsets

The unit has operated for approximately 1,100 hours and has experienced three upsets. The upset conditions that cause the thermal relief valve (TRV) to open are: the temperature in the evaporative cooler is above 500°F; the induced draft fan shuts down; the power fails, or the temperature at the scrubber inlet exceeds 250°F.

In all TRV openings, the fuel feed is discontinued. The risk assessment uses the number of 36 25-minute openings and 12 1-minute openings. These numbers were based on data from the Bog Creek and Old Midland site remediations multiplied by two. This appears to be a conservative estimate. Based on three upsets in 1,100 hours, the report states that only 16 unplanned openings of 5 minutes or less would be expected. A detailed assessment of past openings is needed, and the potential risk from future openings (over 18-24 months) addressed. Much of the rationale behind the process upset conditions was not included in the report (but referenced as Volume II, Appendix 3B of the 1996 trial burn report). Some of these data would be useful if included. Also, other potential upsets (failures) need to be discussed specifically.

The risk assessment should re-evaluate the assumption of a constant temperature of 1800°F from the TRV during an upset condition. Discussion included the effects of cooling gas coming back through the system; this could be calculated. The assumption of isothermal discharge becomes less likely as time goes on and it should be evaluated as to whether it is true at 25 minutes.

Fugitive Emissions

Several points need to be investigated further pertaining to fugitive emissions. In addition, for the risk assessment to be truly integrated, this section should be included in Volume 1. First, leakage from the seals may occur. Does experience show evidence of positive pressures in the kiln without opening the safety vent? If so, what was the duration of these leakages and should they be considered as emissions or fugitive emissions? This must be clarified. In the chemical processing industry, emissions from seals, pumps, valves, etc., must be assessed and these emissions are classified as fugitive emissions.

Second, no mention was made of volatilization of high vapor pressure organic compounds during excavation, relocation to stockpiles, and transport to the incinerator feed inlet. Volatilization of certain "proposed" organics would be a strong function of season and ground cover. What do the existing data show and how will the monitoring plan address this issue?

Long-Term Research Recommendation

The prediction of organic emissions is based entirely on an analysis of the formation of specific compounds via homogeneous gas phase reaction. There is significant potential for heterogeneous (gas-surface) reactions that may increase or decrease emissions of a given compound (POHC or PIC). Little quantitative information is available from laboratory studies that can be brought to bear on this point.

AIR DISPERSION MODELING/DEPOSITION MODELING

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This experts in the breakout session agreed that the risk assessment should have considered the following:

- Baseline air quality in the Lock Haven airshed.
- Meteorological climatology, with emphasis on stagnations.
- Estimation of emissions of fugitive organic vapors associated with feedstock soil handling.
- Quantification of uncertainties in modeled estimates of concentrations and depositions, and application of these values into quantified uncertainties in modeled health effects.
- Deposition of fugitive dust.

The reviewers stated:

- The operation of the incinerator facility should provide for continuous stack monitoring to assure that emissions do not exceed design limits.
- "Criteria Pollutants" (PM_{10}, $PM_{2.5}$, CO, NO_x, O_3, SO_x) should be measured in the Lock Haven valley.
- Procedures should be in place to predict "stagnation alerts," and federal or state machinery should be in place to require reduced emissions during severe events.

EXPOSURE ASSESSMENT

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General Comments

The following comments reflect common observations of the experts in the exposure assessment breakout session:

- Reviewers noted that the exposure assessment is thorough but not necessarily complete. Based on the experts' review, they agreed that the assessment was generally conservative. However, the following general issues were noted:

  Sources. The assessment evaluated emissions from the stack and fugitive dust from soil, but did not evaluate volatile emissions and subsequent human exposures from site soils.

  Chemicals of concern. A very comprehensive list was developed, which included not only chemicals measured in site soil but also chemicals predicted to occur in emissions based on site history, those predicted to occur during combustion, as well as those measured in stack emissions. As noted by the reviewers in the combustion breakout session, a number of combustion by-products (e.g., benzoquinone) were not included in the analysis.

  Exposure pathways. All relevant exposure pathways were evaluated, with the exception of vapor inhalation from site soils.

  Fate and transport modeling was conservative in that chemicals were not assumed to degrade and mass balance was not accounted for. This approach is likely to overestimate media concentrations.

Receptors. All relevant receptors of concern were evaluated. All receptors were conservatively assumed to be located at the point of maximum air concentrations and deposition.

Uncertainty. Even though uncertainty was qualitatively evaluated in the assessment, a more quantitative evaluation of sources of uncertainty that may substantially affect risk estimates is warranted. In effect, a sensitivity analysis should be performed to identify those key areas of uncertainty that require quantitative evaluation. A more quantitative evaluation of uncertainty would enhance communication of the magnitude and direction of uncertainty for these key parameters.

Some major sources of uncertainty that may warrant or benefit from quantitative evaluation are exposure concentrations and uptake factors. Uncertainty associated with the pathways of exposures that contributed most to risk (i.e., beef and dairy ingestion) should be quantified. Some key factors to evaluate include bioconcentration factors (BCFs) for plant uptake, BTFs for air-to-leaf transfer, BTFs for cow ingestion to beef and milk, and the fraction of meat and milk ingested from the contaminated area (FI values). Secondly, it should be noted that exposures are affected by emissions; therefore, uncertainty associated with emission rate estimates should be quantified. This analysis be carried out for the chemicals that contribute most to overall risk.

- Calculating an average exposure scenario for those chemicals and pathways that contribute most to risk should provide a more realistic risk estimate and enhance understanding of overall predicted risks.

- It is unclear whether an assessment of vapors emitted during soil handling was performed. It may have been presumed that real-time monitoring would be indicative to on- and offsite receptors. This may not necessarily be valid. Monitoring data obtained during earlier investigations (i.e., during the 30-day SUMMA canister monitoring) could be used to evaluate exposures to specific volatile during soil handling events.

- Long-term research objective: Field studies should be conducted to verify predicted media concentrations. It would be useful to measure the concentration of select chemicals in air, surface water, soil, plants, and cow beef and milk two years after facility operations and compare measured values to predicted concentrations.

Specific Comments

- A full-blown, quantitative uncertainty assessment (e.g., a Monte Carlo-type assessment) is not necessary, but should be performed for chemicals that contribute most to overall risk.

- Speciation of chromium and treatment in the risk assessment was appropriate. In one scenario all chromium was assumed to be hexavalent chromium, while another scenario assumed that all chromium present was total chromium.

- Some concern about uncertainty associated with wet deposition scavenging coefficients was raised. These coefficients can vary by as much as an order of magnitude. The percent

contribution of total air, water, and soil concentrations that can be attributed to wet deposition could be addressed (perhaps in a tabular format). If the percentage is low, then the uncertainty associated with wet deposition scavenging coefficients is not likely to have substantial effect of risk predictions. If the contribution is large, uncertainty associated with these coefficients needs to be evaluated in a more quantitative manner.

- The surface water modeling approach is appropriate for the human health risk assessment. Because most individuals obtain water from a municipal source, it is reasonable to assume that water passed through the treatment plant would be thoroughly mixed before consumption. This approach may not be appropriate for use in the ecological risk assessment, however. It may not be reasonable to assume complete, instantaneous mixing. Lack of mixing could result in higher surface water concentrations than predicted in the risk assessment; therefore, modeled surface water concentrations may underestimate ecological risks. It is also noted that the runoff concentration could be used as a worst-case exposure concentration for ecological receptors.

- Fate and transport equations in more recent guidance documents should be reviewed, including the 1997 North Carolina incineration guidance document.* This document has corrected some errors in modeling equations reported in the EPA 1994 and 1997 documents. The revised Exposure Factors Handbook should also be consulted..

- Whether any individuals potentially exposed to stack emissions obtain their drinking water from a private well should be determined. Risks to these receptors may not have to be quantified, but should be acknowledged because concentrations in groundwater are likely to be much lower than those estimated in the Keller Reservoir.

- Evaluation of vapor transport to root crops is incomplete. The risk assessment should acknowledge that root crops could be contaminated for 30 years via vapor transport from soil. Similarly, it should be acknowledged that plants may be contaminated via resuspension of soil after facility operations cease.

- The risk assessment document should acknowledge that the subsistence farmer, resident, and nursing mothers may consume fish if this scenario seems reasonable after consulting with the public or other appropriate agencies.

- A discussion should be provided in the risk assessment report on lead exposures in terms of the Integrated Exposure Uptake Biokinetic (IEUBK) model. Lead levels predicted to occur in various media are lower than the default values used in the IEUBK model; therefore, blood lead levels in children living near the facility are not expected to exceed federal regulatory levels.

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* *North Carolina Protocol for Performing Indirect Exposure Risk Assessments for Hazardous Waste Combustor Units*. 1997. Research Triangle Institute, Center for Environmental Analysis. Research Triangle Park, NC.

HUMAN HEALTH

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Toxicity Assessment, Risk Characterization, And Uncertainty Sensitivity Analysis

This section summarizes and highlights the discussion of the human health breakout session. These comments are presented in three groupings: deficiencies/omissions, clarifications/considerations, and future research issues. The comments within each grouping are not necessarily presented in order of priority.

Deficiencies/Omissions

Background Exposures

There is a notable deficiency of background information on contaminant levels for this particular environment and the population considered in this risk assessment. It is important to know whether this population is already exposed to elevated levels of chemicals to which the Drake incinerator may contribute. This may be a significant issue for the consideration of incremental risks. It is recognized that it is difficult (if not impossible) to obtain background information on all the chemicals considered in this risk process; nevertheless, it is useful to document any information that may already be available, especially for those chemicals that contribute a large percentage of the total risk, or for which background exposures may

already be at or near recommended exposure levels. Of particular interest are ambient air pollutant concentrations of criteria pollutants and blood lead levels for children. During the discussions, several individuals indicated that blood lead data are available from the local Head Start program. Blood lead data may also be available through the State Department of Public Health. Reliable local air monitoring data that have been collected before, during, and after the trial burns should also be included in the risk assessment.

The group viewed the inclusion of these data, if available, as important for several reasons. As indicated above, these data may indicate whether this population is already exposed to high levels of any particular chemical or groups of chemicals. In addition (although this is in part a future research issue), these data, coupled with monitoring procedures during and after completion of the remediation process, may also indicate whether the incineration process has added significantly to background levels present prior to the start of the process. Thus, empirical data would help to validate the predictions made through this risk assessment process that depend heavily on many assumptions and models.

As a footnote to the omission of background exposures, the group noted that it would be useful to know the outcome of using the IEUBK lead model for children for the estimation of child exposures and risk. This was noted to be a curious omission. Discussion of the value of this model, the use of this model for this particular population, and any possible incremental risk due to the incineration based on estimated or known blood lead levels in the local population of children should be included.

Asthma (Including Childhood Asthma)

Asthma appears to be one of the most likely potential health effects associated with the operation of the incinerator. As such the potential should be examined more carefully and thoroughly. The ambient concentrations of PM_{10}, $PM_{2.5}$ (if available), and irritant gases associated with asthma should be collected for the Lock Haven area. The concentrations under normal and inversion conditions should be obtained, if possible. The predicted increase in these pollutants due to the incinerator operation under normal, upset, and inversion conditions should be calculated and added to ambient concentrations. The total concentrations should be compared with literature data regarding pollutant concentrations that trigger asthmatic reactions. The concentrations can also be compared with data regarding air concentrations and emergency room visits

for asthma. Attention should be paid to the appropriate averaging time when reporting and calculating concentrations.

Use of Toxic Equivalency Factor (TEF) Approach for Polyaromatic Hydrocarbons (PAH) Cancer Risk

The "TEF approach" should not be used for the consideration of risk for PAH exposures. There are several reasons for this that should be brought out in the document. For example, there are several mechanisms by which individual and mixtures of PAHs may act, e.g., formation of DNA adducts, DNA intercalation, and alteration of gene expression via their interaction with the Ah receptor (like the dioxins). The TEF approach assumes that a considerable amount of information is known for each of the PAHs and that there is a common mechanism. While this is true for the dioxin-like compounds, this is not the case for the PAHs. In addition, there are many PAHs that are likely to be present, but not identified. Others have been identified, but no toxicity or mechanistic information is available. Thus, presently there is not a clear scientific basis for using the TEF approach for the PAHs. At this time, a better, and conservative, approach would be to assume that all the carcinogenic PAHs are similar to benzo(a)pyrene and to approach the risk assessment in this manner. It is also recommended that the provisional cancer inhalation value for benzo(a)pyrene be used for the PAHs.

Fugitive Volatile Emissions from Soil

The present document has not considered the risk from exposure to fugitive volatile emissions that is likely to occur due to the presence and movement of contaminated soil at the Drake site. A thorough risk analysis of this potential and likely source of chemicals for human exposure should be incorporated into this document. This should consider multiple scenarios of emissions and exposure pathways, as well as the monitoring data that are available.

Acute Inhalation Exposures

The manner in which the dosage for acute inhalation exposures is calculated for the TRV openings should be corrected to be consistent with benchmark values that are available. These benchmark values are averaged over a 15 to 30 minute period and not a 1-hour period as was done in the present document. It is recommended that a 15 minute averaging time be used. This is likely to yield a 2- to 4-fold increase in the estimated acute hazard quotient.

Use of "Margin-of-Exposure" Methodology to Estimate Risks From Exposure to the Dioxin-Like Compounds

The reviewers recognized that at this time the use of the margin-of-exposure methodology may be the best way to estimate risks due to potential exposure to dioxin-like chemicals from the Drake site. The rationale for using a margin-of-exposure approach in this document, however, is not clear and needs more explanation. In particular, it is not clear why the use of dioxin reference doses (RfDs), e.g., previous RfD values as estimated by EPA or more recent ATSDR values, were not considered for this risk assessment. The lack of use of these values is inconsistent with the procedures used for the other chemicals in the document, and it is not clear why the dioxin-like compounds represent a special case. If these values are not to be used, a clear and scientifically-supportable rationale should be presented. The use of an EPA "policy decision" here should be avoided. If the use of margin-of-exposure is predominantly a policy decision in lieu of an upcoming RfD value from a future EPA dioxin document, then a statement to this effect should be made. The document should also clearly point out that the present background exposure levels may already exceed ATSDR recommendations for noncancer endpoints.

Clarifications/Considerations

Intake Factors

The values selected as intake factors for milk ingestion and fruit and vegetable consumption should be reexamined, especially those for young children and nursing mothers. Values used in this document should be compared to those published in the newly revised Exposure Factors Handbook and, perhaps,

altered to be consistent with these new estimates. If the old values are retained, the rationale should be clearly stated.

Dioxin TEFs

There are several assumptions and uncertainties with the use of dioxin TEF values. While this is the best approach at this time, the inherent assumptions and uncertainties should be discussed more thoroughly.

Total Risk Analysis - Lead and Dioxins

Due to the methodology used in this document for estimating the risks for exposure to lead and dioxins, possible risks due to exposure to these chemicals have not been incorporated into the "total risk" for exposure to chemicals at the Drake site. This should be made clear and a qualitative discussion should be incorporated into the document considering what the implications are for the total risk analysis.

Absorption Factors

Justification for the dermal absorption factors used in this document is needed. For most, no explanation has been provided. The development of two dermal absorption factors is based only on consideration of route and gross nature of exposure, with little consideration of vehicle or, more importantly, the time period over which the dose was administered. If broad estimates of absorption factors are going to be applied to numerous chemicals, the bases for these estimates should be supported with more evidence.

Sensitivity Analysis

A sensitivity analysis of the pathways and chemicals that drive the risk should be performed. This should include the milk ingestion pathways and the inhalation of volatilized chemicals from water pathways.

Combination of Pathways

The risks associated with infant and childhood exposures (for the subsistence farmer and the residential scenarios, separately) should be combined, because infants will also be exposed as children if the families remain in Lock Haven. The combination of infant, childhood, and adult exposures is also reasonable for the 30-year exposure time frame. These should be included in the summary risk estimates.

Executive Summary

Recognizing that the Executive Summary needs to be concise, it should be thorough. In addition to the comments regarding the Executive Summary already made in the "Premeeting Comments," this group noted that a discussion of the major uncertainties and how these may affect the overall risk should be clearly and simply given.

Research Initiatives

Based on the Drake site risk assessment, several important research initiatives were identified.

PAHs

It is clear that PAHs are a major part of the risk assessment for the Drake incinerator, as well as other incinerators. The data to date do not support the use of a TEF-like approach for assessing risk of exposure to the PAHs. While more mechanistic and potency data may assist movement in this direction, it may be extremely difficult to clearly sort out these data due to mixture effects and the variability that these cause. The use of meaningful and validated *in vitro* assays may be a useful alternate approach to consider. This may, for example, necessitate the classification of the PAHs into several subclasses based on their different mechanisms of action and the design of *in vitro* assays to test for each mechanism.

Route-to-Route Extrapolation

Route-to-route extrapolations are important and significant sources of uncertainty in the risk analysis. Effort should be directed to develop a uniform and scientifically-based approach whereby route-to-route extrapolations are made.

Childhood Risk Issues

This represents an important issue that is likely to have significant impact in any risk assessment analysis. The present risk assessment methodology is viewed as inadequate to accurately address childhood health issues for both cancer and noncancer endpoints. Thus, this represents a major uncertainty in the present risk analysis methodology. More research needs to be performed to expand the database so that we may be able to accurately determine such parameters as appropriate child absorption factors, pre- and post-natal exposure levels for acute and chronic exposures, critical times and periods of exposures, and sensitive endpoints. In addition, it seems intuitive that a 70-year average lifetime risk for the development of cancer is inappropriate when an exposure may occur at a critical time of development *in utero* and the time for cancer development is much shorter. Realizing the difficulties and the numerous considerations, child-specific factors and parameters should be developed and/or determined.

Integration of Public Health Information With Chemical- and Site-Specific Risk Analysis

The group noted that the document failed to consider the background incidence of particular diseases in the local Lock Haven population. The consideration of these data may be of use to suggest sensitive endpoints to be considered. In addition, it is possible that the exposure to chemicals at the Drake site may exacerbate or add to some existing disease conditions. Finally, the increased incidence of a particular disease in the local area may suggest elevated exposure to environmental agents and/or chemicals. This may significantly alter the total and/or incremental risk analysis due to chemicals released from the Drake site; however, there is no good and/or accepted manner with which to quantitatively or qualitatively integrate this information in a risk analysis similar to that performed at the Drake site. Methodologies and approaches should be developed to integrate health data into a quantitative human health risk assessment.

ECOLOGICAL RISK ASSESSMENT

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A screening level ecological risk assessment is a tool used by risk managers to determine the potential risk to ecological receptors from a proposed action. Predicted environmental concentrations of chemicals of concern (e.g., soil and water concentrations) are compared to concentrations known or suspected to cause toxicological effects in plants, fish, and wildlife. This information is then put into an ecological context in order to interpret what it means in terms of sustainable populations and communities of plants and animals, and presented to the risk manager along with a discussion of how much certainty there is in the estimate.

The approach used at the Drake site lacked several key elements in the presentation of the risk assessment. For instance, there was no clear statement of the systems at risk or a definition of the assessment endpoints. Site-specific species of special concern (i.e., Federal and State listed species) were not identified and addressed, there was no consideration of bioaccumulation potential of contaminants in the terrestrial environment, terrestrial wildlife were not considered, and there was very little discussion of the uncertainties and shortcomings of the benchmark values that were used nor why alternative sources of information were not accessed. In the comments that follow, we have provided suggestions for how these deficiencies could easily be rectified. The comments are presented in a format consistent with the standard format for an ecological risk assessment (problem formulation, exposure assessment, effects assessment, risk characterization), which, if followed, would result in a more readable ecological risk assessment.

Problem Formulation

A problem formulation section should be developed for the ecological risk assessment. Because neither the public nor decision makers are typically familiar with ecology or ecological risk assessment, a problem formulation provides an important communication function in explaining which ecological resources are at risk (and why) and how those resources might be affected by existing conditions or by future actions such as incinerator operations. Problem formulation also helps the assessor sort out, from all of the possible factors that might be included in an assessment, the critical factors that must be addressed to support the management action for which the risk assessment is being performed.

Guidance on problem formulation can be found in EPA's Draft Guideline for Ecological Risk Assessment (U.S. EPA 1996) and Interim Final Superfund Ecological Risk Assessment Guidance (U. S. EPA 1997). The problem formulation should include: (1) a brief site description, (2) a discussion of assessment and measurement endpoints, and (3) a site conceptual model.

The site description should identify the ecological resources, both terrestrial and aquatic, that could be affected by incinerator operations. A variety of information sources for this section were identified at the workshop. Descriptions of aquatic biota in the Susquehanna River and tributaries are available in the environmental impact statement prepared by the Corps of Engineers for the Lock Haven Levee Project and in a Pennsylvania Department of Environmental Resources (DER) report on environmental impacts of mining. Information on unique ecological features of the region can be found in the Lock Haven Public Library and in a Nature Conservancy report for Clinton County. Information on endangered/threatened species is available from the National Heritage Foundation, the U.S. Fish and Wildlife Service, and the Pennsylvania DER.

The discussion of assessment endpoints should describe the valued ecological resources that should be protected. At the workshop the importance of fishing, hunting, and other outdoor recreation to the area was noted, therefore, fish, game, and birds such as raptors should be included as assessment endpoints. Because maintenance of healthy ecosystems that support fish, game, and birds requires healthy plant and invertebrate communities, terrestrial plants, soil-dwelling macro invertebrates, and aquatic invertebrate communities are also appropriate assessment endpoints.

As noted in the premeeting comments, except for endangered species, the appropriate level of organization for ecological risk assessments is the population/community rather than the individual organism. In other words, management action is warranted if an action or a chemical release can affect the abundance or persistence or composition of a population or community, but not necessarily (except for endangered species) if a small number of individual organisms may be affected. Screening-level assessments, such as the one performed for the Drake Incinerator, assess effects on individuals. If, under conservative assumptions, even the most sensitive organisms will not be affected, then populations and communities are also protected. Although this approach is technically valid, it is difficult to communicate to nonscientists. An additional population-level context can be provided, at least for terrestrial populations and communities simply by comparing the location and size of the potentially affected areas (defined from plume deposition studies) to the size and location of important local ecosystems. For the Lock Haven area, information on the size and location of important landscape types can be found in the Atlas of Pennsylvania Resources.

The conceptual model provides a graphic and narrative depiction of the linkages between chemical releases and adverse effects on organisms. An example of a typical pathways diagram is provided in Appendix F. The principal route of chemical transport from the Drake Incinerator is atmospheric dispersion and deposition. Aquatic biota can be exposed to chemicals deposited directly on surface water or to chemicals initially deposited on land and subsequently transferred to surface water through runoff or leaching to groundwater. Terrestrial biota can be exposed directly to chemicals through inhalation or through ingestion of chemicals deposited on vegetation or on the soil surface. Organisms at higher trophic levels in both aquatic and terrestrial ecosystems can be exposed to chemicals that have been absorbed by prey organisms.

All of these pathways should be included in the conceptual model; however, not all must necessarily be quantified. The water, soil, and plant benchmarks used in the current ecological risk assessment are (subject to comments provided below) sufficient to address impacts of direct contact with water and soil. Impacts of bioaccumulative chemicals such as dioxins and furans can and should be addressed using available screening-level food chain models. There are two pathways, inhalation exposures to wildlife and direct exposure to vegetation, that cannot currently be addressed due to lack of readily available toxicity information. These pathways should still be noted in the conceptual model and discussed as significant uncertainties in the risk characterization section.

The possibility of additive effects should be acknowledged in the narrative component of the conceptual model description, given the history of water-quality degradation in the Susquehanna watershed. Background information on water quality in Bald Eagle Creek, Spring Creek, and the Susquehanna River is available. Any chemicals that are known to be important contributors to past or present adverse conditions should be quantitatively addressed by comparing loadings expected from the Drake Incinerator to existing background concentrations.

Exposure Assessment

The most important issue concerning exposure assessment is that wildlife food-chain exposures should be quantified using existing screening-level food chain models. Predicted concentrations of chemicals in fish can be obtained using the methodology of Thomann.[a] Ingestion rates and exposures to fish-eating birds and mammals can be estimated using information available in EPA's Wildlife Exposure Assessment Handbook. Concentrations of chemicals in terrestrial food chains can be assessed using information available in Sample and Suter.[b] These assessments need be performed only for chemicals that are known to accumulate in aquatic or terrestrial food chains. Of the chemicals included in the Drake Incinerator risk assessment, the chemicals that should be addressed include dioxins/furans, PCBs, pesticides (DDT, DDE, and Endrin), and mercury.

Several additional refinements to the exposure assessment should be considered. The 1 cm incorporation depth appears conservative; 12 to 15 cm is more realistic and appropriate. The assessment currently assumes that all chemicals are deposited directly onto soil. This is a reasonable assumption for screening ecological risks associated with direct soil exposure, soil ingestion, and soil-to-plant uptake. For screening effects of phytotoxic chemicals deposited directly on plant surfaces, an alternative scenario in which all chemicals are deposited on leaves should be considered.

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[a] Thomann, R.V., J.P. Connolly, and T.F. Parkerton. 1992. *An Equilibrium Model of Organic Chemical Accumulation in Aquatic Food Webs with Sediment Interaction.* Environmental Toxicology and Chemistry. 11:615-629.

[b] Sample, B.E. and G.W. Suter, II. 1994. *Estimating Exposure of Terrestrial Wildlife to Contaminants.* ES/ER/TM-125. Oak Ridge National Laboratory. Oak Ridge, TN.

Finally, given the prominence of mercury in this assessment, the estimated exposures of mercury should be reevaluated, beginning with the estimated release, transport, deposition rates, and methylation. Conservative assumptions involved in these calculations should be identified and, if possible, more realistic site-specific assumptions should be developed. Although it may also be possible to modify assumptions concerning partitioning and transformation of mercury in soil and water, the environmental speciation of mercury is poorly understood and is highly site-specific. It may not be possible to defend less-conservative assessments concerning mercury partitioning without site-specific data.

Effects Assessment

The effects assessment section of a screening level ecological risk assessment gathers together information about dose- or concentration-response relationships. Ecological Benchmark Values (EBVs) (a.k.a., toxicity reference values [TRV]) are derived from available data and generally are based on the lowest exposure concentration that causes an ecologically relevant effect (e.g., mortality or reproductive changes). For a screening level assessment, available data are preferred, although some effort may be needed to find information on the more obscure chemicals.

Ecological Benchmark Values

Prior to collating information for different data sources, a hierarchy of acceptability should be established. Regulatory criteria should be given the highest priority. In the current risk assessment, Pennsylvania water quality standards would have first priority for aquatic life EBVs, followed by federal water quality criteria. A few national sediment criteria are available and should be given priority for sediment EBVs. Second tier priority would be numbers from peer reviewed published sources, including criteria developed for other similar ecosystems. Thus, in the current assessment, the Great Lakes water quality criteria for piscivorous wildlife would be in the second tier. Third tier numbers are those derived from published data but have not received public comment or peer review in regards to derivation of the EBV. The Oak Ridge National Laboratory databases and the Region III EBVs fall into this category. When these data are used, the supporting documentation must be read carefully, and an appropriate discussion of the assumptions used in the derivation of the various numbers should be included in the assessment

document; details should be provided in the exposure assessment section and a general summary given in the uncertainty section of the risk characterization (see page D-28 of pre-meeting comments in Appendix D for some discussion of these factors).

Once the hierarchy of acceptability is established, EBVs should be derived from the data set that has the highest acceptability ranking, regardless of whether another lower ranked database has a lower EBV. While this may give the impression that the lowest available value is not being used and, therefore, that the risk assessment is not sufficiently conservative, the *a priori* designation of suitability makes this a valid procedure. A lower value, which is derived from a process that contains a large amount of uncertainty or controversy, is not more protective, as it is not known whether the number is correct or has much validity.

The pre-meeting comments suggest several additional sources where data may be quickly accessed for development of additional EBVs for plants (Appendix D, page D-33) and some numbers for amphibians (Appendix D, page D-40). Furthermore, the Oak Ridge National Laboratory database includes EBVs for wildlife species. The current risk assessment did not include an analysis of potential risk to wildlife, other than fish-eating birds and mammals. No conclusions can be fully reached, therefore, about whether or not the proposed incineration poses a risk to wildlife. The following approach is recommended for including wildlife risks in the assessment.

Wildlife EBVs

A simple terrestrial food web should have been derived during the problem formulation phase of the ecological risk assessment. This food web would provide information on how soil-deposited contaminants could move into plants or soil invertebrates and from there be taken into the food chain by herbivores, insectivores, and omnivores. Note that it is not necessary to identify specific species, but rather to delineate general feeding guilds. Several of the chemicals on the list of chemicals of interest are known to be persistent, bioaccumulative compounds that are not a hazard to plants or soil invertebrates (at low concentrations), but readily bioaccumulate in the food web and pose a hazard to carnivores or insectivores. These include DDT (and its derivatives), PCBs, and dioxins/furans. For the purpose of a screening level assessment, non-bioaccumulative compounds should be considered to be in animal diets at the same concentration as in the soil. This is a worst case scenario, as most of these compounds are not taken up by

plants or animals and generally exist in lower concentrations in biota than in the environmental media. For bioaccumulative compounds, trophic transfer factors (a.k.a., uptake factors, bioaccumulation factors) should be used to calculate the estimated concentrations in plants, invertebrates, and first-order insectivores, carnivores, or herbivores. A first reference for finding such values is Beyer et al. 1996 (see page D-39 of premeeting comments in Appendix D for full citation). Note that values used in the ecological risk assessment should be consistent with the human health risk assessment plant uptake factors (PUFs) and animal trophic transfer factors.

Derivation of the EBV for wildlife to use in comparison with calculated dietary values (either estimated as soil concentrations or from soil times appropriate trophic transfer factors) is somewhat complicated by the fact that the values in the Oak Ridge database are given as a dose metric (mg/kg-body weight) rather than a concentration metric (mg/kg-feed). Reconversion into a concentration-based EBV can be accomplished in either of two ways. The first (and preferred) approach begins by referring to the supporting documentation where the actual value from the species that was studied can be ascertained. Almost all wildlife studies are conducted as concentration-based toxicology studies. The Oak Ridge researchers derived the dose by assuming an average food consumption rate and average body weight for the species and making the appropriate calculations. This, of course, adds to the uncertainty of the dose-based EBV, as there is biological variability around the body weight and consumption rate numbers that is ignored. The expert reviewers agreed that using the original concentration-based data was the preferred approach. If the species tested is in a different phylogenetic order than the group of animals of concern (e.g., the test was done in mallards but the concern is insectivorous birds), then it is recommended that the test concentration be divided by an uncertainty factor of 10. If the test species is in the same order, then either no uncertainty factor is used or, if a conservative estimate is desired, a factor 5 would be sufficient. This recommendation is based on a survey of several large datasets of comparative toxicological information that demonstrated that 90 percent of the species responses were within an order of magnitude, and more closely related species responded most similarly.

A second (and less preferred as well as more time-consuming) approach to derivation of the wildlife EBV is to find the species in a feeding guild of interest that has the lowest dose-metric in the Oak Ridge database. Information on body weight and food consumption of this species would then need to be used to back-calculate the dietary concentration that would result in this dose (these data frequently are available in the Oak Ridge supporting documentation or the EPA Wildlife Exposure Factors Handbook). Note that once

again, the uncertainty associated with using a single average value rather than a population distribution of body weights and food consumption rates must be stated and carried through the risk assessment. These values should not be divided by additional uncertainty factors, as they were originally derived by extrapolation from tests conducted on a different species, and uncertainty factors have already been incorporated during this derivation process. Note that this approach includes more extrapolations than does the preferred approach: the test species dose-metric is derived based on assumed body weights and food consumption rates and the species of interest dietary concentrations are back calculated based on similar assumptions.

Mercury

The hazard quotient (HQ) for mercury in piscivores was determined to be 8.55 (using the Oak Ridge EBV) or 2.97 if the (preferred) Great Lakes water quality criteria for wildlife value is used. Both of the values are greater than 1, suggesting that a closer look needs to be taken to determine the risk of mercury to fish-eating wildlife. The recommended approach for doing this in any screening level ecological risk assessment is to review all the assumptions that were used in derivation of the value. For a screening level assessment, very conservative assumptions generally are made. It is now appropriate to review those and make more realistic, site-specific assumptions. It is recommended that such an exercise begin with the exposure assumptions, as they generally contribute more uncertainty to the final HQ than does the effects estimate.

In this case, that would mean revisiting the modeling exercise that was conducted to predict the amount of mercury that would be deposited in the soil, how much would be in surface run-off, and, therefore, how much would end up in surface waters. Further investigation should be made of the trophic structure of the streams (is a 3-level trophic structure appropriate for both the cold and warm water fisheries?) and to the trophic transfer values used (is 15 percent organic mercury in surface water relevant? It is a very conservative estimate and may be too high). Any information about soil type (high organic content? high or low pH?) that may be relevant to movement of mercury from soils to water should also be reviewed.

Note that the expert reviewers for deposition modeling felt that the estimated concentrations had approximately an order of magnitude of uncertainty. An HQ of 3 may be within the "noise" of this estimate and not be real, nonetheless, it is apparent that mercury may be a limiting chemical, particularly if the system already contains large amounts of mercury as suggested in the risk assessment. If mercury levels currently are near the limit of what piscivorous wildlife can tolerate, even a small increment of additional mercury may be unacceptable. Some limited site-specific sampling would help reduce the uncertainty of this estimate, should this prove to be the case. Again, data that would reduce deposition estimation and enhance surface run-off calculations would be first priority, as would direct determination of percent methyl mercury in the surface water. Measurements of mercury in fish from the Susquehanna River may be available from the Pennsylvania Department of Fisheries and, if so, should be examined (note that it is very important to determine where the fish were caught, relative to the site, to make sure that the information is interpreted appropriately). Once again, this further analysis of mercury exposure estimates must remain consistent with the human health risk assessment.

Risk Characterization

The Risk Characterization section summarizes and presents the HQs using the information developed in the exposure and effects assessments, describes the uncertainty associated with these estimates, and then puts everything into a site-specific, ecological context. This section is very important, because it provides the means for risk assessors to communicate their findings to the risk managers, including their professional judgement of the ecological relevance and level of certainty of the risk estimates. This is most important in a screening level assessment where the actual technical information generally is not very site-specific and is an individual-based toxicological estimate.

HQs and Risk Estimates

Presentation of the HQ information as a series of tables was very well done in the Drake ecological risk assessment. Additional tables will need to be added, of course, for the wildlife HQs. What is lacking, however, is a discussion of the chemicals for which no toxicity data are available and, therefore, for which no HQs can be derived. These chemicals cannot be simply ignored, and a blanket statement made of "no risk"

to the environment. In reality, insufficient data exist upon which to make a risk recommendation and, therefore, a statement should be made that it is unknown what the risk from these compounds might be. Further discussion might be added if toxicological similarities exist between those chemicals with no data and others for which data do exist. If HQs are very small (e.g., less than 0.01) for related compounds, then even one or two orders of magnitude difference in response would not result in a calculated risk. Many compounds have not been studied simply because this type of risk assessment (for incinerator-generated deposition of hundreds of chemicals) has only been done in a few previous cases and there has not been any indication of harm as a result of other processes. Nevertheless, an honest statement of the inability for anyone to predict risk from these compounds to ecological systems must be included in the risk characterization.

Note that the current risk assessment cannot make any predictions about risk to wildlife (other than fish-eating birds and mammals, no data were examined on which to base such a prediction). Without going through the exercise of developing HQs for wildlife (including both bioaccumulative and nonbioaccumulative compounds), the risk assessment is incomplete. Note, in addition, that any protected species (rare, threatened, or endangered) should be discussed individually in regard to their potential risk from the incinerator deposition as they are of special concern to many of the stakeholders. This may be as simple as a single sentence stating that HQs indicate no potential for risk to any of the protected species.

Uncertainty

In addition to the tables presented in the uncertainty section, a brief narrative should be included explaining in simple terms the general categories of uncertainty in the assessment. These include all those currently identified, as well as uncertainties generated due to natural biological variability. For example, in the derivation of wildlife EBVs described above, biological variability in body weight and food consumption rates was ignored in converting dietary concentrations to dose-metrics (and vice-versa). This adds uncertainty to the data, and it should be acknowledged that average values were used in these types of calculations.

The significance of the mercury findings (whatever they turn out to may be – HQ > 1 or < 1) also should be discussed in this section. They should be presented in a manner to provide the risk manager with

the appropriate information. If the final determination is of an HQ < 1, what cautionary information does the risk manager need to know about the certainty with which the "no risk" determination has been made? If the HQ remains > 1, how certain is it that a measurable adverse effect actually will occur? Again, professional judgment may come into play here, along with what is known about the uncertainties of predicting mercury biogeochemistry on a site-specific basis using only general principles and no site-specific data.

Ecological Context

Finally, the risk assessment should be placed back into an ecological context. This can best be done by revisiting the site descriptions provided in the problem formulation. The area and extent of various habitat types potentially impacted by the proposed operation could be compared to the amount of habitat in the surrounding area. For example, large tracts of forest exist on the hills behind the site, yet only a small portion would potentially receive deposition of incinerator plume material. Thus, the conservative estimate of no risk to terrestrial forests would be further strengthened by the fact that a very small amount of the available habitat would be at risk. Large mammals and birds that (presumably) are among the species of concern identified in the assessment endpoints may (or may not?) be likely to spend much time in the area because home ranges are large enough to extend beyond the boundaries of the potentially exposed site. Further discussions could be included about how population-level effects would be negligible in such a situation, even for small species that may reside completely within the area of concern but have significant and sustaining immigration from dispersing individuals in contiguous habitat. Similar discussions about plant communities and/or the aquatic systems should be included as appropriate. This discussion should not be long or very technical, but should be presented concisely in a manner easily understood by the risk manager. It is here that the risk assessor has the opportunity to switch from a toxicological approach to an ecological assessment, and draw on their knowledge of site-specific ecology and general ecological principles.

SECTION SIX

COMMENT HIGHLIGHTS

SUMMARY OF PREMEETING PEER REVIEWER COMMENTS

Prior to the workshop, each of the 14 peer reviewers was asked to prepare written comments on the draft report for the Drake Chemical site full-burn risk assessment. Reviewers applied their technical knowledge and professional judgment to comment on the technical accuracy, completeness, and scientific soundness of the assessment. Reviewers evaluated:

- Overall organization of the document.
- Clarity and completeness of the Executive Summary.
- Data and methodology to determine if gaps exist that would preclude the use of the risk assessment for decision making.
- Long-term research that could improve future risk assessments.

The complete charge to the reviewers is presented in Appendix C. Comments appear in Appendix D.

Overall, the peer reviewers found the document to be well-organized. However, some sections of the document lacked important background information and rationale for various analysis approaches and assumptions. Several of the reviewers suggested that more data be presented in tabular format in the body of the report, rather than the repeated references to information that could be located in the appendices.

The peer reviewers expressed concern that the Executive Summary did not contain sufficient detail about the specific test methods and models used, the data, or the conclusions or uncertainties. The reviewers specified that the Executive Summary:

- Does not discuss uncertainty and sensitivity results

- Does not clearly state that the assessment does not consider the additive risks from exposure to existing background chemicals.
- Does not clearly state that dioxins and lead are treated differently (mathematically) and are not added to the total risk for noncancer endpoints.
- Does not address the issue that the risk assessment did not follow the ecological risk assessment approach suggested by EPA guidelines and may not be sufficiently comprehensive to document the decision of no potential risk to ecological receptors.
- Does not present conclusions in reference to fugitive dust emissions or process upset conditions.
- May overstate the conclusion that the full-scale operation will not pose a threat to public health.

Three "significant" methodological gaps were identified by the reviewers:

- The assumption of no existing background of exposure combined lack of baseline data with reference to both human health (particularly childhood asthma) and air quality.
- The ecological screening did not follow EPA guidance or good environmental assessment practice.
- Scarcity of data that provide confidence in the accuracy of the dispersion modeling results that was not emphasized.

In addition, the expert reviewers identified weaknesses in the risk assessment and areas where the risk assessment document could be improved. These include:

- Volatilization of organic vapors during feedstock soil handling was not addressed.
- Deposition of fugitive dust was not addressed.
- Baseline air quality data in the Lock Haven airshed and baseline data for childhood asthma and adult congestive pulmonary disease were not considered.
- Quantification of uncertainties in modeled estimates of concentrations and depositions and in modeled health effects is lacking.
- The use of the TEF (toxic equivalency factor) approach for assessing the risk of exposure to PAHs may not be appropriate.
- The description of the incinerator system and operating parameters was inadequate.

Recommendations for long-term research to improve the risk assessment and the risk assessment process in general, presented by individual reviewers, included:

- Development of risk assessment methodologies appropriate for children.
- Bioaccumulation research.
- Evaluation of failure/upset at the plant to estimate upset emission risk.
- Field studies to verify predicted media concentrations.
- Development of a tool to evaluate site-specific bioavailability of contaminants.
- Evaluation of behavioral and toxicological effects related to inhalation of volatile plume components.
- Evaluation of effects of direct deposition of chemicals on plant surfaces.
- Development of distributions of exposure data.
- Development of field survey instruments to determine the relevance of national and regional data in data exposure assessments.
- Modification of cancer slope factors based on mechanistic information and alternate low-dose extrapolation methods.
- Development of uniform, established approaches for estimating dermal slope factors and dermal intake.
- Definition of approaches for estimating noncancer health effects for dioxins and furans and route extrapolations for PAH.
- Development of methodology and criteria regarding the quantification of nonmeasured emissions.
- Evaluation of heterogeneous pathways in products of incomplete combustion formation.

OBSERVER COMMENTS AND QUESTIONS

Observers were given two opportunities to make public statements during the workshop. Observers were required to register in advance. See Appendix H for a complete list of commenters. In

addition, a question/answer period was provided to give other observers the opportunity to comment or ask questions.

OBSERVER COMMENTS (Thursday, January 15, 1998)

Dean Bottorf, Clinton County Commissioner

Mr. Bottorf provided a packet of materials to the peer reviewers and made the following comments:

- The workshop should have been held in Lock Haven.
- U.S. Senator Specter has requested that EPA halt the remediation process until the report by Bob Martin (EPA National Ombudsman) is made final in March.
- Excavation of the incinerator site was very poorly executed and resulted in high levels of fugitive dust.
- The soil at the Drake site is contaminated to approximately 40 feet, not the 12 feet EPA plans to remediate. He indicated that he had data to verify this point.
- Other contaminated sites exist in Lock Haven.
- Despite EPA's statements, Drake is a dioxin-contaminated site.
- Because of Lock Haven's location in a deep valley, onsite meteorological data are needed.
- Mixing of clean and contaminated soils occurred during the trial burn.

Robert Yowell, Regional Director, Pennsylvania Department of Environmental Protection (PADEP)

Mr. Yowell expressed his appreciation to the peer reviewers and made the following comments:

- An exhaustive search for alternative technologies was conducted and incineration is the best technology to clean up the Drake site.

- PADEP supports the local governments in their efforts to remediate the site rather than leave it untreated.
- All efforts will be made to make the remediation process as safe as possible.

Bill Smedley, Chairman of A.I.R. Legal Committee

Mr. Smedley described Arrest the Incinerator Remediation, Inc. (A.I.R.) as a grassroots organization formed in response to members' concern with EPA's decision to remediate by incineration. His comments included:

- The peer reviewers were "very much on target with [their] initial presentations."
- The peer reviewers brought out several issues that A.I.R. has been raising for more than three years.
- As chairman of the legal committee, it is his goal to force EPA to answer questions about the issues of uncertainties in the risk assessment in a courtroom.
- Exposure to wildlife is an area of concern to A.I.R.
- A.I.R. does not trust EPA and has sent the risk assessment document to its own experts for review.

Vicki Smedley, A.I.R. Chairperson

Ms. Smedley began her comments by stating that she would not be using her prepared statement because she was impressed with the peer review team and the presentations. Her comments included:

- The peer review team raises many of the issues of concern to A.I.R. and appears to be truly independent review.
- This forum represents an opportunity for A.I.R. to get real answers to their questions.
- Will the final meeting report be available to EPA and the public before the scheduled start of the remediation process? Dr. Wood stated that EPA will assess all comments raised by the expert peer reviewers.

- The risk assessment is based on flawed data.

QUESTION/ANSWER PERIOD (Thursday, January 15, 1998)

Bill Smedley (A.I.R.)

Bill Smedley (A.I.R.) raised two issues:

- Should the burning of tires at the International Paper plant be considered in the Drake risk assessment as an additional background source? Will any synergistic or antagonistic effects results from the incineration of tires.

  Ms. Holly Hattemer-Frey responded that the risk assessment is based on emissions from the Drake incinerator and would not be impacted by another facility. Risk assessments are based on the assumption of additive effects, not synergistic or antagonistic effects. Dr. Gasiewicz added that insufficient data exist about synergistic or antagonistic, toxicological effects to incorporate such a discussion in the risk assessment report.

- Mr. Smedley supported the peer reviewers' discussion of the lack of baseline data and expressed a lack of confidence in the moss studies being conducted.

  The EPA, USACE, and Pennsylvania State University are working together on a moss bag study to attempt to determine the background levels of PCDD/PCDF and metals. This effort will continue throughout the duration of the remediation project.

Rose Reeder (A.I.R.)

Rose Reeder (A.I.R.) questioned the wisdom of proceeding with the full burn given the uncertainties that remain. She stated:

- Experts had called "fen-phen" safe and later determined that it could cause heart damage.
- It is documented that members of the Lock Haven community are already chemically sensitive.
- The full burn should definitely not begin until the peer review report is complete.

OBSERVER COMMENTS (Friday, January 16, 1998)

Mick Harrison, Green Law, Attorney for A.I.R.

Mr. Harrison appealed to the reviewers to carry out the charge to conduct a thorough scientific review of the risk assessment document. His comments included:

- The reviewers should be explicit that the dioxin noncancer risk can be addressed by reference dose and hazard quotient procedures. He added that EPA's decision not to include dioxin noncancer risk was based on policy, not science.
- Mr. Harrison requested that the peer reviewers present specific recommendations in their report, specifically in reference to *in utero* exposure (significant endpoints, routes of exposure, chemicals of concern).
- Potential for noncancer effects must be made clear to the community, especially in reference to breast-feeding infants and other highly sensitive populations. This will require explicit information regarding short term exposure.
- Uncertainties must be expressed so the community can understand them. Present all risks quantitatively, as a range based on identified uncertainties.
- Population risk, not just reasonable maximum exposure to individuals, should be considered in a manner to account for the ultimate fate of persistent chemical poisons.
- Committee reports should include all points of view expressed, not simply a consensus opinion.

Bill Smedley, Chairman of A.I.R. Legal Committee

Mr. Smedley's comments included:

- A statement from Vicki Smedley indicating that she was disillusioned and concerned by her perception that the reviewers were accepting a risk assessment document containing so many uncertainties.
- Questions concerning the employment and educational history of the peer reviewers.

Dr. Cohen indicated that EPA has documentation of the peer reviewer panel qualifications.

- Concern that assessment and evaluation assume zero contamination in the background.
- Concern that the lack of baseline data will make proof of damage caused by the incineration project nearly impossible.
- Concern about upset conditions mentioned by three of the reviewers.
- Concern that the breakout sessions involved discussions of how to improve future risk assessments, rather than scientific evaluation of the risk assessment at hand
- Concern about several phrases that he had heard and found disturbing.
- Bioaccumulation has been ignored.
- Suspicion of the destruction and removal efficiency (DRE) values presented for naphthalene and 1,4-dichlorobenzene.
- Reminder to the reviewers of the importance of their work: the results of the reviewers' evaluation will impact future risk assessments, specifically future policy regarding risk assessments.
- Citizens deserve the best available technology, not just a screening level risk assessment.
- This risk assessment was not comprehensive enough and major issues remain unresolved.

QUESTION/ANSWER PERIOD (Friday, January 16, 1998)

Dan Adams, Williamsport Sun-Gazette Staff

Mr. Adams asked two questions regarding the safety of the community:

- Will Lock Haven residents be reasonably protected? Would you live here?
- As independent, qualified professionals, do you have insight for the citizens of Lock Haven?

Dr. Cohen responded that these are critical issues, but are not the charge of the peer reviewers. Dr. Cohen stated that acceptance of risk is a very personal decision; no one can answer that question for anyone else.

Robert Yowell, Regional Director, Pennsylvania Department of Environmental Protection

Mr. Yowell expressed his appreciation to all the participants in the workshop and asked two questions of the review panel.

- Assuming that cleanup, not capping, is the better approach at the Drake site, is there another, better technology available for remediation (other than incineration)?
- The risk assessment has flaws, contains uncertainties, and is very conservative. Does the level of conservatism cover the uncertainties "within a reasonable margin?"

  Dr. Harrison responded. He stated that he does not believe that the air quality estimates from the modeling activity (concentrations, depositions) are conservative. He believes they are appropriate and central, but not conservative. He recommends that the risk assessment process move away from intentionally conservative estimates toward best central estimates with quantified uncertainties.

  Dr. Strauss stated her belief that in reference to long-term effects (chronic effects), the conservatism does cover the uncertainties. Short term effects (such as stagnation conditions) are much more complex and require additional study.

Michael Ochs, Evangelical Lutheran Church in America, Environmental Task Force

Mr. Ochs expressed disappointment in the risk assessment discussion and stated that background data do exist; and noted data from the American Lung Association on pediatric asthma and bronchitis. He cited information for the population of Clinton County based on Pennsylvania Vital Statistics (1991 to 1995):

- The annual average number of deaths from chronic obstructive pulmonary disease is the fifth highest in the state (on a county basis). This average is third highest when adjusted for age.
- The average annual age-adjusted death rate from malignant neoplasms in the Lock Haven area is second highest in the state.

Greg Crystall, EPA Region III

Mr. Crystall assured the reviewers and observers that all comments will be evaluated and a detailed response will be issued. He announced the tentative date of a public meeting (February 10, 1998) to be held to address this peer review of the draft risk assessment and SOAR data.

Mick Harrison, Green Law, Attorney for A.I.R.

Mr. Harrison asked the peer reviewers several questions:

- From this risk assessment, do any of the reviewers know the dioxin and dioxin-like compounds dose to a breast-feeding infant over a 14-day period?
- Does any reviewer know what a safe exposure level is for a breast-feeding infant for dioxin and dioxin-like compounds over a 14-day period for noncancer effects?
- Are any of the reviewers prepared to say that exposure from this incinerator is safe?

Dr. Gasiewicz responded that no one has definitive answers to any of these questions.

APPENDIX A

EXPERT REVIEWERS

United States
Environmental Protection Agency
Office of Research and Development

Drake Chemical Site Incinerator Risk Assessment Peer Review Workshop

Genetti Hotel and Convention Center
Williamsport, PA
January 15-16, 1998

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APPENDIX B

BREAKOUT SESSION ASSIGNMENTS

United States
Environmental Protection Agency
Office of Research and Development

Drake Chemical Site Incinerator Risk Assessment Peer Review Workshop

Genetti Hotel and Convention Center
Williamsport, PA
January 15-16, 1998

Breakout Discussion Assignments

Thursday, January 15: 1:55PM to 5:00PM
Friday, January 16: 8:00AM to 10:45AM

Combustion Engineering
Elmar Altwicker*
Francis Holm
JoAnn Slama Lighty

Air Dispersion and Deposition Modeling
Halstead Harrison*
Jerry Havens
John McCutcheon

Exposure Assessment
Yoram Cohen
Annette Guiseppi-Elie
Holly Hattemer-Frey*

Human Health
Thomas Gasiewicz*
Elizabeth McKenna
Harlee Strauss

Ecological Risk Assessment
Lawrence Barnthouse
Anne Fairbrother*
*= Discussion Leader

APPENDIX C

CHARGE TO PEER REVIEWERS

CHARGE TO REVIEWERS FOR THE DRAKE DRAFT FINAL RISK ASSESSMENT

The draft final Drake incinerator full burn risk assessment is contained within a single volume covering the scientific disciplines of toxicology, environmental fate and transport, combustion engineering, atmospheric modeling, exposure assessment, and ecological risk assessment. The accompanying appendices present additional background information, and data that support the Volume I narrative. As a reviewer of the Drake draft final risk assessment, you should use your best technical knowledge and professional judgment to comment on the technical accuracy, completeness and scientific soundness of the assessment. Each reviewer is asked to focus on several specific issues in his or her area of expertise with comments on other areas invited but optional. Your comments will be considered in finalizing the risk assessment.

For the peer review workshop reviewers will be organized into 5 work groups: Combustion Engineering, Air Dispersion and Deposition Modeling, Human Health, Exposure Assessment, and Ecological Risk Assessment. All reviewers should be familiar with the Executive Summary, Introduction, Risk Characterization, and Uncertainty and Sensitivity Analyses sections of the draft final risk assessment. In addition, each work group should focus on specific sections as specified below:

Workgroup	Risk Assessment Sections and Appendices	
Combustion Engineering*	Volume I §2	Appendix 2A-D
Air Dispersion and Deposition Modeling	Volume I §3	Trial Burn Risk Assessment Volume III (June, 1996)
Exposure Assessment	Volume I § 4 and §5	Appendices 4A and 5A-H
Human Health	Volume I §6 and §7	Appendices 6A-B, 7A-E
Ecological Risk Assessment	Volume I§9	Appendix 9

*Additional fugitive emissions data will be provided by Region 3.

While reviewing these sections of the document, please address the following general issues.

1. Comment on the organization of the risk assessment document. Does the presentation follow a logical format? Is the presentation of information in the document clear, concise and easy to follow?

2. Does the executive summary clearly and accurately reflect the data and methodologies used and the conclusions reached in the risk assessment?

3. As with any risk assessment, there are always additional data and method development efforts that could be undertaken to reduce the level of uncertainty. However, are there any major data or methodological gaps that would preclude the use of this risk assessment for decision making? If so, how should they be addressed?

4. What long-term research would you recommend that could improve risk assessments of this type in the future?

In addition, the following workgroup specific issues should be addressed.

Emissions Characterization

Emissions characterization includes identification of target chemicals of concern and the development of emission rates for these contaminants. Emission rates were developed through a combination of site specific stack test data and models. To characterize the nature of the emissions, emission rates were estimated based on stack gas samples collected during the risk burn period and for those not detected, but assumed present, emissions were estimated from other data sources. Please comment on the following issue with respect to this aspect of the draft risk assessment.

1. Please comment on the trial burn and risk burn operating conditions as to their appropriateness for deriving future full burn emission rates.

2. A multi-step methodology was employed to derive emission rates. Emission rates were estimated for all organic compounds and metals identified in the incinerator emissions or site soils, all compounds identified as potential products of incomplete combustion, and acid gases and criteria pollutants. The intent of this methodology was to arrive at conservative estimates of emissions under normal, steady-state conditions. Please comment on the multi-step methodology.

3. Comment on the approach used to estimate stack emission rates of nondioxin organics that were not detected in the risk burns. The methodology developed for this risk assessment involves estimating relative emission rates and then normalizing to absolute emission rates based on "calibration factors" for a few selected compounds. Is the approach appropriate for estimating emission rates for Principal Organic Hazardous Constituents (POHCs) and Products of Incomplete Combustion (PICs) from the burning of contaminated soils? To what extent has this approach lead to conservative emission estimates?

4. For dioxins and furans, measured values are the primary source of the emission estimates. However if emissions were below the detection limit, a methodology was utilized to derive a representative, relative distribution of dioxin and furan compounds. These ratios were then applied to the total dioxin and furan emission rates measured. Please comment on this approach.

5. As with the organics, the primary source of emission estimates for metals was the emission rates measured during the risk burns. If measured values were not available, an estimation procedure was utilized. Please comment on the appropriateness of the resulting emission rates for metals.

6. Acid gases and criteria pollutants were either measured or, when below detection limits, regulatory and permit limits were utilized as a conservative upper bound on emissions. Please comment.

7. Comment on the potential process upset conditions that were identified. Was the approach used to select these conditions appropriate? Are the conditions chosen (frequency and duration) properly characterized as worst case?

8. Comment on the identified sources of fugitive emissions and the fugitive emission estimates.

9. Overall, is the identification of the key assumptions used in characterizing the nature and magnitude of emissions thorough? Are the magnitude and direction of effect of these assumptions on the overall risk assessment accurately characterized? Is the uncertainty and variability inherent in this analysis adequately discussed? Does the analysis cover the major parameters expected to have an effect on the risk assessment?

Dispersion and Deposition Modeling

To develop this risk assessment, computer models have been used with the risk burn emission rates and meteorological conditions to simulate the air concentrations and deposition rates for contaminants potentially emitted from the Drake Superfund site incinerator. The models used include the CALMET/CALPUFF and the INPUFF models. In your review, please address the following issues.

1. On-site data were collected at various times at the Drake Chemical site; however, a careful evaluation of the data revealed significant problems with data quality which invalidated large portions of the data. As a result, a combination of on-site meteorological data and data from other locations were utilized in deriving a flow field for the Lock Haven area. Please comment on the reasonableness of this approach. Have the representativeness of the off-site data sets been adequately addressed?

2. For the risk assessment, a concerted effort was made to utilize the latest dispersion modeling techniques to provide as comprehensive an analysis as possible. The CALMET/CALPUFF models were selected due to their state of the science status. Comment on the appropriateness of these models for the type of terrain surrounding the Drake Chemical site.

3. The dispersion of process upset emissions were modeled using the INPUFF model. Please comment on the appropriateness of this model for this purpose.

4. Have the various uncertainties associated with the dispersion modeling been adequately characterized? Have any limitations been overlooked that would significantly alter the conclusions of the atmospheric dispersion analysis?

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Human Health Risks

Human Health Risk Assessment includes hazard identification, dose-response evaluation, exposure assessment, and risk characterization. To develop the risk assessment, potentially exposed populations have been identified and the magnitude, frequency, and duration of their exposure quantified. This information was then integrated with the hazard identification and dose response evaluation for the risk characterization. For this risk assessment, both carcinogenic and non-carcinogenic health effects have been evaluated. In your review, please comment on the following issues.

Exposure

1. EPA's documents covering *Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities, Guidance for Performing Screening Level Risk Analyses at Combustion Facilities Burning Hazardous Wastes, and Risk Assessment Guidance for Superfund* identify certain approaches that should be used to characterize exposure estimates at combustion facilities. For example, the reasonable maximum exposure (RME) is defined as "the highest exposure that is reasonably expected to occur at a site." Comment on whether the Drake exposure assessment develops exposure estimates that are consistent with the intent of these guidance documents.

2. Important factors in an exposure assessment include the identification of all the critical exposure sources and exposed populations. Please comment on the adequacy of the Drake assessment in identifying the critical sources and pathways of exposure as well as the critical exposed populations.

3. Have the key assumptions for estimation of chemical concentrations and for estimation of exposures been identified? Are the magnitude and direction of effect correct for the assumptions that have been identified?

4. Supposedly, conservative assumptions have been applied in the Drake assessment to account for uncertainty and to avoid underestimating the exposure to any single individual. Are the conservative assumptions appropriately factored into the ultimate exposure estimates? Please comment on whether the uncertainties were addressed and analyzed in an adequate manner. If they were not, please state what should be done differently.

Hazard Identification/Dose Response and Risk Characterization

Several approaches were developed to derive additional provisional toxicity values in cases where EPA approved toxicity values were not used. One approach was the use of route-to-route extrapolation, the use of a toxicity value for one exposure route to derive a toxicity value for another exposure route. Another approach was to derive toxicity values for use in the short-term inhalation scenarios.

1. Comment on the route-to-route extrapolation approach that was used to derive oral or inhalation cancer slope factors when a slope factor was available for only one of these exposure routes.

2. An extrapolation approach was utilized for the development of dermal slope factors that involved assumptions about absorption factors based on the original laboratory testing. Please comment on the two absorption factors that were assumed in deriving provisional dermal toxicity values.

3. For the majority of the chemicals of concern, traditional approaches to dose response evaluation were employed (e.g., use of a slope factor for cancer and use of a RfD/RfC for non-cancer). However for certain chemicals or groups of compounds a different methodology was used. Specifically, dioxins, furans, PAHs, PCBs, and lead. Please comment on the methodology used for these compounds. Have the uncertainties associated with the methodology been adequately characterized?

4. In this risk assessment chronic reference doses were used to evaluate exposures of greater than 7 years. Chronic reference doses were used to evaluate all oral exposure routes and for the inhalation of volatile organics through household water use. Inhalation reference concentrations were converted to reference doses for summary risk estimates. Subchronic reference values were used to evaluate the inhalation exposures. Please comment on this overall approach for noncancer health effects.

5. Comment on whether or not the non-cancer risks of chemicals of concern have been adequately addressed by the risk assessment? For example, has an adequate discussion of endocrine disrupters been provided which either characterizes their risks or clearly explains why their risks cannot be characterized? Further, have non-cancer chronic toxicities of dioxins and furans been adequately addressed in the risk assessment? Specific approaches were used to develop reference doses for manganese and fenac, please comment on the approaches used to derive reference doses for these chemicals.

6. Please comment on the approach to selection of appropriate inhalation toxicity values for the acute exposures from process upsets.

7. Have the key assumptions for estimation of dose and risk been identified? Are the magnitude and direction of effect correct for the assumptions that have been identified? Please comment on whether the uncertainties were confronted in an adequate manner. If they were not, please state what should be done differently.

8. Please comment on the overall adequacy of the risk characterization. Are the hazard identification, dose-response assessment, and exposure assessment properly presented? Does the risk characterization include a statement of confidence in the risk assessment including a discussion of the major uncertainties. Have sufficient risk descriptors to include important subgroups been presented and discussed?

Screening Ecological Risk Assessment

As with the human health risk assessment, the ecological risk assessment pulls together elements of exposure analysis and dose-response evaluations to develop a risk characterization. For the ecological screening analysis, modeled chemical concentrations in soils, surface water, and sediment were compared to ecological benchmarks. Please address the following issues in your review:

1. Comment on whether the goals and objectives of this ecological screening analysis have been adequately described and to what extent these have been met.

2. Comment on the scenarios selected for evaluation in the ecological screening analysis, the estimation of media-specific concentrations, and the methodology used to predict whether risks are possible. Why do you either agree or disagree with the decision to exclude airborne chemicals from the ecological screening analysis?

3. How appropriate are the ecological benchmarks that were used to evaluate risks from chemicals in soils, surface water, and sediment in this ecological screening analysis? What are the merits and drawbacks of using these data sources for this purpose?

4. Which relevant and important aspects of uncertainty are addressed sufficiently? Which aspects are not, and how could the discussion be improved?

5. Does the analysis support the summary and conclusions presented? In what ways does the risk characterization assist the risk manager in (a) adequately considering ecological risks in making a decision, and (b) communicating the results of the analysis to stakeholders? What, if any, additional information or analysis on ecological risk might the risk manager require?

6. Is the material presented in a clear and concise manner? To what extent is this assessment consistent in approach with documents cited as sources for the methodology: the *Proposed Guidelines for Ecological Risk Assessment* and the *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments*?

7. Describe any major elements that are missing from the ecological screening analysis which you think need to be included or which would strengthen the risk characterization.

APPENDIX D

PREMEETING COMMENTS

Elmar Altwicker

Elmar Altwicker

Drake Chemical Superfund Site Full Burn Risk Assessment

Comments provided by Elmar Altwicker

Workgroup, Combustion Engineering

General Issues

Generally, the risk assessment document follows a logical format. However, the presentation of the information in the document is not always clear, concise, and easy to follow. I certainly found myself searching between a qualitative statement or conclusion and the quantitative information that - presumably - provided the support. I'll return to this point specifically under Emissions Characterization (below).

The Executive Summary does not reflect completely the data and methodologies used and the conclusions reached. Each subheading, for example, could have included one or two sentences stating the major conclusions for that subsection. The question is asked "are there any major data or methodological gaps that would preclude the use of this risk assessment for decision making?" The answer appears to be: probably not. Though a number of aspects could be explored here, it is highly unlikely that any would change the health effect risks (Table ES-1).

Long term research should address several of these aspects. Specifically, three can be noted: 1) methodology and criteria development regarding the quantitation of non-measured emissions (keeping the premise that everything cannot ever be measured). 2) consideration should be given to heterogeneous pathways in PIC-formation. Though the kiln and the cyclone remove large particles, the fine particle number concentrations in the SCC are likely to be high and may either promote or inhibit radical-molecule reactions. 3) catastrophic failure of the plant (or parts thereof).

Emission Characterization

The trial burn (TB) and risk burn (RB) operating conditions and the description of the incineration system strike me as inadequate Copious references are made (p. 1.2-2, and elsewhere) to previous reports, but some additional information could have been included.

Four burns were reported; I constructed the table below from the parameters given (RB = risk burn; TB = trial burn).

Variable	RB #1	RB #2	TB #1	TB #2
Soil feed rate, ton h^{-1}	47.3	40	47.3	40
kiln T, °F	1600	1770	1600	1770
SCC T, °F	1800	1850	1800	2000

What about some other parameters?: burn duration, % excess air, volumetric flow rate, T-distribution (how many measurement locations, i.e., are the values shown single location measurements, averages of several locations, constant over the duration of the burn?); exact sampling location(s) to get emission rates; limiting factor(s) on soil feed rates, kiln dimensions, etc.

It took awhile to find the distinction between RB and TB (the former were not spiked with specific organic compounds or metals, but even then the actual compounds used were not mentioned until much later in the report).

It was also not clear - until one went to the data tables - that RB #1 consisted of 4 runs (all of equal duration? and some with more measured emission rates for specific compounds than others) and RB #2 of 3 runs. The number of runs pertaining to the TB's was not reported.

In fact, trial burn data were essentially excluded from the report. One can understand the reason for that. On the other hand, much could be learned, especially by a side-by-side comparison of identical runs (RB #1 vs. TB #1, except for the naphthalene and 1,4-dichlorobenzene spikes in the latter). Since both of the spike compounds were present in the soil and at least the latter might be expected to participate in PIC-formation (cf. below) a direct comparison could bolster the (quantitative) arguments made.

The block diagram of the incinerator (Figure 1.2.-3) did not mention the fuel used in the kiln (was it natural gas, as used in the SCC?).

The section on the Estimation of Full-Scale Operation Emission Rates (2.2) was not particularly easy to follow. The text ultimately culminated in two decision trees (Figures 2.2-1 and 2.2-2); preferably, sample calculations should accompany these figures. Instead, the data tables were offered largely without comment. The sampling intent, however, was not the same for all runs within a given burn (RB #1).

Appendix 2C divided feed rates into three values, 95% UCL soil, RB-feed rate, and best RB-feed rate, each presented by a single value. Since these are average values one wonders what the standard derivations are. This should be addressed.

My own interests led me to look at a few chlorinated organic compounds (from Table 2.2-1, RB #1). By way of one example:

Chlorobenzene (emission rates, g s^{-1})		Data Qualifier Code
Run 1	2.94×10^{-5}	X3, M
Run 2	3.08×10^{-5}	X3, M
Run 3	2.36×10^{-5}	X3, M
$\bar{x}$	2.79×10^{-5}	(also the value used in the risk assessment)

X3 designates that less than 20% of the data was non-detect. Presumably, it should be clear how such a qualifier designation can be associated with a single value of the emission rate, but it is not. For this particular burn the predicted emission rate was 4.13×10^{-5}. Interestingly, the reverse was reported for RB #2 ($\bar{x} = 4.2 \times 10^{-5}$ and predicted rate = 2.58×10^{-5}). This was not observed for two other compounds I looked at, namely 2,3,7,8-tetrachlorodioxin and 2,3,4,6-tetrachlorophenol, but may have occurred with others. Though this would hardly be a problem at the absolute levels observed, some speculation on reasons for it might be appropriate.

Only in Table 2A-3 (Volume II) were both TB- and RB-data to be found, and then only soil concentration data (µg/kg). Thus (for chlorobenzene)

Range of detected soil concentrations	2- 1.1×10^6
Concentration used for June 1996 risk assessment emission rates	2.06×10^3
Feed data from RB's & TB's	9.45×10^1 - 4.50×10^2
95% UCL-value	3.64×10^2

Chlorobenzene is both a POHC and a PIC. The methodology applied to PIC-assessment is the most direct that can be implemented, though I did note some minor discrepancies when I carried it through for chlorobenzene. Again, a sample calculation would have made it easier. To a large extent (unknown actually, but likely to be very small) the methodology yields a conservative estimate. Since the unknown faction of the feed is small the error introduced into a particular PIC-emission rate from a non-measured organic present in the feed would be small indeed.

I agree with the conclusions that (Appendix 2D.10) "because emissions of PIC's have been estimated <u>independently</u> of estimates of <u>undestroyed soil constituents</u> and total emissions have been calibrated using measured emissions for this risk assessment, the <u>apparent DRE</u> is not relevant for this analysis."

For dioxin/furans I found it a bit difficult to reach a firm conclusion regarding the approach used. The measurements (how many?) cited were not accompanied by a description of the mean ($\bar{x}$) and the standard deviation (σ); how many non-detects were there? No information on phase distribution of these compounds (nor any speculation along these lines) was provided. The same comments would apply to metals.

I counted 82 chlorinated organics in the emissions (a lesser number in the feed). Therefore, I found it surprising to learn that hydrogen chloride (HCl) and chlorine (Cl_2) were zero after blank correction. The former should be the major product from excess air combustion but is obviously neutralized (scrubber). Do we therefore conclude that the scrubber was 100% efficient w.r.t. both HCl and Cl_2? Was a chlorine balance attempted?

It was also stated (Vol. I, p. 2.2-11) that these two gases were zero for RB #1 and non-detects for RB #2, after blank corrections. Do I understand this correctly? Regulatory and permit limits were utilized as a conservative upper bound on emissions. Thus (I am using relative values here), if a measure value is one and a permit value is 10, a non-detect becomes 10?

The absence of a couple of compounds in the emissions surprised me: naphthalene and several of its derivatives were in the feed, yet naphthoquinone was not cited (but quinone was). A similar comment applies to anthraquinone.

The section on upset conditions seemed to focus exclusively on the thermal relief valve (TRV) located after the SCC. What about individual pieces of equipment in the air pollution control train (NaOH feed pump failure, etc.).

Who would make the judgment on the role of "thunderstorms in the immediate area of the site" on TRV-positioning (p. 2.3-3)?

Fugitive emissions analysis emphasized soils transport and emissions. No mention was made of volatilization of high vapor pressure compounds during excavation, relocation to stockpiles, and transport to the incinerator feed inlet. Volatilization of certain "proposed" organics would be a strong function of the season (high ambient temperature or snow cover, i.e.).

Comments were solicited on nine issues. The last one has been phrased in the form of four questions:

1. Overall, is the identification of the key assumptions used in characterizing the nature and magnitude of emissions thorough? I would say that the identification was thorough but not complete.
2. Are the magnitude and direction of effect of these assumptions on the overall risk assessment accurately characterized? They are.
3. Is the uncertainty and variability inherent in this analysis adequately discussed? Not in my opinion. For example, if the total job is to take 15-18 months and the incinerator is to be on-line about 70% of that time, what burn durations, routine maintenance, kiln failure rate (requiring non-routine shut down) are we talking about?
4. Does the analysis cover the major parameters expected to have an effect on the risk assessment? This question seems somewhat redundant vis-a-vis questions 1. and 2. I would say that the major parameters (implying routine operation) have been covered.

Dispersion and Deposition Modeling

A problem with data quality was cited here. Does this pertain strictly to meteorological parameters acquired at the site or to emissions data too?

Lawrence Barnthouse

Larry Barnthouse
12/19/97

Comments on the Drake Chemical Superfund Site Full Burn Risk Assessment

General Comments

The report as a whole seems fairly well organized. The Executive Summary was informative, although I was confused at first about the distinction between a "trial burn" and a "risk burn." These terms are clarified nicely in the Introduction; they should probably be defined in the ES for the benefit of readers who don't get into the body of the report itself.

One particular concern both with the Executive Summary and with the report as a whole is the nature of the intended audience. The document appears to have been written for an audience of engineers, risk assessment professionals, and regulators. Will there be extensive public comment? If so, then additional information and explanation is needed either in this report or in companion reports. Table ES-1, which lists lifetime cancer risks and Hazard Indices for various exposure scenarios, will mean little to a lay audience. It is unclear from the report whether there was any stakeholder input to the risk assessment process. If there was, then the nature of the input should be described and any specific issues raised by the public should be identified.

As noted below, the ecological screening assessment is perfunctory at best and follows neither EPA guidance nor good environmental assessment practice. If EPA is serious about including ecological risks in risk assessments for hazardous waste incinerators, then the agency must make a serious attempt to develop both good scientific information and credible assessment procedures. At the moment, neither exist. Two specific areas in which research is needed are effects (behavioral and toxicological) related to inhalation of volatile plume components and effects of direct deposition of chemicals on plant surfaces.

Specific Comments on the Screening Ecological Risk Assessment

The ecological risk assessment was disappointingly incomplete, although I don't believe that the assessors themselves are wholly to blame. EPA Region VI is the ony region that has explicit

guidance on ecological risk assessment for incinerators, and ecological concerns have not historically been major decision drivers at incinerator sites. Under these circumstances, Project Managers often view an ecological assessment as a minor box-checking exercise to which little attention should be paid.

With regard to the specific questions provided in the charge:

1. The goals of the ecological assessment are cleary described. The problem is that those goals are inconsistent with EPA's *Proposed Guidelines for Ecological Risk Assessment.* What is promised and delivered is a simple comparison of maximum estimated chemical concentrations to toxicity benchmarks developed by EPA and/or ORNL. There is no Problem Formulation and no Risk Characterization.

   A Problem Formulation should provide a conceptual model that (1) identifies the receptors at risk, (2) discusses the relevant exposure pathways, (3) identifies the chemicals of concern, and (4) develops hypotheses concerning the relationships between chemical releases and biological responses. Without this information, it is impossible to evaluate whether the results of the "ecological screening analysis" are meaningful and useful for decisionmaking. According to Section 9.2 , all areas not identified on maps as being industrial or residential were assumed to be "ecological habitats." Are there wetlands? Nature preserves? Protected habitats? How extensive are they, relative to the areas of highest chemical deposition?

   It may seem to the analysts that none of this information is necessary because they have used worst-case assumptions throughout their assessment, but it must be remembered that risk communication is a major function of this document. No one aside from the analysts and their peers are likely to understand the strengths and weaknesses of this assessment unless they are provided with a great deal of additional information. A conceptual model would also highlight the largest glaring weakness of the assessment: failure to address several potentially significant exposure pathways: inhalation

exposures, deposition of phytotoxic chemicals on plant surfaces, and food-chain transfer of bioaccumulative chemicals. Even if no quantitative evaluation is possible, a qualitative discussion of the potential significance of these exposure routes is needed.

A Risk Characterization section should (1) summarize the quantitative results, (2) discuss the significance of the results in terms that are meaninful to risk managers and the public, and (3) describe and interpret the major sources of uncertainty. The principal objective of Section 9.5 seems to have been to emphasize the conservative nature of the assessment. Tabler 9.5.1 lists all of the conservative assumptions, and then at the end alludes to a few genuine uncertainties - mainly lack of data on food-chain transfer or toxicity. Most of the text is devoted to showing that the mercury benchmark is highly conservative, and therefore mercury risks are really insignificant even though the mercury HQ exceeds 1.

In fact, given the information provided, I find it impossible to determine whether the assessment is grosssly overprotective (because of hyper-conservative exposure and effects assumptions) or underprotective (because of unevaluated chemicals and exposure pathways).

2. As noted above, the scenarios evaluated for the screening analysis are incomplete. The three missing exposure pathways identified above should be included in the conceptual model, and the chemicals known to be relevant to those pathways should be identified. I can't comment on the exposure concentrations without talking to an expert, however, it's likely that they are highly conservative.

3. The different benchmark types vary greatly in terms of quality and consistency. The surface-water benchmarks are the best, followed by the sediment benchmarks. All values for toxicity in soil should be considered highly suspect at this point. Regardless of data quality, the approach of compiling numerous benchmarks for each chemical and then selecting the lowest for use in the assessment is inappropriate. It would be better to

develop a hierarchy of benchmark types (e.g., use the Region III values when available, use ORNL values when Region III values are unavailable,...). Employing a less-conservative assessment scheme (i.e., something other than a worst-case approach) could have eliminated the need to explain away the mercury results.

4. As noted above, uncertainties aren't really discussed at all. Instead, conservative assumptions are listed. More discussion is needed concerning the lack of toxicity information for many chemicals and concerning the exposure pathways and receptors that were not addressed. The specific discussion of mercury was limited to a more detailed discussion of conservative assumptions concerning the exposure and effects assessment for mercury. This approach to dealing with the mercury issue is unacceptable. The logic of the assessment appears to be (1) if the HQ is less than one under the most conservative scenario that can possibly be imagined then there is no risk, and (2) if the HQ is greater than one onder this scenario then, because the conservative scenario is unrealistic, there is no risk. This circular logic will not be accepted by stakeholders who are concerned about potential environmental risks. The proper approach for dealing with this issue would have been to lay out, at the beginning of the Risk Characterization section, the steps that would be taken to re-evaluate the exposure and effects estimates for chemicals whos HQ's exceed one. These steps should ideally include revision of the quantitative analysis using more chemical-specific or more site-specific information.

5. The analysis does not support the summary and conclusions, and could significantly mislead both the risk manager and the public. Uncertainty related to the absence of scientific information regarding potentially important exposure pathways and receptors is understated or ignored. Moreover, the treatment of mercury in the assessment could provide some readers with an impression that an important risk is being hidden.

6. As noted above, the assessment is inconsistent with the *Proposed Guidelines for Ecological Risk Assessment* because it lacks a Problem Formulation and a Risk

Characterization. It is partially consistent with the *Ecological Risk Assessment Guidance for Superfund* in that the initial screening step employs worst-case assumptions, however, the Superfund Guidance requires development of a conceptual model and identification of all relevant exposure pathways; these components are lacking in the Drake assessment.

7. I think the missing elements have been pretty fully covered above.

Yoram Cohen

DRAKE Chemical Site Incinerator: Full-Scale Operation
Integrated Risk Assessment
Preliminary Review Comments

by
Dr. Yoram Cohen

December 22, 1997

Overview

The 1988 Superfund Record of decision (ROD) for the Drake Chemical Superfund site, selected incineration of soils excavated from the site as the preferred treatment method. Accordingly, risk assessment was conducted by WESTON for the U.S. Environmental Protection Agency to evaluate the potential human health and ecological risk assessment from full-scale operation of the incinerator at the site.

The risk assessment was based on four trial burns under a range of operating conditions. During the trial burns, extensive monitoring was conducted of stack gas emissions, soil feed and bottom ash. Emissions were determined from direct monitoring studies with about 200 organic and inorganic chemicals measured in stack emissions, detected in soils or predicted as products of incomplete combustion, and fugitive dust emissions from the site. In the case of incineration emissions, experimental data were obtained and a correlation was developed to enable the prediction of emissions for selected chemical compounds. The results from Risk Burns 1 and 2 reveal a variability of an order of magnitude in the correlation of predicted versus observed emissions; this observation which deserves an extended discussion in the final risk assessment report.

The risk assessment process was based on estimating ambient concentration levels associated with the operation of the incinerator. The report assumes that fugitive dust emission sources can be represented by a distributed source over the total area of the site. Although this could be a reasonable approach, the implication of a distributed source for near-fence exposure is unclear, especially for episodic exposure events. Overall, however, the risk assessment follows the standard EPA methodology geared to arrive at over-estimates of exposure levels.

The human health risk assessment considered the potential risk due to exposure to a resident, subsistence farmer and a recreational fisherman. The exposure period for inhalation was assumed to be two years for inhalation, with indirect exposure (e.g., ingestion) based on 30 years and 40 years for a resident and a subsistence farmer, respectively. It is noted that the accumulation of the chemicals on land and surface water was associated with deposition during the two years of the full-scale operating period.

Air Quality Modeling

Air quality assessment was conducted using the computer models CALMMET/CALMPUFF and INPUFF. Some of the results were also compared with the predictions of the ISC3 model. The difference in the variability of the predictions of the two models was considered insignificant and the CALMMET/CALMPUFF was used for the full-scale operation risk assessment. Hourly on-site meteorological data were obtained for the period December 1992 through May 1993, while hourly off-site data obtained from Williamsport, PA were for the period June 1993 through November 1993. Precipitation data for the period December 1992 through November 1993 were obtained from Philsburg, PA. Apparently, on-site data for June through November 1993 were not available and the CALMET model was used to generate local wind field as needed. The air quality modeling yielded air phase concentrations used in the exposure assessment part of the study.

Dry and Wet Deposition

Deposition of particulate matter to soil was estimated based on the assumption that organics were distributed in the particle phase according to particle surface area. The distribution of inorganics (except inorganic mercury) in the particle phase was based on particle mass. For organics, gas phase/particle partitioning was determined using the Junge correlation; this correlation was assumed to apply for all chemicals, although it was developed specifically based on data for polyaromatic hydrocarbons. For the purpose of estimating exposure via inhalation, however, it was assumed that the total concentration of the chemicals in the atmospheric phase is available for inhalation exposure.

An empirical wet scavenging coefficient was utilized in the CALPUFF model. It is known that estimates of rain scavenging rates using empirical scavenging coefficients can often lead to order of magnitude errors in the prediction of the rate of wet deposition. A qualification of the impact of such uncertainties on the estimated wet deposition rate would better clarify the importance of wet deposition. Another area which deserves discussion is rain versus snow scavenging and the reasons for assuming that the rate of snow scavenging is 1/3 the value of rain scavenging. It is also noted that rain scavenging of gaseous chemicals was not considered in the report since it was assumed that the contribution of wet scavenging to the total chemical deposition would be minor.

Dry deposition of particles was calculated by the CALPUFF model while gaseous dry deposition was assumed to be negligible. The assumptions and origin of the parameters used in calculating the dry deposition rate would have to be clearly documented and the effect of uncertainties in parameter values on the resulting risk assessment documented.

Chromium VI, Mercury and Other Inorganics

a. The analysis of exposure to chromium assumes that 15% of chromium in combustion emission is in the hexavalent form. Although this assumption may be reasonable, the report does not provide an adequate quantitative justification and consequences of uncertainties of this assumption. It was also assumed that 15% of the inorganic mercury in surface water was converted to the methylated form while 85% of the remaining mercury remained in the inorganic form. Again, the consequences of uncertainties associated with this assumption are unclear.

b. Exposure to inorganic compounds via mothers' milk was not considered in the risk assessment. The report states that data for biotransfer factors for inorganic in humans are lacking and that bioconcentration of inorganic is likely to be insignificant; justification based on published literature would be useful in this regard.

Intermedia Transfers

c. The estimation of surface-water concentration, due to input from the atmosphere and runoff appear to be based on steady-state calculations which assume complete mixing (Appendix 4A). Stratification could lead to significant concentration gradients which would affect the results of the exposure analysis. Therefore, the impact of imperfect mixing on the resulting risk assessment could be considered in the uncertainty analysis.

d. Gas mass transfer coefficient as calculated in Table 5B-3 is inappropriate for transport to soil. The expression was developed specifically for mass transfer from a liquid phase (spill) of a pure chemical to air. This mass transfer coefficient decreases with the size of the contaminated zone in a way which is likely to be different when the chemical is incorporated into the soil matrix. There are other more suitable approaches for chemical exchange between soil and the atmosphere

e. The approach used to calculate aboveground plant chemical concentration due to air-to-leaf transfer relies on biotransfer factors. The biotransfer factor correlations were developed based on a limited set of plants and chemicals and their extrapolation to other types of chemicals and vegetation could result in significant uncertainties. An expanded documentation of the validity of the approach and impact of uncertainties in the calculated air-to-plant biotransfer factors would help to better understand the importance of exposure via vegetation.

Closure

In all cases the total cancer risk was estimated to be of the order of 10^{-7} or lower, while non-cancer health risks were below the reference dose by a factor of 100 or greater. Exposure assessment estimates would have to be at least two orders of magnitude higher to lead to a cancer risk estimate below a level of 10^{-6}. Therefore, in assessing the overall risk assessment, one should then examine the areas of the analysis where uncertainties have the highest potential for affecting the estimated risk. The results reveal that exposures via beef and milk ingestion have the highest contribution to the calculated cancer risk. For example, the published literature documents significant uncertainties (greater than an order of magnitude) associated with biotransfer factors estimated from correlations for beef and milk. The effect of such uncertainties can be quantified and incorporated into the reported risk assessment.

Anne Fairbrother

Screening Ecological Risk Assessment

My detailed comments of the screening level ecological risk assessment (EcoRisk) are presented below in response to the specific questions provided by Dr. Wood. In summary, I do not believe the EcoRisk approach was sufficiently comprehensive to document the decision of no potential risk to ecological receptors. There was no clear statement of the systems at risk or a definition of the assessment endpoints. Site-specific species of special concern (i.e., Federal and State listed species) were not identified and addressed, there was no consideration of bioaccumulation potential of contaminants in the terrestrial environment, terrestrial wildlife were not considered, and there was very little discussion of the uncertainties and shortcomings of the benchmark values that were used nor why alternative sources of information were not accessed. The risk assessment did not cite or follow the EcoRisk assessment approach suggested by Agency guidelines. Given the amount of information made available by the requirements for the human health risk assessment, it would be possible to conduct a more comprehensive and better substantiated ecological risk assessment, with relatively little additional time or monetary investment.

Have the goals and objectives been described adequately and to what extent have they been met?

The stated goal is to "*provide an indication of the potential for ecological effects to occur from exposures to incinerator emissions*" (pages 9.1-1 and ES-3). The objective of the screening analysis is to "*provide a rapid evaluation of the potential for ecological impacts by comparing predicted media concentrations with established benchmarks or screening values*" (page 9.1-1). Furthermore, it was noted that "*the screening analysis does not actually estimate risk, but identifies issues that need additional investigation*" (ES-3).

The goal and objective of the screening level ecological risk assessment was identifiable and, in a general sense, clearly stated. The final statement about the screening analysis not estimating risk is, however, not accurate. The risk quotients developed in the EcoRisk screening process are analogous to the hazard quotients developed for noncancer agents in the human health risk assessment. The human health assessment uses these quotients in a risk context and, indeed, the EcoRisk

used them in a similar vein. For example, the statement is made on Page 9.2-3 that "none of the predicted soil concentrations exceed benchmarks, indicating that an *ecological risk* is not expected..." [italics added for emphasis]. Both the human health and screening EcoRisk suffer from the fact that deterministic assessments were conducted, rather than using probabilistic approaches[1], so the *probability of an the occurrence of an adverse effect* (the true definition of risk) cannot be determined.

However, once general goals are established for an EcoRisk, it is important to define *assessment endpoints.* These are defined by EPA guidance as "*explicit expressions of the actual environmental value that is to be protected*".[2] In contrast to human health risk assessments where cancer, reproduction, and development have been identified as endpoints of concern, there is no single definition of what is meant by "ecological risk". Ecological systems vary from one location to another and the value placed on those systems depends upon who is asking the question. At a minimum, the assessment endpoints should state whether the assessment will focus on risk to individual plants and animals, local populations, and/or community functions. There may be several assessment endpoints for a single risk assessment, as different organisms often are afforded different levels of protection. For example, Federal or State-listed threatened and endangered species may need protection of individuals, while other species may need only population-level assessments. Furthermore, it is important to clearly identify any ecosystem functions that are important in the local area. Examples include soil stabilization by plants or flood control by wetlands.

EPA lists 3 criteria for selecting assessment endpoints: 1) their ecological relevance; 2) their susceptibility to the known or potential stressors, and 3) whether they represent management goals. EPA concludes that assessment endpoints that meet all three criteria provide the best foundation for an effective risk assessment. Further guidance about each of these criteria is provided.[1]

[1] An example of a probabalistic risk assessment in this context would be to use the range of predicted soil or water concentrations as exposure parameters, rather than a single value.
[2] USEPA. 1996. *Proposed Guidelines for Ecological Risk Assessment.* CFR61(175):47552-47631 Sept. 9, 1996.

Are the scenarios selected for evaluation appropriate? Was correct methodology used to estimate media-specific concentrations and to develop risk predictions? Should airborne chemicals be excluded?

The scenarios selected include direct air deposition of chemicals onto soil and surface water, with subsequent potential movement of chemicals from soil into surface water through surface runoff and soil erosion. Movement of chemicals through soil into groundwater and then into surface water was not considered, although Page 4.5-1 states that loss of chemicals from soil include leaching as well as erosion and runoff. Documentation should be provided to explain why this pathway is not a significant contributing source.

It was not clear whether the effect of a forest canopy was taken into consideration when calculating soil concentrations, although Appendix 5B-2 suggests that it was not. This results in an overestimation of soil concentrations in forested areas. Furthermore, the EPA recommendation[3] for use of a 1 cm depth of incorporation for chemicals in "most land uses" also overestimates soil exposure for most ecological receptors. Generally, the root zone is considered to encompass the top 12 to 15 cm of soil, more analogous to the EPA recommendation of 20 cm for agricultural areas. Therefore, these simplifying assumptions combined with the assumption of low soil bulk density, all result in an overestimation of soil exposures that would lead to a conservative estimate of risk. This should be stated in the Uncertainty section.

I agree with the decision to exclude airborne chemicals as a route of exposure to ecological receptors. While there is evidence that air pollutants can cause adverse effects to plants and wildlife[4], there are insufficient data for determining toxicity benchmark values to use in a screening EcoRisk analysis.

How appropriate are the ecological benchmarks used? What are the merits and drawbacks of using these data sources for this purpose?

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[3] USEPA. 1993. Addendum to the Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions. Review Draft. Office of Research and Development, Washington, DC. EPA/600/AP-93/003. November 1993.

[4] Barker, J.R. and D.T. Tingey (eds.). 1992. Air pollutin effects on biodiversity. Van Nostrand Reinhold, New York. 32pp.

I am unable to comment on the EPA Region III Draft Ecological Benchmarks as I have not seen them. However, I suspect that some of my comments regarding use of the Oak Ridge benchmark values would be applicable to them as well. I will comment separately on the Oak Ridge values, the use of Ambient Water Quality Criteria (AWQC), the Great Lakes Wildlife Criteria, and the Sediment Quality Criteria. I will conclude my comments on this point with a brief discussion of other values that could be used in the screening level assessment.

Oak Ridge soil benchmark values – these values have become widely used in ecological risk assessments because they are readily accessible via the Internet. The major problem with this ease of access is that the supporting documentation does not come along with the database, and must be requested separately from Oak Ridge National Laboratory (ORNL). It is extremely important that this documentation be reviewed so the values may be used in the appropriate context. Furthermore, it is extremely important to keep in mind that these values have not undergone scrutiny and review by the scientific community, nor are there any guidelines about the quality of studies used to develop the benchmarks. These values were developed originally for internal use by the Dept. of Energy to assess risks at the ORNL site, and may not be applicable to other soil types of ecological systems. Many of the plant toxicity studies were conducted in laboratories or greenhouses using agronomically important species, such as lettuce, radish, cucumber, and wheat. These species may have significantly different toxicity thresholds than trees, particular conifers that depend upon micorrhyzal associations for optimum growth. Review of the supporting documentation would indicate which values were developed solely on agronomic species and would allow for a better discussion of the uncertainties associated with the use of these benchmark values. Finally, any threatened or endangered plant species or soil fauna should be evaluated individually, even at a screening level assessment. The assumptions behind the screening level values of the data should be assessed to determine if they would lead to an over- or under-estimation of risk to these species. Having said this, I must add that I like the approach that Oak Ridge used in developing the plant values; i.e., calculation of the 90th percentile of the LOAEC values. This is most analogous to the approach used for determination of AWQC.

Ambient water quality criteria (AWQC) – these values are entirely appropriate to use in a screening context. They carry the force of law (regulation) and have been developed over the course of many years, with significant public input and scrutiny. Moreover, there are quality control guidelines for the type of data that can be used in generating the criteria. Because the AWQC are designed to protect 95% of the species 95% of the time, they may not be protective enough for site-specific threatened or endangered species. This is a missing element in the EcoRisk assessment, which made no attempt to evaluate these species separately.

Great Lakes Water Quality Criteria (GLWQC) – there was no indication in the EcoRisk assessment whether pisciverous wildlife species exist in the area. It can safely be assumed that the bald eagle and belted kingfisher are likely to be present in the area, but I am unable to make similar generalizations about whether mink or otter are found in the rivers. This reinforces my point in Comment #6 that a good description of the site-specific ecological systems (including species lists) is essential to an ecological risk assessment, even at the screening level. Nevertheless, application of the GLWQC can be made in this case, provided the assumptions inherent in such an extrapolation are clearly stated. These are (at a minimum) 1) that the bioaccumulation factors are similar across sites (doubtful for mercury, probable for the others), 2) that the same tropic levels exist and contain similar species, and 3) that the same endpoints of concern are being evaluated (i.e.., reproductive effects at the individual level). It also must be clearly stated that the GLWQC values have uncertainty factors built in, so that the value is at least an order of magnitude lower than the species-specific LOAEC. Therefore, by using these numbers the assumption has been made that the management goal is to afford that same level of protection to individuals of these pisciverous species. Because assessment endpoints were not articulated for this assessment (see Comment #1), it is not possible to determine if this is an appropriate use of these numbers.

It must be noted that the *Oak Ridge Piscivore Benchmark* values actually drove the assessment for mercury (i.e., were lower than the GLWQC). In my opinion, the GLWQC are a better approximation of toxicity threshold levels, even given the assumptions stated above. The Oak Ridge value for mercury, for example, was derived from a single mallard duck study, with adjustments made for body size differences among species (which may or may not have an effect on toxicity) and additional uncertainty factors added. Again, there are no data quality control standards explicitly applied to selection of data for use the Oak Ridge values. The GLWQC, on the other hand, looked at several studies and explicitly stated assumptions and data quality objectives. Furthermore, the GLWQC values have been subject to public review and comment, while the Oak Ridge values have not. Similar arguments apply for the DDD, DDE, and DDT values. In summary, given a choice, I suggest that the GLWQC take precedence over the Oak Ridge values for pisciverous wildlife.

Sediment Quality Criteria – as with the AWQC, these values are undergoing development in an open forum with stated data quality objectives. While there remains considerable debate over the approaches and specific applications of these values, they are appropriate for use in a screening level assessment with the caveat that there are no threatened or endangered species to which special consideration should be given. Whether the Ontario sediment guidelines or the NOAA sediment guidelines should be given precedence, is something on which I am not qualified to comment.

Missing data – Given that over 200 hundred chemicals are being screened for potential effects to a whole host of possible ecological receptors, it is inevitable that there will be data gaps in our knowledge about their toxicological effects. However, some of the gaps could be filled in from other readily available sources. Most notable in this regard are the pesticides. Information on plant toxicity from herbicides can be inferred from label application rates. These same labels provide information on bird and mammal toxicity benchmarks. These data are readily available from the *Farm Chemicals Handbook*[5] *or from the actual labels that accompany the sale of all products.*

Which relevant and important aspects of uncertainty have/have not been addressed sufficiently? How could the discussion be improved?

While I appreciate the use of a table (such as Table 9.5-1) as a means of summarizing information, I find it inadequate for the entire discussion of uncertainty.

[5] *Farm Chemicals Handbook. 1997. Meister Publishing Company, Willoughby, OH.*

One point that is inadequately addressed is how to make a risk determination in the absence of data. Many of the chemicals have no toxicity information relative to ecological receptors. It is unacceptable, therefore, to simply state that there is no risk from incinerator emissions, such as the statement "*that an ecological risk is not expected...*". It must be explicitly stated in the Uncertainty section as well as in the Conclusions that an assessment of the risk of these compounds to ecological receptors of concern cannot be made due to lack of information. I would suggest, however, that these compounds are unlikely to cause adverse effects, given that those which we know to be highly toxic are predicted to be present at concentrations below threshold values. Those compounds with missing values likely have not been tested for toxic effects, as they have not been associated with any obvious environmental effects. Review of the conclusions of the human health risk assessment may provide additional qualitative information about the relatively low toxicity of these compounds compared to others for which more data are available. Note that the table of uncertainties suggest that lack of benchmark data results in an under-estimate of risk (page 9.5-5), which may or may not be true. Currently, the uncertainty associated with missing data and that of ignoring the potential for contaminants to bioaccumulate are the only two identified that may result in an *under*-estimation of risk (see Table 9.5-1). Comments on the bioaccumulation issue are in Comment #7.

I would like to make some specific remarks regarding the discussion of the uncertainties associated with the estimate of risk from mercury. First, I agree with the approach of examining natural background concentrations and determining if the mercury deposited from the incineration process is a large or small fraction of what already is present (in fact, this should be done for all the metals, in soils as well as aquatic systems). However, the statement made on lines 11 –13 of page 9.5-2 that soil concentrations below background are unlikely to be harmful to resident wildlife is a gross generalization that may not always be true. There are areas where naturally occurring concentrations of various elements are toxic to resident animals. The best example are alkali springs and seleneiferous soils in the arid west. Not all animals are capable of adapting to all naturally occurring background conditions. Next, in lines 17-20 on page 9.5-2, the statement is made that the fish tissue BAF used in the Great Lakes assumes that 85% of the mercury is in the inorganic form. I assume this refers to the mercury in the water, not in the fish as most fish have better than 85% *organic* mercury in their tissues if they reside in a lentic system. Thus, a risk assessment in a lentic system likely would be more conservative than one in a lotic system where methylation rates may be lower due to the higher dissolved oxygen in water and sediment and, therefore, fewer anaerobic bacteria to begin the methylation process. It was not clear, however, how the comment on BAF relates to the discussion in the last half of the same paragraph about the toxicity value being based on a mallard study that used organic mercury. Lines 5 – 7 on page 9.5-3 suggest that the toxicity value was "applied to total mercury" concentrations in the water. The water concentration that would result in the toxicity threshold concentration of methyl mercury in the fish diet can be back-calculated using the methods of the GLWQC and will account for the relative ratio of inorganic and organic mercury in each level of the food web (using data from Page 5.4-5 to 5.4-6 of the report to develop a site-specific food web). Alternatively, the exercise presented in Volume II, Appendix 5F for estimation of fish tissue concentrations can be used to compare directly estimated fish mercury concentrations with the toxicity threshold values of piscivorous birds and mammals (extrapolated from mallards and mink, respectively). Note that there may be significant differences between cold and warm water ecosystems in regard to bioaccumulation

potential for mercury and chlorinated organic compounds due to the different fish species in the food web.

One final comment regarding uncertainty. Table 9.5-1 and on Pages 9.2-3 and 9.3-3 state that hazard quotients were not added across chemicals to calculate a cumulative hazard index. This is exactly correct: hazard quotients should NOT be added together – ever (not even in human health risk assessments). Hazard quotients for different chemicals are different metrics because the dose-response relationship differs significantly among chemicals and between species. Ten times more chemical does not always result in a ten times worse effect. Moreover, not all chemical effects are additive. This is particular true for exposure of plants and animals to metals (although in aquatic organisms, effects may be considered additive as a first approximation). For those chemicals that are known to have a similar mode of action, the Toxicity Equivalence Factor (TEF) approach is recommended, as this puts the dose-response relationships onto a common scale. Then, exposures can be added and compared to the common effect threshold for a *single* hazard quotient. EPA is working on development of TEFs for PCB exposure to terrestrial wildlife. Therefore, the correct approach of nonadditivity of hazard quotients was used in this EcoRisk assessment and the last line in Table 9.5-1 should be deleted.

Does the analysis support the conclusions presented? How does the assessment support the risk manager in making and communicating risk-based decisions?

No, not entirely. Risk to wildlife was not evaluated, with the exception of pisciverous birds and mammals (discussed more fully in Comment #7). Also, as previously discussed, risk from contaminants for which there are no toxicity data were not addressed, although some qualitative statements could be made in this regard. Therefore, I believe that at this point the Risk Manager has incomplete information for making a decision about potential risk to the environment.

In regards to communicating this information to Stakeholders, I think the Risk Manager would have a difficult time based on the way the data have been presented. First, there needs to be a more detailed *ecological* description of the areas at risk – where they are located, what types of ecosystems are present (forests, wetlands, streams, and rivers), and what are the major species that are likely to be in the area. A better definition of the assessment endpoints would help the Risk Manager communicate the goals of the assessment, such as whether population-level protection is being estimated and whether threatened and endangered species are being given particular attention. A conceptual model diagram would help show how the pollutants would move from the source (the incinerator plume) to the environments of concern and then into the various food webs. Maps with isopleths of estimated soil or water concentrations also are helpful in communicating why certain areas were selected for a "worse case" analysis. The Risk Manager also would benefit from a brief discussion of the strengths and weaknesses of the ecological toxicity database (and the particular benchmark documents used). Finally, an overall Conclusion section that put the whole assessment back into an *ecological* context would be particularly helpful in communicating how this one small event fits into the larger ecological interactions, stresses, and patterns of this portion of Pennsylvania.

Is the material presented clearly and concisely? Is it consistent with documents cited as sources for the methodology?

The material is, if anything, too concise. As pointed out in my response to previous questions, there is a lot of material produced for the human health risk assessment that also would be useful and relevant for the EcoRisk. This could easily be incorporated by reference, minimizing the duplication of effort, such as was done for referencing how predicted soil and water concentrations were derived.

The documents suggested as sources for the methodology[1,6] were not included in the reference section for Chapter 9. It is likely that these documents were not consulted, as the screening level risk assessment presented here does not comply with the suggested approach of either of these two documents. Most notably missing was the Problem Formulation phase, where assessment endpoints are clearly elucidated, receptor species and ecosystems identified, and conceptual site models formulated. It may be that this information was presented in previous documents associated with the risk assessment of the Drake Chemical Site, but as the Incinerator assessment is meant to stand-alone, it would be worth repeating them here.

Describe any elements that are missing.

Several missing elements were identified in the responses to the above questions and a few others will be added here. First, the missing elements will be listed in a summary form, following the outline of phases of an ecological risk assessment. I will then elaborate on a few of the elements that were not discussed previously.

Problem Formulation

- Assessment endpoints
- Description of the ecology of the area
- Species lists
- Identification of threatened and endangered species
- Description of site soil types, including general background concentrations of metals
- General description of other contaminant sources in the area, particularly upstream of the deposition zone
- Conceptual site model

Analysis

- exposure

[6] USEPA. 199? Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments

- Discussion of why vegetation canopy effects were ignored when calculating soil concentrations (leads to an over-estimate of risk, so is an acceptable and conservative assumption)
- Discussion of why an estimate of deposition onto foliage was ignored (i.e., as a potential route of exposure for herbivorous wildlife).
- Discussion of why only top 1 cm of soil was used for estimation of soil concentrations
- Discussion of why leaching of contaminants through soil into groundwater with subsequent input to surface water was ignored as a potential exposure pathway
- Discussion of potential differences of bioaccumulation (particularly of mercury) in the cold water versus warm water aquatic systems and lentic versus lotic systems

Effects

- Data on effects of herbicides to plants
- Data on effects to terrestrial wildlife, both as direct effects and as a result of food chain bioaccumulation
- Data on effects to amphibians

Risk Characterization

Discussion of potential risk to threatened and endangered species

Discussion of lack of risk estimate for pollutants and species for which no toxicity data are available

Discussion of the ecological context within which the potential for risk from the incineration should be considered

Summary of how the uncertainties listed in Table 9.5-1 result in an over- or under-estimate of the total risk to the environment.

The major element missing from this risk assessment is potential risk to terrestrial wildlife. While I agree that the inhalation route need not be considered, terrestrial wildlife may still have both direct and indirect exposure to the incinerator pollutants. Exposure routes include ingestion of material deposited on foliage (likely a minimal amount and probably could be dealt with in a qualitative manner) and ingestion of soil. Most animals ingest about 2-5% of their diet as soil, but some may ingest as high as 17%[7]. Note that some of the highest ingestion rates are for shorebirds foraging for invertebrates in stream or wetland sediments. Thus, the potential for exposure through direct ingestion of contaminated soil and water should be considered.

[7] Beyer, N., E.E. Connor, and S. Gerould. 1994. Estimates of soil ingestion by wildlife. Journal of Wildlife Management 58(2):375-382.

Bioaccumulation potential in both the aquatic and terrestrial systems is something that cannot be ignored. There are several persistent, bioaccumulative compounds on the list of incinerator pollutants, most notably DDT and its metabolites, dioxins/furans, endosulfan, endrin, PCBs, mercury, and selenium. The Oak Ridge database provided information about potential for bioaccumulation through the aquatic food chain and subsequent exposure to piscivores (but see qualifications discussed above), but similar benchmarks for the terrestrial food chain were not provided. However, a review of some of the summary literature about these compounds should provide reasonable data on bioaccumulation factors (BAFs) and tissue-based toxicity threshold values that could be used in a screening level assessment[8,9]. Note also that Volume II, Appendix 5C of the report presents plant uptake factors for vegetables, forage, and grains and Volume II, Appendix 5D presents a similar exercise for cattle. The appendices then calculate the predicted concentration in these plants and animals. These concentration data can be used to compare with toxicity threshold values for herbivores, granivores, and carnivores. Only invertebrate uptake and tissue concentration information is lacking and would need to be generated specifically for the EcoRisk assessment. Similarly, Volume II, Appendix 5F estimates fish tissue concentrations; these data also should be examined when determining potential effects to piscivorous wildlife, and may give better site-specific information than the use of the generic Oak Ridge benchmarks or the Great Lakes specific GLWCQ. Note: Wildlife toxicity benchmarks also are available from the Oak Ridge internet database. However, I have some problems with how several of these values were derived; I believe some of the values are overestimates, while others are underestimates of effect thresholds. Moreover, many of them build in uncertainty factors that must explicitly be called out. This would need to be addressed in the Uncertainty section if these data are used.

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[8] Beyer, W.N., G.H. Heinz, and A.W. Redmon-Norwood (eds.). 1996. Environmental contaminants in wildife: interpreting tissue concentrations. Lewis Publishers, Boca Raton, FL. 494pp.

[9] Fairbrother, A., L.N. Locke, and G.L. Hoff. 1996. Noninfectious diseases of wildlife, 2nd edition. Iowa State University Press, Ames, IA. 219pp.

Herpetofauna (reptiles and amphibians) were ignored completely in the report. There essentially are no toxicity data for reptiles, so the Uncertainty section should identify this as a data gap. For amphibians, some data are available, primarily for the aquatic portion of the lifecycle[10]. This information should be retrieved and compared to predicted water concentrations for a screening level assessment of some of the chemicals. For those chemicals for which there are no data, the Uncertainty section should identify this as a data gap.

Finally, the approach described here that was used to conduct a screening level EcoRisk assessment is very generic and is, essentially, a *toxicological* assessment not an *ecological* assessment. It could, essentially, be applied anywhere in the world, merely substituting an appropriate soil value into the table and comparing it to the same benchmarks. It essentially assumes that the species at risk in a forest, pasture, or urban environment have equal or less sensitivities to the pollutants than those that were used in the toxicity tests, and that there are no peculiarities of their exposure routes that would differentiate their risk depending upon what environment they inhabit. Cold water systems are treated the same as warm water systems, which assumes that bass and trout behave in a similar manner both ecologically and toxicologically. Most importantly, this approach also assumes that bioaccumulation is similar in all food chains which, by extension, assumes that all food chains are the same. All of this is, of course, a gross oversimplification of extremely complex systems. Therefore, it is important that the Risk Manager feel comfortable with the level of conservatism in all the assumptions so that the conclusion of "no ecological risk" is acceptable even in the face of such great uncertainty. Without the addition of the elements identified here as missing from this assessment, I would feel very uncomfortable asking a Risk Manager to make such a decision.

[10] Devillers, J. and J.M. Exbrayat (eds.). 1992. Ecotoxicity of chemicals to amphibians, Volume Gordon and Breach Science Publishers, Philadelphia. 351pp.

Thomas Gasiewicz

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Dr. Tom Gasiewicz
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General Comments:

1. The document is, in general, well organized. Items in Volume 1 and in the Appendices were appropriately labeled and well referenced.

2. The executive summary lacks two important aspects which could mislead an uninformed reader. It is not clearly stated that additive or incremental risks from exposure to the chemicals from this incinerator on an existing background of exposure are not considered. Indeed, an important assumption of this process is that individuals in this population do not have any other exposures such that additional exposures from the incineratior would impart a significant health risk. It should be clearly stated that no examination for other exposures in this population has been performed and that it is assumed the exposures of this population is similar to the average population in the U.S.. Also, it is implied that risks to all the chemicals are added to obtain a total risk. This is not true since the dioxins and lead are treated differently and never really added to this total risk for the non-cancer endpoints.

3. The treatment of the dioxins and lead apart from the total risk process is troublesome. It not clear how this may affect the decision making process. In reality, it seems that if the reference dose (RfD) method were chosen, the exposures for the dioxins might be above this value. So what does this mean for this and the other compounds? It is not exactly clear why the particular methodology for the dioxins was chosen. If the exposure is above the RfD value and an alternative method of evaluation is chosen to make the appearance of the exposures less hazardous, then what

is really the purpose of this risk assessment process for this and the other chemicals. In some sense this invalidates the whole process. A consistent process should be used for all chemicals unless there is a well-justified reason. One has not been presented.

4. To improve the quality of risk assessments of this type in the future the following recommendations are made: 1) Some evaluation of the population considered should be made to determine whether excess exposures to other chemicals from other sources might be occurring. 2) Present existing site-specific data for the presence of these contaminants in the media to be considered as sources of exposure, i.e. air, water, soil, fish, vegetables. Some of this data may already be available. 3) The risk evaluation of all chemicals should be consistent when possible. If not, a clear explanation should be made.

Executive Summary:

1. ES-1, line 8: It should be indicated that the operation will not pose a significant threat to public health. There may be a very sensitive subpopulation that the risk assessment does not consider, and/or a small percent of the population may elicit some toxic endpoint that cannot readily be assessed. Nevertheless, the assessment, as such, may not consider these to be "significant".

2. ES-1, line 18: The differences between "risk burn" and "trial burn" should be explained.

3. ES-3: It should be explained here that the dioxin-like compounds and lead are treated differently for non-cancer endpoints. Furthermore, these are never really incorporated into the total risk for non-cancer endpoints. The reasons for this should be clearly stated.

4. It should be clearly stated in the Executive Summary that this document only deals with the health risk from the chemicals produced by this facility and not with any possible additive risk that these chemicals might have on an already existing background of exposure in this population. Furthermore, it should be clearly stated that it is assumed that the particular population does not have any exposure to any other agents above that which might be considered for the average US population.

5. 1.2-3: As previously, the exact differences between the risk burns and the trial burns are not clear. It is previously indicated (ES-1) that data from the trial burns were used for this risk assessment. What was the data for the risk burns used for? How and why were they different? (Actually, this is explained on p. 1.3-2, but there is some confusion until this point. It might be better explained earlier that this risk assessment mainly deals with data from the risk burn, although these data are supplemented with those from the trial burns when appropriate.)

6. 1.3-5, Risk Characterization: As in #3 above, the different treatments for the dioxins and lead should be indicated and explained.

Exposure Assessment

1. 5.3-3, Chemical Exposure Concentration estimation: It would be useful to have some data for the analysis of any of the chemicals considered in the media, i.e. fish, water, soil, vegetables, to be considered as exposure sources. Some of this data probably already exists for the particular area. It would be useful to present and cite this data. This would also assist in a determination as to whether the population might already be exposed to very high levels of any contaminants from other sources.

2. 5.4-2, Residential Use: Is there a basis for the numbers used, e.g. child assumed to live in the residential area for 6 years up to the age of 6? If there is, it should be cited.

3. 5.5-9, Chemical-specific factors: Are there other metals, e.g. arsenic, for which speciation should be considered? If not, a statement to indicate this should be made.

4. 5.5.6.7 Mother's Milk: Appendix 5E (Table 5E6) does not contain values for the organic metals, e.g. methyl mercury. If this is not considered, an explanation should be made.

5. 5.6.1.1., 5.6.1.2. It is assumed here that the critical dosimetric is the daily dose or lifetime daily intake. There are several recent publications suggesting that an alternative dosimetric, e.g. body burden, or cumulative body burden, may be more relevant especially for cancer endpoints. There should be some justification of the dosimetric used and the reasons why alternative dosimetrics were not considered.

6. Overall the estimates of exposures are consistent with the concept of reasonable maximum exposure (RME). In most cases, calculations and assumptions for both the presence of a chemical in media and the human exposure to this media are conservative resulting in likely an over-estimate of exposure.

7. It appears that, at least in terms of the Drake incinerator, the critical sources and pathways of exposure have been identified. In terms of the critical exposed populations, those exposure scenarios representative of the most of the indivituals living in the area are certainly considered. Although greater sensitivity due to potential exposure is considered, greater sensitivity due to other predisposing conditions of individuals such as genetics, illness, occupational exposures to other sources of these chemicals, are not considered. These are largely unknowns and thus difficult to factor in. Nevertheless, a statement indicating that these other factors were not considered should be made.

8. Several key assumptions for estimation of chemical concentrations and for estimation of exposures have been made. In most cases, it appears that these would result in an over-estimate of exposure. It would be useful to cite if for any particular chemical real data is available to back up the assumptions made. In several cases, however, there is a value given for the degree of over- or under-estimate, mostly over-estimate. These values appear to be reasonable in most cases.

9. In general, I found the conservative assumptions appropriately factored into the ultimate exposure estimates whenever possible. The uncertainties appear to be addressed appropriately.

Toxicity Assessment

1. 6.2.2 Derivation of Cancer Slope Factors: It is indicated that "..EPA usually derives slope factors by using a linearized multistage model..". It should be specifically indicated here or in the Appendix for which chemicals the linearized model was not used and for what reason. If in fact all the slope factors were derived using this model it should be stated that an assumption is that the risk of cancer is linearly related to dose and that this is likely to be an overestimate especially at lower doses. Some rationale should be presented for this (without going into excess detail). This is a conservative assumption that should be stated as such.

2. 6.2.2: See above discussion for consideration of dosimetrics.

3. The route-to-route extrapolation approach appears to be reasonable and well-qualified. This may be a conservative over-estimate approach for many chemicals. However, it is also appropriate that this extrapolation was not used for chromium VI and nickel.

4. The absorption factors used, i.e. 0.9 for chemicals administered by gavage, inhalation, etc., and 0.5 for chemicals administered in the diet, are reasonable as conservative estimates. It would be useful to cite examples, if any, where this may underestimate toxicity, i.e. where a chemical, e.g. iron, may be very poorly absorbed regardless of whether administered by gavage, inhalation or dietary exposure. On the other hand, if poorly absorbed by these routes it is likely to be poorly absorbed by the skin. Thus, the estimates are likely reasonable and the error is certainly much less than 5-fold. An additional inherent assumption is that the absorption from dermal exposure is 100%. This should be stated clearly.

5. 6.2-7: One should check whether the TEF values used here are the same as those accepted internationally. If not, sufficient justification should be provided. (e.g. Chemosphere 20: 751-7, 1990). If they are, it would be useful to make such a statement.

6. 6.2-7, lines 24-26: Stimulation of AHH activity is only one of the endpoints used to determine TEF values. Thus, the sentence should be qualified to read "..were determined, in part, from the ability...". Also, the next sentence should read "Binding to and activation of the intracellular..."

7. 6.2-8, line 2: Line should read "..biological changes that may eventually lead to cancer".

8. 6.3.4: It is not clear why a "modifying factor of 3" was used for manganese. This should briefly be indicated. In addition, the endpoint basis of the "critical dose" for manganese of 10 mg/day should be explained further.

9. 6.3-5: For fenac, in the absence of additional data, the RfD used here is likely very conservative but appropriate.

10. 6.3.6: It should be indicated that the method used for determining the potential noncancer health effects for lead does not allow this metal to be included into the total noncancer risk assessment. This should be clearly explained. What is the significance for interpreting the goodness of the risk assessment process as described in this document? It should also be discussed how this underestimates the total risk.

11. 6.3-8, line 15: Should be "Based in part on differences in receptor binding capacity...."

12. pp. 6.3-8 - 6.3-9: The rationale that is given why a RfD for the dioxins has not been developed is not a good one. Why should the RfD be treated differently than any of the other compounds. In effect, this indicates that the RfD values are really of limited use. If it is not appropriate to use the RfD for evaluating the dioxins, why should it be used to evaluate any of the other compounds here. The presented rationale seems somewhat contradictory to the process used in this document. This should be clearly explained. If this is a policy decision than it should be stated as one that is not based on science. Recommendation: Be honest and consistent with the approach. The RfD approach should be used here as well and the relative risk above that for the background exposures should be indicated. Actually, this will likely indicate that the relative risk from the incinerator is very, very small compared to the risk already present. Furthermore, as for lead, this indicated that the risk for the dioxins is not incorporated into the total risk for the incinerator. A reason for this has not been clearly presented. It is my opinion that this is a major flaw of this document and seriously compromises the risk assessment process used in this document.

13. 6.4-1, line 6: "...release of chemicals and particulates...?

14. This review felt that in the absence of complete data it was appropriate to use chronic RfD values to evaluate all oral exposure routes and for the inhalation of volatile organics through household water use. Again, this likely over-estimates the risk. It was also appropriate that the subchronic RfD was used to evaluate the inhalation of ambient air since the the facility would only be in operation for two years.

15. This reviewer felt that the discussion for the "endocrine disruptors" was appropriate. As indicated above, the non-cancer chronic toxicities for the dioxins and furans have not been adequately addressed. The approach used is inconsistent, and somewhat misleading, as compared to the approach used for the other chemicals.

16. The approaches used for the selection of inhalation toxicity values for acute exposures from process upsets seem appropriate.

17. Given the manner in which lead and dioxins are treated and additional assumption is that the exposure to these chemicals do not significantly add to the total risks. The validity of this assumption should be discussed. The other assumptions and uncertainties appear to have been appropriately addressed.

Risk Characterization

1. 7.2-2, General: Again, it should be pointed out here that total noncancer health risks evaluated from the summation of the hazard quotients for all chemicals does not include the dioxins and lead.

2. 7.2.2.2: Again, it is not clear to this reviewer why the use of the RfD is appropriate for other chemicals but not for the dioxins. This should be clearly and simply stated again here. The same comment applies to the lead section (7.2.2.3).

3. 7.2-4, line 9: "...release of chemicals and particulates..."?

4. 7.3-1, line 3: It is not clear here what the term "extrapolated" means.

5. 7.3: For clarification, it might be useful to briefly indicate how these burn conditions are different from or similar to the burn conditions used under normal operation. At least a cross-reference would be appropriate.

6. Given the assumptions and data on exposure assessment, the risk characterization appeared appropriate. The discussion of the assumptions, uncertainties, and sensitivity was appropriate. While numbers for hazard indices, lifetime carcinogenic risk , for example, were given for particular exposure subgroups, in most cases risk descriptors were lacking. It would be useful to have a table summarizing the risks for all subgroups used risk descriptors instead of numbers. This summary table would be most valuable.

Annette Guiseppi-Elie

A. Guiseppi-Elie

PEER REVIEW WORKSHOP ON THE DRAKE CHEMICAL SUPERFUND SITE INCINERATOR

PREMEETING COMMENTS

GENERAL ISSUES

Comment on the organization of the risk assessment document. Does the presentation follow a logical format? Is the presentation of information in the document clear, concise and easy to follow?

The risk assessment document (Volume I) is well-organized. The sections follow the typical risk assessment format: Introduction which includes the goals/objectives; exposure assessment preceded by the "determination" of relevant environmental concentration; toxicity assessment and risk characterization. In addition, the major uncertainties associated with each determination (e.g., air quality modeling, toxicity assessment) are identified and discussed (although only qualitatively) in the relevant section. Further, the major uncertainties in the overall assessment are summarized in a separate section which also serves to provide the results of additional evaluations (termed the Sensitivity Analysis) not covered in the main assessment.

For the most part, the presentation is clear, concise and easy to follow. However, opportunities for improvement include:

- Better contextual problem formulation is needed, i.e., in addition to the obvious goal of the risk assessment "to estimate potential human health and ecological risks from exposure to chemical emissions from the full-scale operation" of the incinerator, other specific issues that may be of concern should be referenced in the goals and objectives. These issues include, for example, the possible acute effects of catastrophic failure or those items identified in the sensitivity analysis (e.g., emission of dioxin at the contract limit) and generation of fugitive dust from normal operations.

- Graphical presentation of the results (e.g., bar charts, distributions) which show at a glance results relative to "acceptable levels".

- Graphical presentation of the "trial burn process" including a timeline, conditions, and the relationship between the four burns in January/February 1997 and the risk assessment of the trial burn process (June 1996). Although presented as part of the history, there was some confusion which required several readings of the document to clarify.

Does the executive summary clearly and accurately reflect the data and methodologies used and the conclusions reached in the risk assessment?

This section is perhaps the least well-written part of the document. The descriptions of the key steps in the risk assessment is far too general and could be have written for almost any assessment. Referencing of site-specific conditions is warranted, e.g., specific air model(s) used, the overall geographic area covered by the assessment, watershed/surface water bodies identified as "receptors", etc. These issues and informational items are intimately linked to the methodology but are not provided in the Executive Summary.

The main results are summarized in the form of a Table. This is acceptable but a more explicit discussion of the results is needed rather than the "for instance" discussion of results for the hypothetical adult resident. The section also fails to discuss the uncertainties identified in the assessment and the net effect of these uncertainties. This is a major omission. A visual representation of the results would also be helpful.

As with any risk assessment, there are always additional data and method development efforts that could be undertaken to reduce the level of uncertainty. However, are there any major data or methodological gaps that would preclude the use of this risk assessment for decision making? If so, how should they be addressed?

The assessment appears to have been performed using a conservative, i.e., health-protective bias: co-location of receptor in the maximum contamination zone; conservative accounting for loss processes; evaluation of high-end estimate of exposure. Thus, although there are numerous uncertainties identified, I do not believe that there are major data or methodological gaps that would preclude use of the assessment.

I would suggest, however, that a "true" sensitivity analysis be performed to identify key parameters. The current sensitivity analysis provides evaluation of apparently other issues of concern not addressed in the main assessment. For those key parameters identified, a quantitative uncertainty analysis could provide a better context for decision-making. The use of distributional analysis is one mechanism that would be useful to address the contribution of uncertainty (and variability) in this analysis.

Finally, some "field" validation (for example, using a simple survey instrument) should be considered for ensuring that national exposure data (e.g., beef, milk, fish consumption) used are appropriate for local conditions.

What long-term research would you recommend that could improve risk assessments of this type in the future?

- Development of distributions of exposure data to facilitate the use of probabilistic evaluations
- Development of simple field survey instruments to determine the relevance of national vs regional vs local data in exposure assessments

- Research in the area of bioconcentration factors including for plants, beef, milk, fish
- Simple test to evaluate site-specific relevant bioavailability
- Consensus toxicity data

HUMAN HEALTH RISKS

Exposure

EPA's documents covering Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities, Guidance for Performing Screening Levels Risk Analyses at Combustion Facilities Burning Hazardous Wastes, and Risk assessment Guidance for Superfund identify certain approaches that should be used to characterize exposure estimates at combustion facilities. For example, the reasonable maximum exposure (RME) is defined as "the highest exposure that is reasonably expected to occur at a site." Comment on whether the Drake exposure assessment develops exposure estimates that are consistent with the intent of these guidance documents.

The document does appear to follow the intent of these guidance documents in that it produces an assessment that errs on the side of being conservative (health protective). In addition, the now standard EPA approach of using some high-end and some average exposure factors to develop reasonable high-end exposure was used. These assessments have typically been found to be within the bounds of realism but the exact level of protection achieved is not quantifiable. The use of distributional analysis (using key exposure factors) to support the point estimate would clearly be beneficial in explaining these results.

The concern with this assessment is that several other conservative constraints (e.g., co-location of receptors in at the maximum potential contamination where this is not realistically feasible; not accounting for mass balance, not accounting for degradation processes) may lead to

unrealistic results. However, since even under these conservative conditions "acceptable risk" levels are not exceeded, the assessment can be viewed as performing a screening role to determine that there is no problem.

Fewer considerations (e.g., compounds without toxicity data were not evaluated) may potentially produce a result that is not as conservative as it could be. The analysis supports the premise that the effect of these are outweighed by the general conservative nature of the assessment.

Important factors in an exposure assessment include the identification of all the critical exposure sources and exposed populations. Please comment on the adequacy of the Drake assessment in identifying the critical sources and pathways of exposure as well as the critical exposed populations.

The conceptual model developed appears to be a consistent representation of local conditions (Figure 1.3-2). The major apparent source omission, i.e., fugitive dust generation, was subsequently addressed in the later report. Additional exposed populations could include children at the playground and schools NNW of the facility and potential trespassers at the facility. However, both of these populations are probably well accounted for through both child and adult resident exposures (24 hours/day; 350 days a year for the appropriate exposure duration).

The rationale for the use of the Keller Reservoir (for potable water) over the Castanea and the Bald Eagle Creek (for fish consumption) over McElhattan Creek appear to be reasonable. However, since there appears to be some concern (particularly for maintaining the availability of the Castanea Reservoir), I would suggest that simple screening level analyses be performed with these media. These analyses would be similarly conservative to the rest of the analysis and could potentially provide further support that the appropriate media were taken into account.

Have the key assumptions for estimation of chemical concentrations and for estimation of exposures been identified? Are the magnitude and direction of effect correct for the assumptions that have been identified?

It would appear that most of the key assumptions have been identified. The major concern is the lack of validation of national intake rates for such items as beef, milk, vegetables and fish relative with local conditions. The general direction of the effects also appears to be appropriate. The term "magnitude of effect" may better be described as small, medium and large. In general, I agree that the assumptions that were identified as being potentially underestimating the risk, typically would be expected to have a small effect. Potential exceptions would be for those chemicals which lack data (either toxicity or physical/chemical/biological parameters). All chemicals detected (or tentatively identified, TIC) were potentially evaluated. If any chemical without data exits in the feed in significant concentrations, an effort should be made to "develop" data. I do not believe in that such a case exists (even including the beta-naphthylamine). The fact that a TIC (2-butenal) is primarily responsible for the inhalation risk for the resident, suggest that this is a gap that should be further evaluated.

The effect of omitting mass balance considerations (all material accounted for in air and also available for deposition on soil, plants and surface water bodies) and neglecting volatilization and degradative could have potentially large effects on overestimating risks. I, therefore, disagree with the categorization of these effects as low.

Supposedly, conservative assumptions have been applied in the Drake assessment to account for uncertainty and to avoid underestimating the exposure to any single individual. Are the conservative assumptions appropriately factored into the ultimate exposure estimates? Please comment on whether the uncertainties were addressed and analyzed in an adequate manner. If they were not, please state what should be done differently.

As discussed previously, the net effect of those factors that are either unknown or potentially under-estimate the risk are outweighed by the generally conservative assumptions and methods used. As a result, the overall assessment appears to err on the side of over-estimating rather than under-estimating risks.

Uncertainties are identified and addressed in a qualitative manner. This is acceptable for many of the assumptions/approaches used. However, for the magnitude of this assessment a more quantative treatment of the uncertainties associated with key assumptions and approaches should have been explored. For example, since local data was not available for the intake rate for certain controlling pathways (e.g., comsumption of diary milk and beef consumption) for the resident, then use of the full distributions is appropriate. The use of probabilistic analysis should have been used for all key pathways. These analyses are better are to account for both variability in the potentially exposed populations and uncertainty in the estimate. A comparison of the single point estimate on the distribution would also provide confidence in these estimates.

Holly Hattemer-Frey

REVIEW OF THE DRAKE CHEMICAL SITE
HUMAN HEALTH RISK ASSESSMENT

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General Comments

1. The organization of the document is clear and logical. Presentation of the information is clear and concise, although a bit wordy in places. Acknowledge that I may find it wordy, because I am very familiar with the topic.

2. Agree that the Executive Summary clearly and accurately reflects the data and methodologies used and the conclusions reached in the assessment.

3. Based on the Sections that I reviewed, there are no major data gaps that would preclude the used of this assessment for decision making purposes.

4. Risk assessments of this type could be improved by obtaining measured (versus empirically estimated) bioconcentration (BCFs) and biotransfer factors (BTFs) (e.g., soil-to-plant BCFs, air-to-leaf BTFs, intake to beef and cow milk BTFs). Measured values for these parameters would substantially improve food chain modeling, which accounts for a large percentage of human health risks. Measured dermal absorption factors (ABS values) and dermal permeability constants (K_p values) would contribute to more accurate modeling of dermal exposures.

5. The Drake risk assessment relies primarily on EPA April and December 1994 guidance. The State of North Carolina came out with additional guidance in January 1997. This 1997 guidance should be considered in preparation of the final risk assessment.

SECTION 5

Agree that the use of maximum soil concentration data to estimate noncancer exposures is conservative. Defining the concentration term for estimating carcinogenic exposures as the concentration averaged over the exposure duration is appropriate, conservative, and consistent with current guidance.

Use of a 1 cm mixing depth for evaluating exposures to surface soils is consistent with current guidance.

p. 5.1-1, line 6: The statement that a conservative estimate over estimates true risks is strongly worded. Recommend changing the text to state that a conservative estimates tends to over estimate risks.

p. 5.3-1, lines 21-23: Residents, subsistence farmers, and mother's were not assumed to be exposed via fish consumption. Please clarify the basis of this assumption (e.g., was it because residential and farm areas are not located near potentially-affected surface water bodies?). It seems possible that residents and farmers could consume fish taken from nearby surface water bodies.

p. 5.3-2, lines 3-10: If dairy cows are present in the area surrounding the facility, why don't child and adult residential receptors ingest milk taken from cows raised in affected areas? Admittedly, this might be a minor exposure pathway, although it seems possible that residents could purchase beef and dairy products from local subsistence farmers. If a pathway is possible but minor it should be acknowledged but may not need to be quantified. It also seems possible that a subsistence farmer might raise chickens and consume chicken and eggs.

Section 5.4.1: Agree that the three residential receptors identified (infant 0-1 yr, child 1-6 yrs, and a 30-yr adult) are relevant. However, the exposure scenarios lack an integrated receptor (i.e., an individual that spends 30 years on site, six as a child and 24 as an adult).

p 5.5-3, lines 7-9: Agree that assuming all organics and metals exist in the vapor phase to calculate inhalation doses is very conservative and likely to overestimate inhalation exposures. Conversely, inhalation typically is not a major pathway of exposure.

My copy is missing pages 5.4-6 through 5.5-4. Please provide these pages, and I will review them for the January meeting.

p. 5.5-10, lines 5-8: Please clarify what ratio of hexavalent to trivalent chromium was used in the risk assessment.

p. 5.6-3, lines 13-14: Agree that it is reasonable to assume that individuals would only be exposed via direct inhalation while the facility is operating. If is possible, however that individuals could inhale particluates resuspended from the soil surface and vapors that volatilized from soil for a period beyond the two years of facility operation. These additional pathways may not need to be quantified but should be acknowledged.

p. 5.6-7, lines 19-21: Child ingestion rates were estimated by scaling from adult body weights and ingestion rates. EPA's (1990) *Methodology for Assessing Health Risks from Indirect Exposure to Combustor Emissions* list 50th and 95th percentile child ingestion rates for seven plant groups. How similar are the rates obtained from scaling to those reported in EPA (1990).

Table 5.6-6: The assumption that 50% of the beef consumed by the average rural household is consumed by hypothetical future resident seems reasonable and conservative. Assuming that 100% of the beef and milk consumed by subsistence farmers originates from an area affected by site emissions is extremely conservative.

Table 5.6-13: Assuming that children and adult fishermen consume only fish taken from surface water bodies affected by facility emissions is very conservative.

p. 5.8-2, lines 1-4: Agree with the conclusions noted concerning the uncertainty associated with the exposure assessment (that overall exposures and risks are likely to be overestimated).

Table 5.8-1: The effect of uncertainty associated with estimating soil loss via runoff, leaching, and erosion was "unknown." Recommend including some explanation, such as the variability of loss coefficients (i.e., whether available coefficients under- or overestimate loss).

Table 5.8-1: Recommend expanding the comment on uncertainty associated with estimating infant exposures through mother's milk Since the chemical-specific data need to quantify infant exposures via this pathway are not known for many organics, exposures for many organics and metals could not be quantified. This lack of data is likely to underestimate infant exposures.

Recommend discussing the uncertainty associated with quantifying dermal exposures due to the high variability and uncertainty associated with ABS and K_p values.

APPENDIX 5A

Frequently throughout Appendix 5A, the text refers the reader to another Appendix (see for example, p. 5A-2, line 15) for additional information needed to understand a topic raised in Appendix 5A. This approach is very cumbersome for the reader. Recommend more user-friendly organization of Appendix 5A. All information, equations, etc. needed to understand the topic raised in a given Appendix should be included in that Appendix. Recommend moving (or at least copying) the text on determination of Fv, vapor phase fraction, from Appendix H to Appendix 5A. It would be helpful to include the equation used to calculate Fv in the discussion of determining dry and wet deposition rates.

p. 5A-5, lines 3-4: The text states that total deposition rates were used for surface water modeling. Please clarify what rates were used for deposition onto soil and plants.

APPENDIX 5B

Table 5B-3: A discussion of how the d_e value for the resident/farmer (200 m) was derived would be helpful. It is interesting that the same value was used for both the resident and the farmer. For example, the resident's value is typically based on an average-sized yard, which may not be relevant for the farmer.

APPENDIX 5C

p. 5C-1, line 22: The text should acknowledge that it is possible that below-ground crops could accumulate organics via air-to-leaf transfer, since their leaves are often above-ground. Agree that not quantifying air-to-leaf transfer for root vegetables is acceptable, but the fact that plant concentrations may be slightly underestimated is possible should be noted. The dilemma is that scientists are not sure if air-to-leaf transfer is a surface phenomenon only, or if accumulated organics are transferred to other plant parts. If it is a surface phenomenon only, the extent of contamination to root and protected crops would be minimal. The same comment applies to grains consumed by cattle.

p. 5C-2, lines 1-9: Disagree with the phrasing used to describe the accumulation of organics in above-ground vegetation. As written, the text implies that air-to-leaf transfer will occur only during the two years that the facility is in operation. As long as surface or near-surface soils are contaminated with organics (or mercury), these chemicals could volatilize from the soil and be taken up by aerial plant parts. It is true that the maximum soil concentration, and therefore maximum root uptake and air-to-leaf transfer, will occur after the 2 years of operation, but both processes could continue after operations cease.

p. 5C-2, lines 19-20: Measured (versus estimated) plant uptake factors (PUFs) are available for some organics (e.g., benzene, BaP, TCDD). Measured values should be used where available. PUFs should be estimated only in cases where measured values are absent.

Section 5C.2: A minor point but please clarify if PUFs used to calculate plant concentrations via root uptake for above-ground plants are dry or wet weight.

Section 5C.3 and 5C.4: Plant contamination due to deposition and air-to-leaf transfer may be underestimated since the former did not account for resuspension of particluates from the surface soil to plants and the latter did not reflect the continued volatilization of organics from the soil surface after facility operations cease. Chemical concentrations in above-ground crops could continue to increase for years after plant operations stop due to these two pathways. Please clarify why these two pathways were not quantified.

Table 5C-1: Disagree with the equation used to calculate the average concentration in plants for three reasons. It is correct to use the maximum 2-yr soil concentration to evaluate noncancer effects and the average soil concentration to evaluate carcinogenic effects. It is inappropriate, however, to further reduce plant concentrations by 2/ED. While it is true that deposition will only occur for two years, plant concentrations due to deposition can only be correctly reduced by weathering. Secondly, dividing the total plant concentration by 2/ED is reducing plant concentrations from all three pathways (root uptake, air-to-leaf, and deposition). Thirdly, as noted above, air-to-leaf transfer and deposition can continue after facility operations halt (via resuspension of contaminated surface particulates and continued volatilization of organics in surface soils).

Table 5C-2: For accuracy sake, it should be noted that CS in on a dry weight basis.

Table 5C-4: Agree that the guidance recommends using a correction (reduction) factor, what it defined as VG_{bg}. Recommend that the text acknowledge that the reduction factor used (0.01) was developed for dioxin-like or very lipophilic compounds, which are likely to sorb to outer plant parts, rather than being taken up and translocated throughout the entire edible plant portion. Application of this reduction factor to non-lipophilic organics (e.g., benzene) may underestimate the concentration of organics in below-ground crops.

Table 5C-8: The Jan. 1997 guidance recommends a VG_{ag} value of 0.1 for organics and 1.0 for metals.

APPENDIX 5D

p. 5D-1, lines 10-11: For consistency, the text should note that cattle could be exposed to facility-related contaminants via inhalation and ingestion of surface water from the Keller Reservoir. If these pathways are expected to be minor relative to forage, silage, grain, and soil ingestion, they do not have to be quantified.

APPENDIX 5E

p. 5E-1, lines 11-15: It is true that an infant's dose after one year would be lower than its mother's after two years if their exposures began at the same time. It is possible that the infant could be exposed after the mother had received a 2-year dose (or a 10-year dose for that matter). In that case, infant exposures would not be over-estimated.

Include information on how many of the organic COPCs could be quantitatively evaluated (and how many couldn't due to a lack of necessary chemical-specific information).

SECTION 8

p. 8.2-1, lines 13-16: Given the uncertainties associated with current air models (i.e., questions about the ability of these models to accurately predict the true distribution and deposition of contaminants released from the incinerator), stating that risks are "significantly overestimated" seems strong. Recommend rephrasing to "likely to be substantially overestimated" or something similar.

Jerry Havens

Jerry Havens

Premeeting Comments on: **Drake Chemical Site**
Incinerator Full-Scale Operation
Integrated Risk Assessment
Draft Volume I - Risk Assessment Report
Weston Consultants, November 1997

Introduction

This provides my comments on first reading of Draft Volume I of the Risk Assessment Report. My comments are intended to provide a basis for discussion at the Workshop scheduled January 15-16, 1998, in Williamsport, PA. As such, they should be considered preliminary.

I read all of Volume 1, but I focused on Paragraph 3 "Air Quality Modeling". In preparing these comments I did not evaluate any of the other volumes which were provided. Since it is impractical to make an absolute judgment of the accuracy of the models or of the results of their application to this task, my comments assume that there are no technical errors in the presentation (particularly the air modeling calculations). My intent, therefore, was to skip over the voluminous details of the exercise and to state my preliminary judgment of the propriety of the risk assessment. I am informed regarding the technical issues involved in the destruction-by-incineration of the numerous hazardous chemicals at the Drake Site, and I concur that it is an appropriate method for "final" resolution of the problems at this site.

General Issues

The charge to reviewers requested address of several general issues:

1. Organization - I have no problem with the organization.

2. Executive Summary - The executive summary is too brief. I was struck with the statement in the Introduction (to the E.S.) that "Based on the risk analysis in this report, it is concluded that the full-scale operation will not pose a threat to public health". I believe the voluminous detail presented indicates the propriety of the proposed resolution of this chemical waste problem, and (taking into consideration my limited knowledge of the specific facts regarding this site) the risks appear to be entirely acceptable (at least to me). However, it cannot be concluded that there is no risk to public health. This section needs work, especially since it is

the only thing that will be read by the policymakers.

3. Data or Methodological Gaps - Regarding the Air Modeling Section specifically, I believe attention should be paid to the scarcity of data which provide confidence in the accuracy of the dispersion modeling results (which, in my opinion, tend to be (overly) accepted as fact by most readers). More about this in my specific comments on Dispersion and Deposition Modeling.

4. Long Term Research Needs - It occurs to me that there may not come a better chance to evaluate many of the predictions which have been made for this risk assessment. More about this in my specific comments on Dispersion and Deposition Modeling.

Dispersion and Deposition Modeling

The charge to reviewers requested specific address of four issues:

1. Representativeness of the off-site data sets - The use of the Williamsport meteorological data is probably not too bad, given the overall measures of risk which result. I would not expect the uncertainty associated with the application of the "surrogate" data to raise the risk measures to a level of significantly greater concern. There is a lesson here though ... despite the good intentions of those involved, the met data program effectively *did not work*, and it is sobering to consider that the met data program would be expected to be more easily accomplished (successfully) than the (target, as designed) two-year-long incineration program will be. This suggests consideration of a strong QA program for the incineration program.

2. CALMET/CALPUFF models - While I am generally familiar with the modeling approaches used in CALMET/CALPUFF, I am not privy to any evaluation(s) of the model which could be used to assign confidence in the model's accuracy or applicability to the present case. I agree that a model which caters for the effects of terrain-wind-guidance as well as consideration of low-wind-speed cases is indicated, and I am not aware of an obviously better choice. Nevertheless, it should be clearly understood that there is no way I (or anyone else, in my opinion) can make any absolute judgment of the model's propriety for this application without data which can be used for validation.

3. Key Assumptions - Based again on this preliminary consideration, the key assumptions (made in the model) for estimation of chemical concentrations as well as for estimation of

exposures appear to have been adequately identified. Association of magnitude and direction-of-effect of the key assumptions also appears to have been treated reasonably. Of course, the correctness of those assumptions (which I have no specific reason to question) cannot be verified without data which can be used for validation.

4. Conservative Assumptions - My first reaction is that it appears that the conservatism incorporated in the modeling process(es) generally can be expected to overestimate the risk enough to make up for (unknown and known) factors whose lack of consideration might tend to result in underestimation. I will try to consider this question more thoroughly during the review process.

Closure

My overall response to this first reading of Volume I can be summarized as follows:

1. The low risk measures associated with the dispersion model(s) predictions are, in my judgment, clearly the result of the small (assumed) emission rates from the incinerator. In fact, I believe that the end health risks will be determined by the successful operation of the incinerator without exceeding those design rates. It is unlikely that the uncertainty in inputs to the models other than the emission rates will control the risks of this operation. I believe this is true for the steady-state operation, upset-condition operation, as well as for fugitive emissions. The key to ensuring that the risk is not significantly greater than predicted here is operate the incinerator (and associated equipment) subject to a QA program which ensures its operation as assumed in this risk assessment.

2. I observed that comparisons between ISC and CALMET/CALPUFF model runs for the trial burns were in remarkable agreement (better than a factor of two for the predicted concentration). This suggests, as I would expect, that the two models have basically the same air entrainment sub-models (which are based on generally accepted data sets). Consequently, they are likely to differ mainly in the (secondary) bells and whistles which different model developers choose to use. The important point is that this agreement signifies, in and of itself, very little regarding the accuracy of either model. I believe it would be a great service to those who are asked to believe the conclusions of this risk assessment, which are almost wholly based on model

calculations, for EPA to consider a followup program in which key measurements are made to provide data sufficient to validate the applications of the models by comparison with field measurements made during the incineration program. I am not aware that this kind of excercise has been attempted before, but it is important to consider that very little effort (or money) has been expended to evaluate the model predictions upon which the public is being asked to place its confidence. This is not the place to get into details, but I will be interested to consider it further in the peer review process.

Halstead Harrison

Halstead Harrison

(This was converted from a direct e-mail message)

A Review of "Drake Chemical Site Incinerator Full-Scale Operation Integrated Risk Assessment"

Volume I, Risk Assessment Report
Volume II, Appendices 1-9.
Volume III, Air Quality Modeling Analysis
Volume IIIb, Fugitive Emissions

November, 1997, SATA Contract #68-55-3002

This review by:
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December 22, 1997

I. Introduction:

In a series of phases beginning in 1982, Region III of the US Environmental Protection Agency [EPA] is supervising removal of toxic wastes at a site formerly operated by the Drake Chemical Company at Lock Haven, Pennsylvania. Phase 3 of this operation involves incineration of approximately 200,000 cubic yards of contaminated soils and sludges by an on-site rotary kiln incinerator, with which trial burns were conducted in January and February of 1997. Based on data from these burns a draft Assessment document has been prepared to assess risks associated with the full-scale operation of this facility.

The present memo contributes pre-meeting comments to a risk-assessment forum convened by EPA to review this Assessment at a workshop scheduled for January 15-16, 1998. The reviewers are charged to focus sharply on science-based information related to scientific and technical issues, only, with concern for significant methodological errors or errors of omission. In this review I respond to questions in the outline of the charge to reviewers. I conclude with eclectic questions and general remarks.

II. Organization

1. The Assessment is well organized and its presentation logical. The document is clear, but not concise, nor should it be. Useful compression would be achieved by combining the largely repetitive data, tables, and discussion of emissions and model conclusions from the three separate risk burns.

2. The executive summary is clear, but incomplete. I expect that this section will be amplified at a later time, with greater emphasis on conclusions.

3. In my judgment, the Assessment is methodologically flawed by assumptions of "zero base", both with respect to air-quality data and modeling, and to estimates of health and ecological risks.

The incinerator does not exist alone, but is immersed among other local and regional sources that contribute to environmental degradation. Health effects from the incinerator are similarly superimposed on other health stresses affecting the community. It is a first principle of economic analyses that decisions are best made "at the margin", rather than from "base zero". Thus, we should be concerned with increments of air-quality degradation and health stress, above present levels, and should assess the risks of the combined levels, not of the facility alone, as does the present Assessment, from a zero base.

* It is, in my judgment, a serious deficiency of this Assessment that no baseline data are presented, no information is presented on the frequency and magnitude of present exceedances of air-quality standards, if any, and no estimates are made of the likelihood of additional exceedances attributable to increments from the Drake incinerator.

* Further, in my judgment, the Assessment is flawed by omission of any discussion of childhood asthma, likely the most detectable non-cancer risk hazard attributable to the incinerator.

I shall amplify upon these points in later sections of this review.

4. Baseline air-quality and health data should be gathered and presented. What are the climatologies .. not just of the winds but of observed air-pollution indices? Of cancers? Congestive heart disease? Asthma? How do these compare with state and national averages?

III. Emissions Characterization

1. The trial- and risk-burn protocols and measurements appear to be thorough and appropriate. The suite of catalogued emission constituents is impressive. As with all tests of complex machinery and processes, that are to be examined by external regulators, it is likely that these trials were carefully supervised, were selected for "best" times, were conducted by alert staff, and used newer and better maintained machinery than will be typical of later operations. Thus these emission data should best be regarded as lower limits, rather than as "typical", or "conservative".

2. The multi-step methodology of estimating emissions of normal, steady-state operations seems sensible to me.

3-6 The methodology for emission rates of undetected non-dioxin organics, non-detected dioxins and furans, unmeasured metals, and acid gases seems sensible to me. Other panelists will be more competent than I to comment on this.

7. The only process upset condition discussed in the Assessment results from overheated kiln operations that trigger a relief-valve that bypasses the scrubbing/filtering. Estimates of the frequency and durations of these bipasses are based on experience with similar kiln operations and are therefor reasonably confident.

A more serious but less frequent accident might occur when the relief valve fails to open, with damage to the kiln's refractory lining and shell rupture. The Assessment would be strengthened by an historical survey of kiln accidents.

8. Unlike commercial toxic-waste incineration facilities, which must adapt to widely varying, volatile, and potentially explosive feed stocks, the Drake site will operate on soil feed only, whose physical and chemical properties will be largely constant. This is an enormous advantage that should be mentioned in the Assessment.

The Assessment reasonably discusses fugitive emissions from dust lift and transport from the feed-stock soils. It does not mention volatilization of contaminants adsorbed on the soils. It would be revealing to know if the local community presently smells the disturbed soil in hot summer months. If so, the presumption would be strong that a significant additional fugitive emission source should be considered.

9. The key assumptions used in characterizing the nature and magnitude of emissions appear reasonable. They may not be "conservative", for reasons discussed above. Again, it would be interesting to know if there were community complaints of perceived smells during the test burns.

Uncertainties and variabilities associated with the emissions are not well discussed. Key assumptions are highlighted, but no attempt is made to access the effects of these assumptions as they propagate through multiple risk descriptors.

IV. Dispersion and Deposition Modeling

1. I sympathize with the deep frustration that must have accompanied the recognition of quality-assurance problems in the meteorological data. Given those problems, the use of Williamsport Met data for the summer months at Lock Haven [and Pittsburgh soundings for upper air] is not unreasonable, in the sense that one really has nothing much better to suggest, but still deeply unsatisfying.

2-4 The CALMET/CALPUFF and INPUFF models are appropriate for complex terrain, such as in the Susquehanna river valley at Lock Haven. It is not clear, however, whether their output is "conservative". The strength of these models is that they account for time-dependent wind fields and for the modifying influence of local terrain upon the wind speeds and directions. Accounting for these important physical processes should result in improved estimates of the spatial and temporal patterns of the concentration and deposition fields. These models are still experimental, however, and comparisons with observations are so far meager, and their scores are uncertain.

My experience with similar Lagrangian-puff dispersion models [NFSpuff and WPUFF] and with a mesoscale wind-field model [MM5] applied in the Pacific Northwest, suggests their high sensitivity to the parameterization of near-surface drag. CALMET/CALPUFF, INPUFF, and MM5 all do this through Monin- Obhukhov [M-O] similarity theory, applied to measured temperature lapse rates, near the surface. At low wind speeds and positive Richardson numbers, however, when the air-pollution potential is greatest, M-O theory becomes progressively less
applicable.

For these and other reasons, it is not clear that simulations from CALPUFF and INPUFF a[illegible] conservative. This can be shown by a very simple comparison:

An emission source of 1 gm/sec, uniformly dispersed by winds of 1 meter/sec into a downstream prism 2000 meters wide [about the width of the valley] by 100 meters high [about the height of a radiation inversion, and about twice the height of the stack plus plumerise], produces a steady-state mass concentration of 5000 nanograms/m^3. The highest at-the-surface concentrations reported by CALPUFF were about 700ng/m^3 [Table 3.6-3]. The order-of-magnitude difference between these two numbers results from all the complications of stack heights, plume rise, meteorological variations, and time-averaging, but the larger number is neither unphysical nor implausible during near-stagnant conditions when the valley is capped by radiation inversions [usually in the early-morning hours, often in winter].

So, how often do such conditions occur? The Assessment offers no good discussion of th[illegible]t the wind rose of figure 3.4-3 suggests "calms" [usually defined as wind speeds less than 1 m/s] as occuring 6.2% of the time, with an additional 22% of the wind-rose vectors showing 0-3 knots [or 0-1.5 m/s]. The higher concentrations of the preceding, seemingly trivial calculation would
therefor appear to be "not implausible" during 10-20% of the reported hours. The Assessment does not adequately discuss these conditions of severe stagnation.

In a related question, table 3.3-2 lists estimated NO_2 emissions as 1.89 grams/sec. With the steady-state prism model of the preceding paragraphs, this works out to about 5 ppb of NO_2, added to other NOx emissions from Lock Haven's vehicles and industry [which are not discussed in the Assessment].

Significant ozone synthesis occurs in hot summer afternoons with NOx levels exceeding about 20 ppb, in the presence of reactive hydrocarbons with mixing fractions exceeding about 50 ppbC [parts per billion, by volume, of carbon atoms, either from urban emissions or from terpenetic compounds emitted by rural vegetation]. The Assessment should discuss this.

IV. Human Health Risks

Exposure

Hazard Identification

Dose Response and Risk Characterization

These subjects are outside my principal training and competence.

I noted inconsistencies in modeled "lifetime" exposure durations, variously listed as 30, 6, and 3 years. Is it correct that the last of these times more nearly approximates the duration of the incinerator operation at Lock Haven?

I noted also that the Assessment neglects discussion of air-quality effects on childhood asthma, likely the most detectable health effect of air pollution. [See appended references.] In an Email response to my recent query, Prof. Koenig [University of Washington, Environmental Health Dept.] wrote:

"Some studies find at least 12% of children have asthma. In our studies we find that for a 10 microgram/m^3 increase of PM2.5 there is a 15% increase in emergency room [ER] visits for asthma among children of ages 1-17. In an earlier published study we found for a 30 microgram/m^3 increase a 12% increase in ER visits, for all ages."

Signals of this magnitude should be detectable at Lock Haven.

It is important, I judge, immediately to undertake a study to determine baseline asthma visits to hospital emergency rooms, private physicians, and school nurses at Lock Haven, to be correlated with air-quality indices, searched later for increments attributable to the incinerator, and still later for decrements when that facility closes. School nurses should be asked to assist in this study, and comparison should be made, if that is possible, between nearer and more distant elementary
schools, at which additional air-quality modeling efforts should be targeted. Such data will be of great value for other risk assessments.

V. Ecological Effects

I have no useful comments on this section.

VI. Eclectic guestions and general remarks.

1. What happens to the process water? Does it all go up the stack? If not, has the impact of this water been evaluated on the downstream waste flow?

2. What happens when the task is finished? Will there be pressure to re-license this incinerator for commercial toxic wastes?

3. Has bioremediation been assessed as a possible alternative or supplement to the incineration program?

4. What provision has been made to ameliorate erosion of the processed incinerator spoil? Is the spoil alkaline? If so, what is to be done to diminish subsequent leaching? What are plans for disposing kiln clinker? Will the site contours be restored? Replante

5. Will the on-site meteorological data-gathering program be continued during the process burns? [One hopes with improved QA.] Will modeling efforts continue?

6. With this decade-and-a-half, multimillion dollar project a greater fraction of effort should have been given to real measurements, as contrasted to model exercises. Modeling is useful when you wish do something sensible with order-of-magnitude estimates, right now, with poor data. As projects grow the inherent limitations of models become conspicuous and their results contentious. In my judgment the EPA has assumed continuing responsibilities to the Lock Haven community, and budgets should be established to account for this.

A Few References on Environmental Asthma

Pierson,W.E. Koenig, J.Q. Respiratory effects of air pollution on allergic disease. J.Allergy.Clin.Immunol. 1992 Oct. 90(4 Pt 1). P 557-66.

Allergic patients have an increased susceptibility to the adverse effects of both natural and man-made air pollutants. This goes for both indoor and outdoor air pollutants and manifests itself with biochemical, cellular, and pathophysiologic expressions of adverse health effects in allergic individuals. ...

Koenig,J.Q., Covert,D.S., Pierson,W.E., Hanley,Q.S., Rebolledo,V., Dumler,K., McKinney,S.E.
Oxidant and acid aerosol exposure in healthy subjects and subjects with asthma. Part I: Effects of oxidants, combined with sulfuric or nitric acid, on the pulmonary function of adolescents with asthma.

Halstead Harrison

Res.Rep.Health.Eff.Inst. 1994 Nov. (70). P.1-36.

Both peak flow decrements in children at summer camps and increased hospital admissions for asthma have been associated with summer "acid haze," which is composed of ozone and various acidic species. The objective of this study was to investigate the pulmonary effects of acid summer haze in a controlled laboratory setting. ...

Larson,T.V., Koenig,J.Q,. Wood smoke: emissions and noncancer respiratory effects. Annu.Rev.Public.Health. 1994. 15. P 133-56.

Animal toxicological studies show that wood smoke exposure can disrupt cellular membranes, depress macrophage activity, destroy ciliated and secretory respiratory epithelial cells, and cause aberrations in biochemical enzyme levels. With respect to the human epidemiological data, the literature summarized in Table 4 shows a coherence of the data from young child with 7/8 studies especially in children with asthma, reporting increased respiratory symptoms, lower respiratory infection, and decreased pulmonary function as a result of exposure to wood smoke. ...

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MEMORANDUM

December 19, 1997

To: William P. Wood, Ph.D.
Executive Director
Risk Assessment Forum
401 M Street SW (8601)
Washington, DC 20460

From: Francis W. Holm, Ph.D.

Subject: Drake Chemical Site Risk Assessment

The draft risk assessment report prepared for the US EPA/Region III entitled "Drake Chemical Site Incinerator Full-Scale Operation Integrated Risk Assessment," is by far the most comprehensive risk assessment I have encountered for a remedial action. For the purposes of this review, I am assuming that the Drake risk assessment is not a total quantitative risk assessment approaching the level of detail needed for examples like: (1) long-term operation of fixed-site hazardous waste incinerators or, (2) short-term operation of chemical demilitarization facilities. Based on this assumption, I believe the draft Drake Risk Assessment is an excellent tool for managing and improving conditions during the operational phases of this remedial work.

I do have 3 primary recommendations to offer to improve the quality of the final Risk Assessment Report. They are:

- Missing Section that Defines Process Upsets: The complete description of the process upset conditions which is supposed to be in Volume II, Appendix 3B (EPA, 1996) is not there (or even referenced in the TOC). This brings into question many of the assumptions regarding upset conditions and the triggered response to these conditions. Volume I of the Risk Assessment refers to this

missing section on page 2.3-2, line 11. This important information needs to be included. Also, the Executive Summary should include conclusions pertaining to process upset emission evaluations on page ES-2, lines 5-10.

- Fugitive Emissions Need to be Included in Volume I of the Integrated Risk Assessment: If this is an Integrated Risk Assessment, not just a chute-to-stack incinerator risk assessment, then the fugitive emissions need to be integrated into Volume I and conclusions characterized in the Executive Summary. I expected Volume I to be a stand alone report and it is not.

Some other issues need to be discussed at our meeting in Williamsport, PA on January 14-15, 1998. I have not prioritized these issues:

1. Oxygen Enriched Combustion: In Figure 1.2-3, which illustrates the incineration system, it appears that oxygen enriched combustion is being used in both the primary and secondary chambers. If this is true or not, it seems evident that a better description of the system is needed.
2. Use of Past Experience: Assuming oxygen enrichment is being used, is the use of information from Bog Creek and other incinerators a conservative approach?
3. Consistent Text: The 8 key assumptions for emission rate development on pages 2.2-3&4 are also recited in the Appendix 2D-3; however, they are not identical. Should they be?
4. Characterizing Risk Burn Tests as 2-Year Average Results: On page 2.2-5, line 17, it points out that the risk burn emissions do not represent worst case emissions, which I understand and agree. On the other hand, it also seems incorrect (based on similar logic) to conclude that the risk burn calculations do represent typical and/or average conditions over 2-years of full-scale operation. I believe that several conservative approximations made in the emissions calculations for this assessment place the results on the conservative side even if (a big if) an average burn sample was selected from the site for the risk burns.

5. Ground Level Emissions: On page 2.3-2, line 6, one reason the safety vent opens during process upsets is to minimize ground level emissions from positive kiln pressures venting through seals. Does past experience or Drake experience show any evidence of positive pressures in the kiln without opening the safety vent? If so, what about seal leakage normal operations ... are these types of emissions considered in the risk assessment as either incinerator emissions or fugitive emissions?

6. Constant Temperature and Dioxin Emissions During an Upset: Assumptions regarding upset emissions are listed on pages 2.3-4, 5, &6. Two of these assumptions are troubling:

- Isothermal TRV Discharge During Upsets: Although incinerators have relatively high thermal inertia, after the loss of flame (which apparently results in 100 fold increases in some PICs) in the primary and secondary, how can one assume that a process upset release from the thermal safety vent will remain isothermal at 1,800 F over the entire duration of the release (25 minutes or more)?

- Constant Dioxin/Furan Emissions During Upsets: If the release from the vent is 1,800 F, then I would tend to agree with the assumption on page 2.3-5, line 21, that dioxin and furan emission rates remain unchanged throughout the duration of a process upset. On the other hand, if the primary and secondary combustion chambers and the gases released through the safety vent cool by a substantial amount, a change in the level of dioxin/furan emissions would be expected.

Finally, based on the observations above I will try to answer the general and specific questions directed to the Workgroup and include the answers in Attachments 1 and 2. If you have any questions about these comments please contact me.

Attachment 1

General Issues to be Addressed by the Group

Comment on the organization of the risk assessment document:

Two significant changes should be made to improve the organization of the document; (1) the section on fugitive emissions needs to be integrated into Volume I since this is a "Integrated Risk Assessment," and (2) the Appendix needs to contain the missing section that defines process upsets (Volume II, Appendix 3B).

Does the executive summary clearly and accurately reflect the data and methodologies used and the conclusions reached in the risk assessment?

Two important conclusions are missing from the executive summary; a conclusion regarding fugitive emissions and a conclusion regarding process upset emissions.

Are there any major data or methodological gaps?

The transient cooling characteristics of evolving and reacting gases during a process upset deserve more attention; however, lacking the time for more in-depth calculations, I am not in a position to assess the sensitivity of this issue on the Drake risk assessment.

What long-term research would you recommend?

There may be a significant effect of transient cooling on evolving and reacting gases during a process upset. Analytical and/or experimental data would be useful for estimating upset emission risk.

Attachment 2

Specific Issues to be Addressed by the Combustion Workgroup

Please comment on the trial burn and risk burn operating conditions.

The test conditions were appropriate for both the trial burn and the risk burn and were well beyond any work I have seen done for a remedial cleanup.

Please comment on the multi-step methodology to derive emission rates.

For steady state operation, I am satisfied that the procedures used in the Drake risk assessment do not underestimate the potential emission of products of incomplete combustion, and acid gas and criteria pollutants ... it is a conservative approach.

Comment on the approach used to estimate stack emission rates of nondioxin organics that were not detected in the risk burns.

Aside from the obvious requirement to obtain a representative contaminated soil sample, I am satisfied that the procedures used in the Drake risk assessment do not underestimate the potential emission rates for Principal Organic Hazardous Constituents (POHCs) and Products of Incomplete Combustion (PICs). The approach is a conservative approach if the contaminated soil sample is representative of the site.

Please comment on the approach used to determine dioxin and furan emission rates.

For steady state operation, I am satisfied that the procedures used in the Drake risk assessment do not underestimate the potential emission of dioxins and furans ... it is a conservative approach.

Please comment on the appropriateness of the resulting emission rates for metals.

Aside from the obvious requirement to obtain a representative contaminated soil sample, I am satisfied that the procedures used in the Drake risk assessment do not underestimate the potential emission rates for metals. The approach is a conservative approach if the contaminated soil sample is representative of the site.

Please comment on the appropriateness of the resulting emission rates for acid gas and criteria pollutants.

Aside from the obvious requirement to obtain a representative contaminated soil sample, I am satisfied that the procedures used in the Drake risk assessment do not underestimate the potential emission rates for acid gas and criteria pollutants. The approach is a conservative approach if the contaminated soil sample is representative of the site.

Comment on the potential process upset conditions that were identified.

Missing Section that Defines Process Upsets: The complete description of the process upset conditions which is supposed to be in Volume II, Appendix 3B (EPA, 1996) is not there (or even referenced in the TOC). This brings into question many of the assumptions regarding upset conditions and the triggered response to these conditions. Volume I of the Risk Assessment refers to this missing section on page 2.3-2, line 11. This important information needs to be included. Also, the Executive Summary should include conclusions pertaining to process upset emission evaluations on page ES-2, lines 5-10.

Constant Temperature and Dioxin Emissions During an Upset: Assumptions regarding upset emissions are listed on pages 2.3-4, 5, &6. Two of these assumptions are troubling and may not lead to a conservative approach:

- Isothermal TRV Discharge During Upsets: Although incinerators have relatively high thermal inertia, after the loss of flame (which apparently results in 100 fold increases in some PICs) in the primary and secondary, how can one assume that a process upset release from the thermal safety vent will remain isothermal at 1,800 F over the entire duration of the release (25 minutes or more)?

- Constant Dioxin/Furan Emissions During Upsets: If the release from the vent is 1,800 F, then I would tend to agree with the assumption on page 2.3-5, line 21,

that dioxin and furan emission rates remain unchanged throughout the duration of a process upset. On the other hand, if the primary and secondary combustion chambers and the gases released through the safety vent cool by a substantial amount, a change in the level of dioxin/furan emissions would be expected.

Comment on the fugitive emissions estimates.

For steady state operation, I am satisfied that the procedures used in the Drake risk assessment do not underestimate the potential fugitive emissions with one possible exception. On page 2.3-2, line 6, one reason the safety vent opens during process upsets is to minimize ground level emissions from positive kiln pressures venting through seals. Does past experience show any evidence of positive pressures in the kiln without opening the safety vent? If so, what about seal leakage normal operations ... are these types of emissions considered in the risk assessment as either incinerator emissions or fugitive emissions?

Are the key assumptions in identifying emissions thorough?

Key assumptions are listed on pages 2.3-4, 5, &6. Two of these assumptions regarding upset emissions are troubling:

- Isothermal TRV Discharge During Upsets: Although incinerators have relatively high thermal inertia, after the loss of flame (which apparently results in 100 fold increases in some PICs) in the primary and secondary, how can one assume that a process upset release from the thermal safety vent will remain isothermal at 1,800 F over the entire duration of the release (25 minutes or more)?

- Constant Dioxin/Furan Emissions During Upsets: If the release from the vent is 1,800 F, then I would tend to agree with the assumption on page 2.3-5, line 21, that dioxin and furan emission rates remain unchanged throughout the duration of a process upset. On the other hand, if the

primary and secondary combustion chambers and the gases released through the safety vent cool by a substantial amount, a change in the level of dioxin/furan emissions would be expected.

Consistent Text: The 8 key assumptions for emission rate development on pages 2.2-3&4 are also recited in the Appendix 2D-3; however, they are not identical. Should they be?

JoAnn Slama Lighty

Drake Chemical Superfund Site Full Burn Risk Assessment
Comments from J. S. Lighty
Workgroup, Combustion Engineering

General Issues

1. While the organization of the document appeared adequate, I found myself wanting more information and constantly needing to go to the Appendix for it. I think the information could be more explicit and it would be useful to have some of it included. In addition, other references are used and at times some of this information should also be available (see additional comments below).

2. The Executive Summary could use some improvement. For example, on Page ES-3, what is HI? Does everyone know that this should be less than 1? It is not defined nor is the significance of the number outlined. The estimated cancer risks are discussed in detail. However, I would specify in line 16/17 that the total "cancer" risk is less than 1E-06. Not initially knowing what the HI number was, this lead to some confusion when looking at the table. It is interesting that the chemicals driving the indirect risk where identified; however, this seems to get "lost" in the rest of the document – I will get back to this later. The Executive Summary does not discuss the Uncertainty and Sensitivity results which should be done.

3. I do not have any comment at this time on the preclusion of the risk assessment for decision making.

4. Long-term research might include a program to look at the chemicals of interest in the media identified in the indirect pathways (in terms of an extensive sampling and measuring effort). What are the levels of compounds in the media where they are to be expected? The Executive Summary states that the driving risks are dairy milk and beef ingestion and the inhalation of volatile organics from indoor water

use (see p. ES-3, line 17/18). Can a study be done looking at the bioaccumulation of the chemicals driving the risk? This might help elucidate whether the assumptions and predictions generated are generally valid and would increase confidence that the results are indeed conservative in nature.

5. Other questions from Chapter 1 – It would be great to see the trial burn process described in the referenced reports in a short summary table. According to Figure 1.2-3, the kiln is fed pure oxygen. Is this correct? The text does not state this anywhere.

Emissions Characterization

1. It is difficult to comment on the operating conditions because they do not appear to be readily available in Section 2. It would be helpful to have a table versus going to other referenced material which we don't have. I couldn't find any additional information beyond page 1.3-2. The questions I would ask beyond this information would be spiking info., where are temperature taken and how, excess air/oxygen rates, etc?

2. The multi-step methodology is, for the most part, acceptable; however, a little more clarification would help. I was lost in terminology and tables! The figures do help but I would like to hear more about it. Let me summarize the information I got:

- 40% of the compounds were detected in the risk burn and an average was used.
- 5% of the compounds showed up in at least one run and the measured data were averaged with the detection limits. What's the predicted value, line 15 page 2.2-3? Is this the one developed in Appendix 2D and later discussed on page 2.2-7? I suspect so, but it isn't that clear?

- 5 to 10% of the compounds were not target compounds but were used anyway at their value.
- 20% of the compounds were not detected in the burns but were target compounds and predicted values were used.
- 20% of the compounds were not target compounds or found in the emissions, but predicted to be there? So predicted values were used.
- 5% of the compounds were included because other facilities had them
- Less than 11% were not evaluated.

How is all this related to the X1, X2, etc.? Actually, I couldn't see where the complete definition of these is given (could you reference it, I'm sure I just missed it?). I need a little more clarification in Tables 2.2-1 and 2.2-2. It would help to refer back to the numbers used on pages 2.2-3 and 2.2-4 to determine what method was used in the emission rate calculation/estimation. Would it be more useful to separate them out according to how they were estimated? I wanted to go back and look at how the emission data were determined for the "driving" compounds, but I can't seem to do this.

3. The only comment I have on this, Appendix 2D basically, is that on page 2D-10, there is a statement regarding the apparent DRE of less that 99.99%. "The process is described is further detail in Volume II, Appendix 3C". Can't find it?

4. No comment

5. No comment except that it would be nice to know how the data in the table are reflected by the method used (same comment as in number 2.).

6. No comment

7. On page 2.3-5, the statement is made that the amount of metal in the soil is depleted and that the emission rates of metals are assumed to decline exponentially. Exponentially from what? I don't understand this statement? Is there any relation to the particulate emissions and the metal emissions? The text states that particulate matter emissions increase by 10,000 in the first minute (page 2.3-6). In table 2.4-1 it states that they increase by 100?

8. No comment

9. The Executive Summary discusses that the indirect pathway of certain bioaccumulative compounds drives the risk. What is the uncertainty in these emission rates? What would be the results of the risk assessment if these rates were off by a factor of 2? I don't have enough knowledge in this area to know that so it is difficult to determine how "good" the numbers have to be. Is this discussed somewhere else in the document? I did not see it in Section 8 either.

Other Sections

No comments.

John McCutcheon

Charge – General Issues

1. The overall organization of the risk assessment document follows a logical format. However, the presentation of some of the materials within the Sections reviewed do not permit a ready review. For example, a concise description of derivation and/or sample calculations for the data in columns 4 through 9 of Tables 3.6-4 through 3.6-7 (same format) would be helpful. It would also be helpful to include the predicted model impacts for the upset and normal operations in the same area of the report to facilitate comparison of the impacts from the two operating scenarios.

2. The incinerator stack emissions were modeled with an EPA-approved air model (Industrial Source Complex Version 3, or ISC3). However, the total risk should also include risks from emissions of all on-site supporting activities (i.e., fugitive dust from on-site vehicle traffic) and various operating scenarios (i.e., thermal relief valve release).

The draft Fugitive Emissions Risk Assessment Report (December 1997) was completed after the Executive Summary of Volume III was written. The Executive Summary would be more complete if it were reworked to address the risks from exposure to fugitive emissions.

The dispersion models used to estimate ambient impacts from these activities (CALMET\ CALPUFF and INPUFF) are not EPA-approved models. Using results from these models is questionable unless prior approval had been granted by the reviewing agencies.

Based on the above comments, the total risks of less than 1E-06 (referred to on lines 16 and 17 of page ES-3) may not be an accurate representation.

3. The level of uncertainty associated with the dispersion modeling could be reduced by incorporation of a larger percentage of on-site meteorological data. Suggested methods are contained within the response to Charge Question #1 below. EPA modeling guidelines recommend one year of on-site data with five years of off-site representative data acceptable as

an alternate. Based on information contained in Volume III, it appears that additional on-site data could be incorporated with a minimal effort.

4. There are many assumptions made in an analysis as complex as this risk assessment, all of which introduce a degree of uncertainty. A clearinghouse of collected on-site data from Superfund sites would be helpful to those involved in risk assessments. Data such as ambient monitoring data, meteorological data, general site description, and media-specific contaminant concentrations could assist personnel in developing more scientifically sound assumptions.

Specific Charge Question #1
Dispersion and Deposition Modeling

Meteorological Data

There are numerous issues to be considered regarding the meteorological data available and that used in the various model runs. Because some of these comments are inter-related, each comment is presented below as a "stand-alone" comment for the sake of simplicity.

(Volume III Section 2.6.1.2, page 2.6-2 paragraph 1)
A statement is made regarding use of surface meteorological data recorded at Williamsport as "it is the most representative data for the Lock Haven area." While Williamsport is nearby (stated to be 22 miles northeast of the Lock Haven site), there is no indication that other sites were considered. The identity of any other candidate recording sites and any respective reasons for rejection would make the analysis more complete.

Reference is made elsewhere in the document that channeling of the wind flow can occur due to terrain features such as those found in the vicinity of the site. Therefore, it may be appropriate to provide a discussion of the terrain (i.e., orientation of the river valley, significant elevated terrain in the vicinity as may be seen on a 15 minute United States Geological Survey map) around the

recording site in Williamsport, noting any differences and/or similarities with the subject site that could affect the wind flow.

Comparison of the Williamsport data for July through October 1993 to climatological data for the region would be helpful. Any unusual meteorological events (i.e., persistent high pressure system) should be identified along with a discussion of the potential impacts on the dispersion modeling results (i.e., increased occurrence of fumigation/stagnation and higher ground level pollutant concentrations).

(Volume III Section 2.6.1.1 page 2.6-1)

Notation is made of a "suspected malfunctioning wind speed sensor" at the site for the period of June through November 1993. No discussion is provided as to the operation of the wind direction sensor at the subject site for this period. If wind direction data recorded at the site for that time period is available, some consideration should be given to merging this data with concurrent wind speed data recorded at Williamsport. With elevated terrain around the Drake site, wind direction may likely be an important factor in determining the maximum ground-level impact of a plume. Pairing the concurrent on-site wind direction with Williamsport wind speed is preferable to use of off-site wind speed and direction. No reference to use of such a "hybrid" meteorological data set or respective recording period length was discovered in a review of EPA guidance on the topic. In general, one-year of on-site data is preferred by EPA, but five years of representative off-site data may be accepted as an alternate. This type of issue is best addressed in a modeling protocol and subsequent discussions with the reviewing agencies.

(Section 4 of Volume III)

It appears that valid meteorological data may have been recorded at the site from November 1992 through May 1993 for all parameters. Although these months did not coincide with the planned Trial Burn period (July through October), a comparison could be made of the site wind data and the wind data recorded at Williamsport. Correlation coefficients for hourly wind speed and direction data could be used as a rough measure of the appropriateness of using the Williamsport data in lieu of site data.

There is no discussion regarding the data capture and validity of the other meteorological parameters recorded at the site during 1992/1993. If the sigma-theta data are available, they should have been used in the modeling analysis. The sigma-theta values are valuable model input as they represent a measure of the site-specific turbulence induced in part by the structures/features upwind of the site.

(Volume III Section 2.6.1.4 page 2.6-3)

A matrix of 36 stability/wind speed combinations were employed in the INPUFF modeling. The EPA now recommends use of a matrix of 55 combinations. Consideration should be given to INPUFF model runs using the expanded matrix.

The meteorological data collected from April 1995 through April 1996 were rejected for use in modeling the incinerator emissions due to a number of data quality issues as detailed in Volume III, Section 4. Based on information contained in Table 4.2-1, the data capture for July through October 1995 was over EPA's ninety (90) percent threshold for wind speed, wind direction, and ambient temperature. Data capture for sigma theta is approximately 88 percent, just shy of the ninety percent recommended level. This data could be supplemented by use of delta T/solar radiation data collected simultaneously at the site. This data could be processed to fill in missing hours of sigma theta data to achieve the required data capture. The document should include data capture statistics for each meteorological parameter for the 1992/1993 and 1995/1996 recording periods.

As noted in Volume III, the 1995/1996 meteorological data set may not be appropriate for modeling elevated sources, such as the incinerator stack, due to the improper siting of the new meteorological tower. Using EPA's GEP-BPIP program and building-specific data contained in Appendix B of Volume III, GEP-BPIP results indicate that wind flow passing by the new tower site is influenced by site structures. (The tower elevation and location were entered as stack data in GEP-BPIP to obtain these results). However, the 1995 data could be used for modeling fugitive dust emissions as this data is representative of the dispersion of emissions from low-level or ground-level sources if a sufficient number of missing sigma-theta data are filled in as suggested above. This data should be considered superior to data recorded off-site (Williamsport) for modeling of low-level sources.

Use of the CALMET program to develop a wind field for use in the CALPUFF model runs introduces uncertainty into the CALPUFF results. Given that seven months of on-site meteorological data were validated (November 1992 through May 1993), a comparison of the validated data to that predicted by CALMET (based on Williamsport data) for the tower location may help in the evaluation of the CALMET processor for this application. A monthly wind rose of each data set (recorded and predicted) for the time period would assist the reviewer to determine if the CALMET processor is a reasonable substitute for periods of missing on-site wind data.

If the wind field predicted by CALMET processor is not accurate, the CALPUFF model results and any conclusions based on the results may be considered to be questionable.

Specific Charge Questions #2 and #3
Dispersion and Deposition Modeling

Model Selection/Use

The CALPUFF model and CALMET processor are not identified in the Guideline on Air Quality Models (40 CFR Parts 51 and 52). Models listed in Appendix A of the Guideline are "preferred" for specific applications. The ISC3 model is listed in Appendix A as suitable for modeling elevated point sources (i.e., the incinerator stack), fugitive dust, and fugitive emissions, but not fumigation or stagnation. In Section 7.2.8 (titled Air Pathway Analyses (Air Toxics and Hazardous Waste)) of the Guideline, ISC is identified as "the basis of the modeling procedures for air pathway analysis". No recommended technique is stated to exist for modeling fumigation, but screening procedures are available to estimate the impacts from this phenomenon. Ambient impacts due to stagnation may be modeled with WYNDvalley, an Appendix B model.

Appendix B of the Guideline lists models that may be "considered with a case-specific justification". There is no mention in Volume III of a modeling protocol document prepared for regulatory agency review prior to the modeling effort. A protocol is usually required in a dispersion study as it allows the agencies to comment on proposed methodologies, models, and meteorological data prior to the labor-intensive modeling tasks.

The INPUFF model is not listed in the Guideline on Air Quality Models. Given this status, use of this model may not be appropriate unless an agreement was reached with reviewing agencies prior to its use.

CALPUFF and INPUFF are state-of-the-science models with options not available with the ISC3 model. However, use of these models in a risk assessment is questionable. Use of models "listed" in the Guideline would be preferred as these models have undergone extensive scrutiny by qualified scientists and have gained widespread acceptance in the modeling community.

Specific Charge Question #4
Dispersion and Deposition Modeling

Uncertainties Related to Modeling

Use of approximately 4.5 out of a total of five years of Williamsport meteorological data in the ISC3 modeling introduces a degree of uncertainty in the modeling analysis. The Williamsport data set must be classified as "off-site" data, being recorded more than 20 miles from the Drake site and in somewhat different terrain. To the extent practical, all valid on-site data should be used, but could be supplemented by Williamsport data to fill in for missing values in order to achieve EPA's data threshold. As noted above, a correlation of valid on-site meteorological data with concurrent Williamsport data for the 1992/1993 would be helpful.

Visual review of the wind roses provided in Figure 4-2 of Volume III indicates that north-northwest winds are more frequent at Williamsport than at the site for the period of December 1992 through May 1993. This bias could result in higher model-predicted impacts in elevated terrain to the south-southwest of the incinerator stack than would be predicted using the on-site data. However, the on-site data indicates more frequent westerly winds which could serve to increase model-predicted long-term impacts downwind.

The EPA's screening meteorological data set has increased to fifty-five conditions, covering a wider range of expected conditions than the previous screening set. If the use of INPUFF has been approved by reviewing agencies for use in this risk assessment, INPUFF model results for the full set of conditions would serve to reduce uncertainties of predicted impacts from this model.

The CALMET processor uses data from one or more data recording sites to develop a wind field for use in the CALPUFF model. As a predictive tool, CALMET is subject to some degree of error even if the off-site data used as input to CALMET is considered to be representative of the site. If Williamsport surface data and Pittsburgh upper air data are not truly representative of the

winds in the Lock Haven area, the wind field predictions may not be accurate. Predicted wind field data will never be better than wind data recorded at a site. One method of reducing uncertainty is to perform a CALMET run to predict the wind at the site tower location for a time period where site wind data are deemed valid, then compare these results on an hourly basis.

Models used in an air dispersion study should be listed in Appendix A of the Guideline, or from Appendix B assuming prior approval by reviewing agencies. Use of unlisted models introduces uncertainty into the analysis.

(Volume I Section 3.6 page 3.6-1 lines 25 and 26)
A statement is made that "wet deposition of vapors is not expected to be a large contributor to the total deposition of vapors". Additional information should be supplied to support this position. A gaseous compound with readily available data should be analyzed with results compared to the total deposition for that compound.

Additional Comments

1. It does not appear that emissions of volatile organic compounds are addressed except as associated with particulate matter emissions (vapor on the particle surface). Depending on the nature of the wastes at the site, significant emissions of these compounds can occur during soil/sludge handling activities. The risk assessment should address impacts from emissions of these activities and any combined risks should be presented.

2. It appears that model-predicted impacts from fugitive dust sources along the site perimeter are significantly greater than impacts from the incinerator stack. A comparison of PM-10 impacts with the National Ambient Air Quality Standard (NAAQS) would be useful.

3. (Volume 1 Section 3.5 page 3.5-2 lines 19 and 20)
It is not apparent where the fugitive emissions are addressed in the uncertainty analysis contained in Volume I Section 8.

4. (Volume III Section 5.3 page 5.3-2 paragraph 3)
A statement is made that relatively large particles emitted during an upset condition would settle close to the incinerator stack and "not affect the off-site population". The incinerator stack is close to the site perimeter (approximately 120 feet to the site north) and the exhaust flow rate under the upset conditions may be sufficient to keep larger particles airborne until the wind carries them beyond the perimeter. Additional information should be provided to support the statement.

Fugitive Emissions Risk Assessment Report

5. (Section 2.3 p 2-3 lines 12-13)
A statement is made regarding materials handled that "the materials stay wet in dry weather". Additional information should be supplied to support this statement.

6. (Section 2.3 p 2-4 lines 12-14)
The emission factor referenced here may not be appropriate to estimate emissions from soil handling activities. This factor is for screening of crushed rock/stone fines. Other EPA-approved soil handling emission estimation equations could be altered to account for particle size and moisture data.

7. (Table 3-2 page 3-7)
The predicted concentrations (column 3) for many of the metals/inorganics exceed the PM-10 NAAQS. For example, the predicted impact of iron is 104 micrograms per cubic meter ($\mu g/m^3$), exceeding the PM-10 NAAQS of 50 $\mu g/m^3$ by a factor of two.

8. (Volume III Section 5.3 page 5.3-2 paragraph 3)

A statement is made that relatively large particles emitted during an upset condition would settle close to the incinerator stack and "not affect the off-site population". The incinerator stack is close to the site perimeter (approximately 120 feet to the site north) and the exhaust flow rate under the upset conditions may be sufficient to keep larger particles airborne until the wind carries them beyond the perimeter. Additional information should be provided to support the statement.

Elizabeth McKenna

Elizabeth A. McKenna

Comments on: USEPA's Risk Assessment Report (Volume I) for Drake Chemical Site, Incinerator Full Scale Operation Integrated Risk Assessment [November 1997]

I. General Issues

1. Organization/Presentation of the Risk Assessment.

Overall, the sections of the risk assessment present information in a clear manner and follow a logical progression for presenting the components of the risk assessment. Information in prior chapters often serves to briefly introduce information whose substance is yet to be presented in subsequent sections, thereby linking terms and definitions for the reader. Although it is understood that this is a technical document, some of the sections could have been written in a slightly more "general reader"-friendly manner (e.g., select sub-sections of the Toxicity Assessment).

Suggest that "Volume II, Continued" be called "Volume III, Appendices Continued", or something similar.

2. Clarity and Accuracy of the Executive Summary.

The Executive Summary was not an easy read, prior to actually reading sections of the risk assessment. a)The background section needs to specifically state that the trial burn risk assessment was conducted before the trial burn runs. It should also define the risk burns, state why they were conducted along with the trial burns, and state the difference between the two. These risk burns and their conditions should then be clearly linked with the two risk estimation procedures; b) The Exposure Assessment paragraph should define the direct versus indirect pathways, since the ES-1 table lists these and has not defined them prior to the table, and describe why they are not broken out individually for cancer risks; c) the Risk Characterization paragraph should state that risks *for individual populations* were added across all exposure pathways; d) Ecological Screening Analysis paragraph should change the wording of the sentence regarding the general rationale for why the mercury exceedance was not significant, since the present wording reads as though prior to the benchmark screening "careful examination" was not done.

Table ES-1 should have the following changes made: a) footnote "a" should list all the indirect risks (not just food chain); b) order of presentation of the receptor populations in the text should follow the same order in the table, or vice versa; c) cancer risks and noncancer hazard indices should not have more than one significant figure, since this implies greater accuracy than the risk estimation procedure can provide; d) suggest alternate wording for footnote "e", from "not evaluated" to "not applicable" or "not quantified" (as warranted), to indicate that they were considered/evaluated and deemed not appropriate to estimate risks.

3. Major Data or Methodological Gaps to Preclude Use of the Risk Assessment.

Instances where data or methodological gaps may have been observed were noted, in particular for the assigned technical section (Toxicity Assessment), and were pointed out in subsequent comments. These issues would not preclude use of the risk assessment, per se, but should be addressed prior to use.

4. Long-term Research Recommendations.

Long-term research needs, especially within the context of the Toxicity Assessment, include: a) modification of cancer slope factors based on mechanistic information and alternate low-dose extrapolation methods; b) development of uniform, established approaches for estimating dermal slope factors and dermal intakes, especially with respect to the determination and application of oral absorption fractions and dermal absorption fractions, respectively; c) better definition of an approach for estimating non-cancer health effects for dioxins/furans; d) a standardized, accepted approach for dealing with route extrapolation for polynuclear aromatic hydrocarbon (PAH) and the application of relative potency factors for cancer, especially for the dermal and inhalation exposure routes.

II. Human Health Risks: Hazard Identification/Dose Response and Risk Characterization

Comments on Specific Charges:

Comment 1. Route-to-route extrapolation for oral or inhalation slope factors (SFs)

a) From the cancer SF table (6A-1) there are approximately 24 chemicals of potential concern (COPCs) which used the oral SF as the inhalation SF, including the 7 carcinogenic polynuclear aromatic hydrocarbons (PAHs) and 17 non-PAH organics.

For the PAHs, the weight-of-evidence to support use of the oral SFs for inhalation SFs should be considered further, prior to using this as a standard extrapolation approach. Empirical studies supporting inhalation carcinogenicity as a point of contact and/or systemic endpoint should be evaluated. The Environmental Protection Agency (EPA) document referenced in this report for the PAHs does not support this extrapolation, and no significant evidence or augmenting information to support this has been provided within the report. At a minimum, the uncertainty of using this approach should be addressed.

For the non-PAH organics, those whose inhalation SFs are oral SFs based on data from acute, gavage treatments (e.g., benzotrichloride, benzyl chloride, bromodichloromethane, dibromodichloromethane, 1,4-dichlorobenzene, ans 3,3'-dichlorobenzidine) seem most likely to have more inherent uncertainty in the extrapolated values. This stems primarily from the vast difference between a single, large dose administration in oral gavage and the ideal, lower dose and semi-continuous exposure of a typical inhalation study. Differences in amounts of chemical absorption, direct contact-effects of gavage studies (i.e., physical trauma and irritation effects), potential for different detoxifying metabolic pathways to be saturated by acute, bolus administration, and differences in distribution kinetics and target organs concentrations would all contribute. The addition of the potential for cross-route effects on top of these factors creates greater uncertainty in the use of these oral SFs for inhalation exposure. This uncertainty should be addressed.

The use of oral SFs for dermal SFs for the PAHs, after simply adjusting for oral absorption, does not seem warranted. The EPA document referenced in this report for PAHs and Toxicity Equivalence Factors (TEFs) does not support this extrapolation. The strength of the evidence for the occurrence of distal tumors (systemic effects) after dermal exposure to PAHs should be addressed more rigorously, and the appropriateness of using a the TEF approach for the dermal route should be substantiated. At a minimum, the uncertainty in this approach should be addressed.

b) There are 3 organic COPCs which derived an oral SF from an inhalation study(ies): benzene, chloromethane and methylene chloride. While there is inherent uncertainty in the benzene oral SF due to the route of administration, this uncertainty can be balanced by the utilization of human data (no animal-to-human uncertainty) and consideration of multiple studies in establishing the SF, as well as the vast amount of literature about this COPC which provide supporting information. Information on the specific data used to derive the oral SFs for chloromethane and methylene chloride is not known, but , to the extent that these data differ from the types used for benzene the uncertainties would compound.

c) In addition, there are 10 COPCs whose oral SF is derived upon a study(ies) which used an acute, oral gavage regimen to derive their oral SF.

The uncertainty in the applicability of an acute, high dose exposure for estimating SFs was addressed above, in the context of comment 1a, paragraph two, and applies here as well.

d) There are 2 organic COPCs whose route could not be determined (i.e, listing in the Route of Administration column is "no information").

In the absence of this information, no comments were made.

[NOTE: This notation should not be permitted in this table, since values were developed by the EPA and were used to estimate risks, and study references should be available to establish route and uncertainty information.]

e) The conversion of the inhalation cancer unit risk (risk per unit dose in air) to an inhalation SF (risk per mg/kg-day) using standard equation and adult parameters for body weight and inhalation rate: does that standard approach apply for estimating risks for a child, whose body weight and inhalation rate are much different? While customized SFs for every receptor type is not prudent or cost-effective, since children were an obvious population of concern, should this have been considered? Addressing any uncertainty would be appropriate.

Comment 2. Development of provisional dermal SFs using two absorption factors

The development of the two absorption factors is based only on consideration of route and gross nature of the route (i.e., oral route was viewed differently for drinking water versus dietary exposures), with little consideration of vehicle or, more importantly, the time period over which the cumulative dose was administered (i.e., gavage was viewed in the same manner as drinking water). If broad estimates of absorption factors are going to be applied to numerous chemicals, the bases for these estimates should be supported with more evidence.

There are no supporting references provided for either absorption factor, nor even an abbreviated survey of absorption literature for representative compounds (i.e., a surrogate for volatiles, semi-volatiles, and inorganics) from which estimates could be extrapolated. The reader is left to assume that 50% and 90% are completely arbitrary and have no bases in fact.

Comment 3. Methodology for Dose-response for: dioxins/furans, PAHs, Polychlorinated Biphenyls (PCBs), lead, and adequacy of uncertainty characterization

Dioxins: methodology is based on the International Toxicity Equivalents (I-TEQ)/TEF approach from pre-1989 data; it does not attempt to utilize any data gathered subsequently to modify 2,3,7,8-TCDD toxicity estimates, nor does it include truly mechanistic considerations regarding dose-response relationships at low dose versus increasingly higher doses. As such, the endpoints on which the TEFs are based vary in: nature and severity, extent of supporting data for each endpoint, and ability to make cause-and-effect conclusions; they are weakened by their limited ability to support a carcinogenic role for TCDD with the specific exposure surrogates/endpoints being used to establish the TEFs (i.e., are there empirical data to link varied enzyme levels, etc. with tumor promotion and/or progression in actual animal/human studies?). It also fails to

address isomer-specific effects, or simultaneous multi-isomer exposure effects (competition, synergism, antagonism, etc.). These limitations should be mentioned, or at least those most likely to impact values, and uncertainty in this approach briefly described

PCBs: a discussion of the tiered approach and the integration of composition considerations, exposure potential, persistence, and sensitive populations should be provided. The text is unclear regarding the values chosen and their bases, and use of the term 'mixtures' followed by a discussion of the seemingly individual congeners may be confusing. It should also be mentioned that the estimation method for the SFs differed from the strictly traditional linear multi-stage model. The justification for using the upper-bound SF instead of the central estimate SF should be provided, and the likely effect on risks described.

PAHs: methodology is ultimately based solely on mouse skin carcinogenesis models, to establish orders of magnitude for relative potencies. Potencies are then applied to oral exposure. Without obtaining all references cited in this methodology a comprehensive discussion of this approach cannot be made. The goal of trying to have a single (exposure) system in which to assess relative potencies seems good, to minimize variation, but the exclusion of data for other routes and tumor types seems too narrow in scope. Obviously, if additional data or research has been conducted those data should also be factored into the consideration and updated appropriately.

It is noted that the use of the relative potencies is specifying prohibited (within the referenced document) for the inhalation route, due to confounding effects of particulate matter and also of other compounds with potential co-carcinogenic activities being present at the same time. However, this application was done in this risk assessment, and sufficient and relative supporting justification should be provided for this approach.

Lead: lead concentrations were compared to stand-alone, medium-specific action levels or guidance levels/standards. In addition, they were used only to estimate effects for the adult resident and subsistence farmer. As such, they may not take into account several factors: a) the most sensitive populations for lead effects, namely infants and children; b) the additivity of incinerator exposure to the existing blood lead levels in these populations (i.e., background blood lead levels); c) the additivity of exposure from multiple sources/media; d) the continued exposure potential for lead in media such as soil, especially for infants/children who contact soil

at higher rates both outdoors and indoors, and, e) the extent to which these action levels or guidelines/standards are (are not) based on health effects applicable to these sensitive populations.

Although the lead levels in these media are modeled to be very low, the potential for low blood lead levels to be associated with adverse effects, and the potential for lead to have both short-term effects and long-term effects past the exposure duration, should be recognized. Discussions of the application of an integrated blood lead modeling approach for these media, for sensitive and adult populations may be warranted, or the justification for the lack thereof provided.

Comment 4. Overall approach for noncancer health effects

a) The simple use of chronic values for sub-chronic values without checking for the duration of the underlying study will tend to overestimate risk by at least an order of magnitude for those compounds whose chronic reference dose (RfD) may be based on a sub-chronic study. This should be examined and sub-chronic values should be adjusted, as needed, if this was not done. Likewise, this would also apply to those subchronic inhalation RfDs based on a chronic oral RfD that was developed from a subchronic oral study.

b) Although the approach to extrapolating cross-route toxicity values for compounds lacking an endpoint (i.e., the lack of doing this) was commendable, there should not be compounds lacking an endpoint, as mentioned above, and endpoints should be obtained (even if such endpoints are based on No Observable Adverse Effects Levels (NOAELs), studies will have delimited what were the measured parameters in the experiment). The lack of toxicity endpoints would make any assessment of toxicity due to common endpoints/target systems impossible.

c) Conversion of reference concentrations (RfCs) to RfDs using the "standard" conversion factors for body weight and inhalation rate is a typical practice, but assumes that these values will be applied for an adult. Differences, if any, in the estimation of these values that could potentially result from their application to a non-adult (e.g., child) due to variation in body weight, inhalation rate, absorption efficiency, and other age-specific factors are not considered. These differences should be stated, if significant.

Comment 5. Adequate consideration of non-cancer risks, specifically for: endocrine disrupters, chronic dioxins/furans effects, manganese, fenac.

Endocrine disrupters: the inability to evaluate endocrine disrupter activity(ies) seems in direct accord with the state-of-the-science at this time. If anything, the language in the report does not tend to convey the extent of the lack of concrete information and the depth of uncertainty surrounding this issue. It is suggested that the bullets supporting the limitations of evaluating these studies be expanded, possibly by the simple addition of examples of each type, or at least be made more "general reader-friendly" so that the extent of these uncertainties can be placed in greater context.

Chronic dioxins/furans effects: the use of the provisional approach, estimation of margin-of-exposure ratios, seems appropriate in light of the inability to quantify risks or possibly to discriminate exposure risks against background risks. Essentially, this comparison is an indication of the level of conservatism built into the exposure estimates in conjunction with the compound concentrations. Given the low concentrations of compounds, variation in the exposure assumptions seems more likely to effect these ratios than any variation in the dioxin concentrations themselves.

Manganese: a) oral RfD - adjustment of the critical dose for "average dietary intake" seems appropriate to account for essential nutrient contribution. Establishment of an oral RfD (for drinking water and soil) based on the residual "allowable" amount suggests that manganese risks might need to be evaluated specifically for manganese (based on a total intake from all routes), in addition to being collectively assessed for noncancer risks. Also, was body burden factored into the critical dose? Is the critical dose the same for adults and children, and if not, should an RfD for children be established? The potential for regional background levels of manganese in soil and drinking water sources should be considered, it seems, to allow for region-specific variations in the "average daily intake", or for the contribution towards the "allowable" amount that does not derive from incinerator activities.

b) sub-chronic inhalation RfD - to the extent that an uncertainty factor of 10 is appropriate for the original extrapolation from the sub-chronic study to a chronic RfD, the practice of removing the factor of 10 and then converting the RfC to an RfD seems appropriate.

Fenac: the use of an oral LD50 (lethal dose for 50% of animals) as the basis for a chronic RfD is not appropriate. The uncertainty in this type of extrapolation is too wide to result in an meaningful chronic RfD. Establishment of the total uncertainty of 10,000 (presumably to account for animal-to-man (10), sub-chronic to chronic (10) and acute to sub-chronic (10), and absence of a NOAEL (10)), still may either underestimate or overestimate toxicity for this compound. Death is a frank effect level of "infinite" severity and should not be handled on the same par with studies whose severity endpoints may include potentially reversible enzyme system effects. In addition, most LD50 studies have additional uncertainty typically due to the age of the study, methodology issues, route being used, dosing time frame, and complications therein. In this situation, compounds with any type of structural/functional analogy to fenac which have even sub-chronic studies would seem preferable for use in establishing the RfD.

Comment 6. Acute inhalation toxicity value approach

a) A brief explanation of the rationale behind the preferred selection hierarchy for these toxicity values should be provided (i.e., Is the preference ordered by those values protective for longer time periods? Does it include consideration of the basis for the value or the extent to which irreversibility is a consideration?), to allow the reader some understanding of context.

b) Conceptually, one might assume that the Immediately Dangerous to Life and Health value (IDLH) which is supposed to be protective for 30 minutes could be a higher concentration than the Threshold Limit Value (TLV), a value not be exceeded for any moment during the day - yet both values are divided by a factor of 10 and used as protective of the general population. Is this an appropriately protective action for each value?

c) Is the factor of 10 based solely on the presumed underlying variation within the human population? If so, is it sufficiently protective of children, a sub-population who may be sensitive due to age, and who may, in addition, have sensitive persons within their population?

d) For several compounds which lacked values, why weren't values for structurally comparable compounds used instead of not addressing them (i.e., using a naphthalene value for 2-methylnaphthalene)? This could reduce uncertainty from acute risk, since less than half the compounds have acute values.

Comment 7. Adequacy of uncertainty with respect to: key assumptions for exposure/risk, magnitude/direction of assumptions for effects on risk

Some assumptions appear to have directional effects that are questionable. For example: The estimation of dermal toxicity values from oral toxicity values states that the effects on risk is unknown. However, if this process was not done, the majority of dermal risks would not be estimated, and therefore the effect could be one of increasing risks for receptor populations where dermal exposure was a route.

Certain categories of uncertainty assumptions, while covered by the general assumption/basis statements, may actually have magnitude and direction components which are not identified within the context of the general assumption. For example: the assumption that dermal toxicity of PAHs can be assessed using oral toxicity values is a special case within the assumption "Dermal toxicity values are derived form oral toxicity values", and the effect may be to over-estimate dermal risks.

The assumptions/approaches are so general that the context of assessing and presenting their effects on the magnitude and effect on risks should be clarified (i.e., are these meant to portray the uncertainty of this assumption in general, or the combined/cumulative uncertainty of using these assumptions for every chemical on the overall risks in this assessment (something which seems likely to never be assessable)?).

Comment 8. Overall adequacy of the risk assessment: clarity, confidence and uncertainties, risks to important subgroups addressed

Overall, the risks are characterized clearly and concisely for all groups under both burn conditions. Comparisons of both risk burns and key factors influencing risks for burns are also presented well. Risks appear to be addressed for all important subgroups, especially since both child and infant for the farmer and resident are included.

However, as mentioned earlier, risks from lead exposures to children could be quantified in an integrative manner, or since lead concentrations in various media are so low, the limitations of the approach for lead could at least be described in the risk and uncertainty sections.

Harlee Strauss

Comments on Drake Chemical Site Risk Assessment Report
Harlee S. Strauss, Ph.D.
December 22, 1997

General Comments

1. Organization of the risk assessment document.

The risk assessment document is well organized. The separation of the highly technical aspects from the general description of the risk assessment and the description of the results is useful for a public document where much of the readership will not be interested in the technical details. The locations of the details are adequately referenced in the main text.

2. Adequacy of the executive summary.

The executive summary is a little too short; it should provide more information about the methodology. The conclusions are adequately represented, but none of the uncertainties are discussed. The importance (or foolishness) of basing a comprehensive risk assessment on a tentatively identified compound should be discussed. There is no superscript f in the summary table.

3. Major data or methodological gaps.

I have not identified any major data or methodological gaps that would preclude the use of this risk assessment for decision-making. The deficiencies discussed below should not have a major impact on total risk estimates based on the current risk assessment methodology.

4. Long term research needs.

As has already been identified by the USEPA, there is a critical need for risk assessment methodologies appropriate for children. The methodologies need to include relevant changes in estimation of absorption of chemicals into the body, development of appropriate dose-response factors, and the appropriate period for averaging the dose. For example, infants and fetuses (exposed transplacentally) may be more than 10 fold more susceptible to toxicants (including carcinogens) than the adult animals on which the toxicological datasets are derived. As another example, an averaging period of 70 years is clearly inappropriate for childhood cancer where animal studies have shown that a single exposure during a critical period of pregnancy or early neonatal development may result in cancer. The risk assessment conducted here shows that children are at higher risk than adults. This risk may well be underestimated because of current methodological shortfalls.

Comments on Human Health Risks

The risk assessment takes an adequate approach to estimating the populations who represent the reasonable maximum exposure (RME) scenario. This is a "seat of the pants" type of reckoning, however, as there is no quantification of the exposure distribution. The risk assessment intended to use conservative values (those intended to overestimate risks) in exposure calculations more often than not. They did not always succeed, based on some exposure estimates provided in the newly revised Exposure Factors Handbook. This revised EPA document was not used in this risk assessment.

The exposure assessment generally did a good job of identifying and selecting important sources and locations of exposure, and other elements of exposure pathways. I have a few questions and comments about specific decisions:

- The drinking water source was assumed to be the Keller Reservoir. Is that really the case for the subsistence farm family, or do they use groundwater wells located on their property? In addition, are there farm ponds for fishing?

- The dose calculation from the mother's milk pathway should include the highly persistent contaminants (chlorinated dioxins and furans) from the 2 months of test burns in addition to the full scale use of the incinerator. These contaminants have a very long halflife in the body, and excretion via milk is a major elimination pathway from the mother.

- The calculation of contaminant concentrations in underground vegetables does not consider translocation of contaminants from the leaves to the edible roots. While this may or may not be negligible, it should at least be mentioned. It is a potential source of underestimation.

- The estimation of fruit and vegetable intake should be revised to include the data provided in the recent revision of the Exposure Factors Handbook. For children, the fruit and vegetable intake should be at least ten fold higher than incorporated into the current risk assessment.

- The intake for fluid milk consumption is a low/median value, based on the data in the revised Exposure Factors Handbook. It is below the mean value for fluid milk consumption for 6-11 year old boys. Since milk consumption is the pathway that drives the cancer risk for the child of the subsistence farmer, this intake value should be reconsidered and revised upward. Milk consumption should also be reconsidered for the pregnant and lactating subsistence farmer. Again, milk consumption will be substantially higher than estimated in the risk assessment, and this intake is important to the subsequent calculation of exposure and risk to the farm infant. At the same time, the PAHs that contribute to the risk estimates of this pathway should be

more closely examined to see if there is substantial metabolism to non-carcinogenic metabolites.

- The estimation of exposure due to direct contact with soil (dermal and inadvertent ingestion) is too high based on the revised Exposure Factors Handbook and its description of the data from Kissel. The risk from this exposure pathway is more conservative (higher estimate) than necessary.

- The weight of an infant (newborn to 1 year) is assumed to be 10 kg (22 pounds). This is too high. The mean weight of a 6-11 month old is 9.2 kg. Infants less than 6 months weight even less. This is an important point because it relates to dose (mg contaminant/kg body weight) at one of the most vulnerable times during development, especially nervous system development. The use of too high a body weight leads to an underestimate of dose.

Response to questions on hazard identification/dose response and risk characterization:

- The route-to-route extrapolation approach was adequate for oral and inhalation exposures. The approach for dermal exposure was adequate based on current methods and data. However, the deficiencies in the dermal absorption database, and the differential absorption by children, render this calculation much less certain.

- The margin of exposure approach used for dioxins and furans seems appropriate given the current state of knowledge and that the concentrations already present in the environment may have adverse effects. The approach used to assess the risk of lead, namely a comparison with standards, harks back to the 1986 risk assessment approach of comparison with ARARs. It is

adequate in the present circumstance, although it may be inadequate if the estimated exposure point concentrations were higher.

- The risk assessment used a toxic equivalency approach for both dioxins/furans and polycyclic aromatic hydrocarbons (PAHs). It would be helpful to state the toxic equivalency factors (TEFs) for dioxins/furans are based on the internationally agreed to I/TEF-89 values. The use of TEFs for dioxins/furans is reasonable and widely accepted in current practice. The use of TEFs for PAHs is not appropriate because of the evidence that combinations (mixtures) of PAHs have synergistic and/or antagonistic effects. Moreover, there may be N- containing or S-containing heterocycles emitted, which have toxicity (including cancer-causing potential) that are not looked dfor in the chemical analysis. I think the PAHs that have been included in routine chemical analysis should be considered marker compounds for the presence of many PAHs rather than the only PAHs with carcinogenic activity. As such, I think the cPAH fraction as a whole should be evaluated as having the carcinogenic potency of benzo(a)pyrene.

- I agree that it is premature to evaluate endocrine disrupters in a risk assessment. You can always give more data and explanation for decisions, but there is value in brevity.

- The approach to chronic and subchronic non-cancer effects was adequate and appropriate.

- The approach to calculation and evaluation of the acute exposures may have some problems. I am concerned about the 1 hour averaging time when the acute exposure is estimated to last 1-15 minutes. Especially when the NIOSH IDLH and the ACGIH ceiling values are utilized as the basis for the assessment, the 1 hour averaging time is too long: 10 to 15 minutes would be

more appropriate. In principle, consideration also should be given to the combined effects of the criteria pollutants and the toxic pollutants. Specific reference should be made to the impact on sensitive receptors, such as children with asthma. How do the levels of acute exposure compare with the levels found to cause an effect in studies of asthmatics?