

**Responsiveness Summary
Von Roll America, Inc.
Ohio Permit No.: 02-15-0589
U.S. EPA I.D.: OHD 980 613 541**

Note

Ohio EPA issued a draft renewal Hazardous Waste Facility Installation and Operation Permit (Permit) to Von Roll America, Inc., a/k/a Waste Technologies Industries (VRA/WTI) on January 24, 2003. A public comment period was held from January 25, 2003 until May 9, 2003. During the public comment period, Ohio EPA received written comments from several persons and organizations. These included Evelyn Cuthbert, Dr. Halstead Harrison, Tri-State Environmental Council (Tri-State), Save Our County, Inc. (SOC), Greenpeace International (Greenpeace) and VRA/WTI. Comments were also received during the public meeting held at the East Liverpool Middle School Auditorium, 810 West Eighth Street, East Liverpool, Ohio, on Tuesday, February 25, 2003. Comments received during the public comment period included comments related to issuance of the draft Title V permit as well as the draft renewal hazardous waste permit. This responsiveness summary is intended to address only those comments relating to issuance of the draft renewal hazardous waste permit. Please note that both the comments and the responses presented in this responsiveness summary may refer to VRA/WTI by a variety of names, such as Von Roll/WTI, WTI, VRA/WTI, etc.

A separate responsiveness summary from Ohio EPA, dated September 25, 2003, is associated with Title V permit issuance and addresses comments pertaining to the draft Title V permit.

Comments received during the public comment period cover a range of issues. In order to facilitate our response and to make it easier for review, similar comments were grouped together in categories. Comments are in most cases excerpted verbatim to best preserve the commenter's intended meaning. The source of each comment is identified. Paraphrasing or summarizing is used to a limited extent and only where necessary to clarify the meaning of comments. The categories are as follows:

- 1) issues related to siting;
- 2) issues related to emissions monitoring;
- 3) issues related to health (cancer, lead, asthma);
- 4) issues related to accident scenarios;
- 5) issues related to allegations of wrongdoing;
- 6) issues related to ownership;
- 7) issues related to permitting (termination, expiration, operating conditions);
- 8) issues related to compliance;
- 9) issues related to the request to fund an independent study;
- 10) issues related to the public participation process;
- 11) issues related to construction (emergency vent, stack height);
- 12) issues related to citizen access to monitoring data;

- 13) issues related to lab packs;
- 14) issues related to permit-specific comments from VRA/WTI;
- 15) miscellaneous issues;
- 16) issues related to the 1997 U.S. EPA risk assessment;
- 17) transcript from the public hearing.

U.S. EPA responded to comments in Category #16 as they had primary responsibility for the comprehensive site-specific risk assessment completed for the VRA/WTI facility. U.S. EPA also provided assistance with the responses for other categories.

The complete text of the submitted comments and the transcript of the public meeting comments are available and can be requested from Ohio EPA. Changes to the Permit as a result of permit modifications approved since the draft issuance on January 24, 2003 and other corrections are addressed in separate sections at the end of this Responsiveness Summary. Added Condition A.27.(d)(i) of the renewal permit requires VRA/WTI to update the permit application for changes resulting from permit modifications approved between the date of issuance of the draft renewal permit and the date of issuance of the renewal permit. There are several separate documents which are attached to this responsiveness summary for reference. The Attachments are as follows:

Attachment A - Letter from Halstead Harrison, Assoc. Professor of Atmospheric Sciences, University of Washington, Seattle WA, dated April 6, 1999 (As referenced in the Response to Comment 16A.22).

Attachment B - Memo from Timothy Fields Jr., Assistant Administrator for the Office of Solid Waste, USEPA, Washington D.C., dated January 19, 2001 (As referenced in the Response to Comment 7F and Response to Comment 15F).

Attachment C - Memo from Francis X. Lyons, Regional Administrator of USEPA Region 5, dated December 5, 2000 (As referenced in the Response to Comment 17A).

Attachment D - Document entitled EPA's Draft Final Guidelines for Carcinogenic Risk Assessment, issued 2003 (As referenced in the Response to Comment 16B.14).

Attachment E - Document Entitled A Review of the Reference Dose and Reference Concentrate Process, Final Draft, Prepared by the Risk Assessment Forum of the USEPA, Washington D.C., dated November 2002 (As referenced in the Response to Comment 16B.14).

Attachment F - Document entitled PCDD/F Signatures for November 2000 Air Concentrations and Stack Emissions containing two charts, undated (As referenced in the Response to Comment 16D.4).

Attachment G - Letter from Valdas V. Adamkus, Regional Administrator of USEPA

Region 5 to Terri Swearingen, President of the Tri-State Environmental Council, dated August 17, 1995 (As referenced in the Response to Comments 15A and 15D).

Attachment H - Letter from David A. Ullrich, Acting Regional Administrator, USEPA Region 5, to Donald Schregardus, Director, Ohio Environmental Protection Agency, dated April 22, 1998 (As referenced in the Response to Comment 16A.7).

Attachment I - Information Regarding Potential Non-Cancer Effects of Dioxin. A summary of information and conclusions presented in the Draft Dioxin Reassessment for the three human organ systems mentioned in the response to Comment 16B.14.

Attachment J - Letter from Randy Ohlemacher, Ohio EPA, to Alfred Sigg, VRAWTI, dated July 20, 2004 (As referenced in the Response to Comment 8L).

1) ISSUES RELATED TO SITING:

- 1A)** "Von Roll/WTI should never have been allowed to operate a toxic waste incinerator in its present location. Von Roll/Waste Technologies Industries (WTI) hazardous waste incinerator in East Liverpool, Ohio is located just 400 yards from the East Elementary School and even closer to homes. It is the belief of the citizens that the permit was rushed through the system (according to the Hearing Examiner, with an incomplete application) in order to get in under the old law when there was no siting rule. New laws don't just happen overnight. Ohio State law enacted a prohibition on the siting of any incinerator within 2,000 feet of a school, home, hospital, prison or within the flood plain just four (4) months AFTER WTI was granted its original permit in 1984, but nearly eight (8) years BEFORE was built." (Tri-State)
- 1B)** "The US EPA's (1997) hazardous waste siting criteria identified eight (8) locations as inappropriate for siting any hazardous waste management facilities. WTI's location meets 5 of these inappropriate locations." (Tri-State)
- 1C)** "You wonder why we are NIMBY's? Maybe it is because we understand human nature with regard to money and we feel you don't. We don't have to right but we should to affect what is built in our neighborhoods especially if it could adversely affect the health, well being and life expectancy of the residents and their families and this is sad." (Cuthbert)
- 1D)** "We go through the motions of meaningless hearings. If the OEPA grants this permit....I hope the many many lives that are adversely affected will haunt each member of the OEPA granting this permit. How will you sleep at night? I could never understand why the OEPA with all the employees with such extensive education would even consider have a waste incinerator built on a river so close to children and a community. Sometimes you defy common sense." (Cuthbert)

- 1E) "Floodplain - Federal Floodplain requirements are addressed by the General Accounting Office (GAO) beginning on page 42. The GAO wrote, "Executive Order 11988, as amended, requires that federal agencies not support development within a floodplain unless no other practicable alternative exists. ...The Executive Order applies to all federal actions affecting land use, including issuing permits, in a floodplain. ...EPA's issuance of WTI's permit was subject to the requirements of the executive order." EPA failed to follow the law, and as a result, people are suffering. The U.S. EPA had been warned by the Ohio Department of Natural Resources (ODNR) that the Executive Order on floodplain management requires that alternative sites be considered. A December 29, 1982 letter from ODNR to U.S. EPA Region 5 states, "Protection to the 500-year flood level, as proposed by the Port Authority, does not adequately assure complete protection from pollution from toxic wastes. Because the proposed HWMF will be receiving, storing and treating hazardous and toxic wastes, it is inappropriate to locate it in a flood hazard area so near public waste (*sic - water?*) supply provided by the Ohio River. ...Executive Order 11988 (Floodplain Management), Section 2 (a) states, "If the agency has determined to ...allow an action to be located in a floodplain, the agency shall consider alternatives to avoid adverse affects and incompatible development in the floodplain. In summary, regardless of site preparation, flood hazard areas are inappropriate for a hazardous waste management facility. Based on this and other considerations, it appears that siting considerations and alternatives were not fully and properly evaluated in this case. Alternatives out of flood hazard and major aquifer areas should be evaluated." (partial statements from the Tri-State outline, Section III.A.10)

Response to 1A through 1E:

Waste Technologies Industries (WTI) applied for a hazardous waste facility installation and operation permit with the Ohio EPA in 1981. Pursuant to the Ohio Hazardous Waste Law, a review of WTI's application was carried out by staff of the Ohio EPA. This occurred over a period of fourteen months. Once the WTI application was determined to be complete and a preliminary determination was made by the staff that the application appeared to comply with the hazardous waste requirements specified in Ohio law, Ohio EPA transmitted WTI's application to the Ohio Hazardous Waste Facility Approval Board (Board). The Board then gave notice of a public hearing on WTI's application. The hearing was held in East Liverpool, Ohio, in January of 1983. The Board also conducted an adjudication hearing on WTI's application (in March and April of 1983) to hear testimony and take evidence on the issues in dispute between the parties with respect to the approval or disapproval of the application for this hazardous waste facility. The parties to the Board's adjudication hearing were the applicant (WTI), the staff of Ohio EPA, the Columbiana Board of County Commissioners, the Mayor of East Liverpool, the Columbiana County Board of Health, and the Community Protection Association. The State of West Virginia also participated as a guest of the Board. Finally, in April of 1984, the Board entered into its journal an Opinion and Final Order approving the WTI application.

The commenter's statement "that the permit was rushed through the system....in order to

get in under the old law when there was no siting rule" is unfounded in several respects. First, the application was not rushed through the Board's process because it was unnecessary to do so. The August 1984 statutory amendments referred to by the comment~~er~~ also specifically excluded its newly enacted amendments from applying to "any application for a hazardous waste facility installation and operation permit...that the Director of Environmental Protection has transmitted to the Hazardous Waste Facility Approval Board prior to "August of 1984 (see Amended Substitute House Bill 506, Section 2). As indicated above, the application was transmitted to the Board in 1982.

Second, siting criteria did exist under the Ohio Hazardous Waste Laws in effect at the time the Board acted on the Waste Technologies Industries permit application; the provisions of Section 3734.05(c)(6) Ohio Revised Code require that the Board not approve an application unless it finds and determines:

"The nature and volume of the waste to be treated, stored or disposed of at the facility;

That the facility complies with the Director's hazardous waste standards adopted pursuant to section 3734.12 of the revised code;

That the facility represents the minimum adverse environmental impact, considering the state of available technology and the nature and economics of various alternatives, and other pertinent considerations;

That the facility represents the minimum risk of:

- *Contamination of ground and surface waters by leachate and runoff from the facility;*
- *Fires and explosions from improper treatment, storage, or disposal methods; or*
- *Accident during transportation of hazardous waste to the facility; and*
- *That the facility will comply with Chapters 3704, 3734, and 6111 of the Revised Code and all rules and standards adopted under these sections."*

In its 1984 decision, the Board found and determined that the state's siting criteria were met. This decision was appealed to and subsequently upheld by both the Franklin County Court of Appeals (West Virginia v. Hazardous Waste Facility Board (No.84AP-496)) as well as the Supreme Court of Ohio (affirmed December 24, 1986, 28 Ohio St. 3rd 83).

The document referenced in comment 1B, the May 1997 federal publication "Sensitive

Environments and the Siting of Hazardous Waste Management Facilities has no relationship to the State's renewal standard (see response to category #7 on renewal standard and ORC Section 3734.05(H)). Additionally, the stated purpose of the 1997 federal publication is to raise awareness and discuss sensitive types of environments that pose special challenges to siting of Hazardous Waste Management facilities rather than impose absolute prohibitions on siting. Throughout this document, recommendations are made in the alternative. For example, it is recommended that while facilities "should avoid building in flood plains," the regulations allow facilities to be built in the 100 year flood plain if it is "built to withstand the flooding event." The Ohio Hazardous Waste Facility Board considered many of the same issues as part of its 1984 decision on this matter as affirmed by the Ohio Supreme Court in 1986.

With respect to the flood plain issue, Ohio administrative rules, in effect in 1984 as well as at the present time, require applicants for a Part B hazardous waste permit to submit certain data and information concerning the location of a facility within a one-hundred year flood plain (OAC Rule 3745-50-44(A)(11)(c) and (d)). In addition, Ohio administrative rules, in effect in 1984 as well as at the present time, provide that a hazardous waste facility located in a one-hundred year flood plain must be designed, constructed, operated and maintained to prevent washout of any hazardous waste by a one-hundred year flood (OAC Rule 3745-54-18(B)). The Board's Opinion and Final Order and permit included consideration of these administrative requirements requiring the facility to be built to an elevation of 695 feet above mean sea level, which is at the 500 year flood plain level (see Permit Conditions B.33 and B.34) These conditions would appear to satisfy applicable Ohio hazardous waste facility permit rules. As indicated in the comment, Executive Order 11988 (May 24, 1977) was directed to federal agencies and did not impose an absolute prohibition.

U.S. EPA, in their letter responding to the petition, addressed assertions in the petition that the WTI permit should be terminated because it was issued in violation of Executive Order 11988, regarding flood plains. The U.S. EPA did consider that Executive Order in promulgating its location standards in 1980 (see 40 CFR 264.18), and the WTI permit was issued in compliance with those standards. Issues related to Ohio EPA's siting of the incinerator are addressed in Ohio EPA response to comments 1A through 1D.

Siting the facility was a valid decision that was made almost twenty years ago and the facility has been constructed and operating for ten years. The renewal standard (ORC Section 3734.05(H)) does not allow the Agency to re-site the facility.

2) ISSUES RELATED TO EMISSIONS MONITORING:

- 2A)** "Von Roll/WTI is permitted to release many toxic substances into the air such as lead, mercury, and other heavy metals and super toxins such as dioxin. As WTI continues to release daily emissions of dioxin, mercury and lead, hundreds of children have spent their elementary school years breathing the vile byproducts."

(Tri-State)

Response to 2A:

Yes, to a certain extent, VRA/WTI is permitted to release toxic substances into the air. However, the duly promulgated regulations which allow these emissions, also ensure that the emissions have a minimal impact on the surrounding community and environment. This is accomplished through trial burn testing of the incinerator and the establishment of operational parameters such as combustion temperature, residence time for the flue gas in the system and turbulence within the combustion system. These operating parameters ensure complete combustion of hazardous and non-hazardous waste in the incinerator. System removal efficiency (SRE) of the incineration system is determined for metals so as to establish feed limits of metal bearing waste. The SRE is tested routinely via stack testing of metals emissions. The formation of dioxin, a by-product of incineration, is controlled through rapid temperature reduction of the flue gas in the air pollution control units and via the facility's Enhanced Carbon Injection System (ECIS).

Emissions monitoring of constituents such as carbon monoxide, particulate matter (monitored as opacity at the stack), sulfur dioxide, oxides of nitrogen, hydrogen chloride, and total hydrocarbons is performed continuously at the stack. Emissions of constituents such as metals and dioxin/furans must be monitored through discrete testing at the stack which is currently conducted, at a minimum, annually.

Regarding the protection of the air quality of the area, ambient air sampling was conducted by the U.S. EPA during the Fall of 2000. Sampling and analysis for dioxins, lead, chromium, and other metals found these constituents were not at levels of health concern. Ambient concentrations of chromium and manganese were found to be higher than expected, and the possible source(s) are still under investigation. However, the particle characteristics of the chromium and manganese collected during the ambient air monitoring are not indicative of combustion operations and do not indicate VRA/WTI as the source.

The web page which includes the monitoring report can be accessed at http://www.epaosc.org/site_profile.asp?site_id=WTI. Highlights of the report can be found in the response to comments document from Joseph P. Laformara, Ph.D, dated April 30, 2003 addressed to "Dear Interested Party,". Questions pertaining to the response letter can be directed to JoAnn Camacho via e-mail at camacho.joann@epa.gov or by mail to U.S. EPA, ERT, 2890 Woodbridge Ave, Building 18, MS-101, Edison, New Jersey, 08837.

- 2B)** "Permit conditions must reflect all state, local and federal rules requiring that public health be adequately protected. At Von Roll/WTI, chemicals are released during routine operations, upset conditions and during accidental releases. In order to make a determination that WTI's operation is not a threat to public health - in order for EPA to claim that the Agency is protecting public health - EPA needs to require from Von Roll/WTI an accounting of all releases. In addition, we are interested in all emissions released from the WTI incinerator. For this reason, we need additional CEMs and Ambient Air Monitors. We also request CEMs and ambient

air monitoring for cadmium, arsenic, beryllium, chromium and other chemicals of concern." (Tri-State)

Response to 2B:

Permits are purposefully written to reflect state and federal rules, as appropriate. The conditions in the permit for VRA/WTI are intended to adequately protect human health and the environment. The majority of routine operations which involve processing hazardous waste are performed under vapor recovery at the VRA/WTI facility. Examples include splitting waste into smaller charges, the addition of absorbent, sampling, pumping waste from containers to tanks, extruding the waste from containers, and consolidation. In these situations, no or negligible amounts of vapors are released. Regarding the potential for release during upset conditions in the incineration system, constituents such as carbon monoxide, particulate matter (monitored as opacity at the stack), sulfur dioxide, oxides of nitrogen, hydrogen chloride, and total hydrocarbons would be detected by the continuous emission monitors (CEMs) in the stack. Potential emissions that may occur during accidental releases can not be monitored as they are unexpected events. However, the majority of operations at the facility occur within buildings, some of these with vapor recovery inlets. If an accidental release occurs in a building, the facility can adjust the vapor recovery system to increase recovery in that area.

The U.S. EPA has regulations in place, 40 CFR 264.1050 to 264.1091, to monitor and control fugitive emissions from process units such as tanks as well as flanges, valves, pumps, and pipes on a regular basis. The Title V permit will require terms and conditions on all non-insignificant emission units. MACT addresses fugitive emissions, not as an emission unit, but on a facility-wide basis.

Regarding the statement about additional CEMs, Ohio EPA assumes you are referring to CEMs to monitor metals and dioxins. There are no certified monitors for these constituents available on the market currently. Emissions of these pollutants are controlled via operating parameter limits related to the generation of these pollutants.

Ambient air monitoring provides information regarding air quality and pollutants. Ambient air monitoring is used to determine compliance of an area with National Ambient Air Quality Standards (NAAQS) and to determine attainment status for that area. It is difficult to trace the pollution to any one entity. Stack sampling is the most accurate method of determining what is coming from a source.

The provisions in the VRA/WTI permit are protective of human health and the environment and the Ohio EPA does not believe additional monitoring is required.

2C) "Under RCRA and MACT, EPA has the authority to establish site-specific conditions, make decisions and establish requirements for incinerators on a case-by-case basis. Because of WTI's unique location next door to homes and an elementary school, in a flood plain, immediately on the bank of the Ohio River and in a valley with thermal air inversions, the EPA MUST use extra caution in it's

regulation and oversight of the incinerator. Instead of merely evaluating Von Roll/WTI's compliance a few times a year with planned stack tests, CEM's and ambient air monitoring should be used." (Tri-State).

Response to 2C:

As described above, VRA/WTI currently has CEMs in their stack to monitor carbon monoxide, particulate matter (monitored as opacity at the stack), sulfur dioxide, oxides of nitrogen, hydrogen chloride, and total hydrocarbons. CEMs for dioxin/furans and metals are not currently available on the market.

Ambient air monitoring is not conducted to determine the compliance of a facility such as VRA/WTI with permit limits. Please refer to Comment 2B for additional information.

As described in Comment 2A, site-specific conditions for operating parameter limits (OPLs) which control the generation and removal of pollutants in the combustion system were established for the VRA/WTI incineration system based on the trial burn results and the risk assessment. These parameters are directly correlated to the performance of the incinerator and air pollution control equipment and hence to the emissions from the stack. The OPLs are listed in the permit and are enforceable.

2D) "Title V is intended to confirm that the facility has adequate air monitoring and parameter monitoring of its process units to determine the facility is in complete and continuous (24/7/365) compliance with all applicable rules and regulations at both the state and national level so that the public health and environment are protected at all times. Monitoring is a big concern. There is inadequate stack and CEMs for different toxic pollutants like dioxin, mercury, lead, cadmium, arsenic, beryllium, chromium, etc. to prove that Von Roll/WTI is complying with its permit special conditions and demonstration complete and continuous compliance with emission limits and MACT limits. In order to show complete and continuous compliance, there must be more stack monitoring and more ambient air monitoring. Title V can address both." (Tri-State)

Response to 2D:

Ambient air monitoring is for area air quality, that is, to demonstrate an entire area's (such as a county) attainment of the National Ambient Air Quality Standards (NAAQS) for criteria pollutants. The Title V permit does not include ambient air monitoring for a specific source or facility. Ambient air monitoring is not as effective in ensuring a facility's compliance with permit limits as is stack monitoring. Monitoring at the stack is used to measure and record emissions of constituents of concern from the source. Stack monitoring may be continuously recorded with CEMs for specific constituents (e.g., HCl, carbon monoxide, sulfur dioxides and particulate matter in the form of opacity), or may be conducted during discreet testing events when CEMs are not available for the constituent of concern (e.g., dioxin/furans and metals).

Parametric monitoring, the establishment of operational parameter limits during stack tests,

is used when a CEM does not exist for a particular pollutant such as dioxin/furans or metals. Parametric monitoring, using operational parameters, ensures the source (VRA/WTI) continues to operate in compliance for emissions at all times.

Based on the Fall 2000 studies conducted, there are no plans for additional ambient air monitoring at this time. Based on current technology, i.e., the monitors available on the market, we see no need for additional stack monitoring.

2E) "We are requesting additional perimeter monitoring around Von Roll/WTI, as well as additional stack and community air monitoring for all the metals, PM, HCL and dioxin. Von Roll/WTI must demonstrate full and continuous compliance with the emissions limits (dioxin, metals including mercury and lead, etc.) — instantaneously and annually. Ambient air monitoring and CEMs are a good way to determine if Von Roll/WTI is in compliance with its permit and any applicable state and EPA ambient air standards and emission limits. Title V can require that WTI demonstrate it's in full and continuous compliance with the use of stack monitors and ambient air monitors." (Tri-State)

Response to 2E:

The commentee is correct in that the Title V permit requires a facility to demonstrate full and continuous compliance with permit limits using stack monitoring, as well as parametric monitoring. The requirements are technology based and risk checked and are generally protective of human health and the environment. In addition to the Title V requirements imposed on all incinerators, results from trial burn and MACT testing establish facility specific operational parameter limits (OPLs) and, in some cases, emission limits, to be included in the RCRA and Title V permits.

VRA/WTI can demonstrate full and continuous compliance via:

- (1) stack monitoring for the constituents with certified CEMs available,
- (2) OPLs for those constituents that do not have certified CEMs available, and
- (3) annual testing for metals and dioxin/furan emissions.

There are currently no certified CEMs for dioxin/furans or metals available on the market.

Title V permits do not require ambient air monitoring for a facility. This includes perimeter monitoring. Data from perimeter monitoring, air monitors placed at the perimeter of a facility, become questionable when trying to determine the source given a sudden wind change or some other meteorological aberration.

In light of the above, Ohio EPA will not require additional stack monitoring of the facility and cannot include perimeter monitoring or ambient air monitoring in the Title V or RCRA permits. This does not mean that community air monitoring for constituents of concern may not be conducted in the future, only that it will not be included in the VRA/WTI Title V or RCRA permits.

- 2F) "The EPA must require the use of a dioxin continuous emission monitor as well as ambient air monitoring for dioxin. Hitachi makes a dioxin CEM, and a dioxin semi-continuous stack monitoring system (AMESA) is being used in Germany and other EU nations to prove compliance with dioxin standards." (Tri-State)

"EPA has determined that the risk is 10 times greater than previously acknowledged. In July 2000, the government released the findings of their latest dioxin reassessment, showing that the risk from dioxin is 10 times greater than previously acknowledged. In fact, the risk to humans for developing cancer from existing background levels ranges from 1 per 1000 to 1 in 100, if your diet consists of meat and dairy products. And if you live near of source of dioxin, such as an incinerator, the risk increases 2 to 3 times. This is cause for revocation of WTI operating permit. In the least, it is cause for recalculation of the dioxin risk from WTI and an emission limit reduction." (Tri-State)

"With the new information, the EPA must lower the Von Roll/WTI emission limit for dioxin, and to ensure that the facility is in complete and continuous compliance with their dioxin emission limit, we are requesting that EPA require a Dioxin CEM at Von Roll/WTI. We recommend the AMESA method. According to Pat Costner, Senior Environmental Scientist for Greenpeace International, "the AMESA system for the quasi-continuous monitoring of dioxin releases in incinerator stack gases is well proven and has accumulated a substantial record of successful application with solid documentation of the benefits of such quasi-continuous monitoring in comparison to the standard occasional 6-8 hour sampling period. While the development of other methods of continuous or quasi-continuous stack gas sampling and analysis is to be encouraged, there is no sound rationale for waiting for their development rather than using the AMESA system, which is already well-developed, widely used and well-proven." [See the official comments of Pat Costner for further explanation and discussion.] Hitachi also makes an in-stack CEM for Dioxin." (Tri-State)

Response to 2F:

See generally, *Response to 16D.3 on AMESA® and response to 16B.3 and 4.*

Regarding the request to lower the Von Roll/WTI emission limit for dioxin, the mass emission rate of PCDD/Fs have been restricted in the RCRA permit to approximately the same levels as those used in the risk assessment by establishing required minimum feed levels of activated carbon. The use of the Enhanced Carbon Injection System (ECIS) and the operating parameters in place to remove PCDD/Fs from the flue gas has resulted in dioxin emissions that are lower than the MACT dioxin limit. This has been demonstrated each year during the annual performance test. Consequently, incineration according to the permitted operating conditions and continued use of the ECIS will ensure lower than required dioxin emissions. In addition, the feed rate of carbon in the ECIS can be much more easily and frequently monitored than actual stack emission of PCDD/Fs which can

only be measured during stack testing.

2G) "According to Dr. Nuber, mercury is difficult to measure in ambient air. EPA must monitor the ambient air for mercury, but it is absolutely essential that Von Roll/WTI have a CEM for mercury that measures it directly in the stack." (Tri-State)

"In November of 2000, ETV Advanced Monitoring Systems Center scheduled tests for Mercury CEMs. At the time, five vendors were to participate in the first phase of the verification test for commercially available CEMs for mercury. The test was to be held at the Rotary Kiln Incinerator Simulator (RKIS) at EPA's Risk Management Research Lab at Research Triangle Park, NC. The second phase was to be conducted in 2002. Experimental mercury stack monitors are currently being tested by EPA contractors at several sites in the US. If the mercury CEM is still in the testing phase, testing can continue at Von Roll/WTI." (Tri-State)

"According to the US EPA: "An experimental continuous metals emission monitor is also installed, but that unit is not yet being used to demonstrate compliance with the RCRA permit. Problems with equipment reliability and with developing an appropriate test method to demonstrate accuracy (i.e., testing the continuous monitor against the more accepted stack sampling technique discussed in paragraph 'a, above) have caused delays in making this new monitor fully operational. Because WTI is not required to have or operate this equipment, this is not a violation of the permit." (Tri-State)

"We request that Von Roll/WTI be required to maintain a CEM for metals, whether it is the one that is presently being used at the facility, or one that is being tested at other US operations." (Tri-State)

Response to 2G:

Regarding ambient air monitoring, please see Response 2B above.

System removal efficiency (SRE) for all metals except mercury was established during the trial burn. At that time, it was determined that the incineration system did not have an adequate SRE for mercury and consequently, VRA/WTIs permitted feed rate must equal the permit emission limit at all times. Ohio EPA believes this control for mercury is protective of human health and the environment. Since the issuance of the draft renewal permit, VRA/WTI has demonstrated compliance with the MACT standard for mercury. In addition, the final renewal permit has hourly as well as annual feed and emission limits for mercury.

Regarding the commenters statement that a CEM for mercury be installed in VRA/WTIs stack, a certified CEM for mercury is not available on the market at this time. In addition, EPA does not interpret its regulations as allowing it to require a facility to install such a CEM. However, once the CEM becomes certified for use as an alternative to the established EPA test protocols and testing frequencies specified in the regulations, owners

and operators of these facilities will have greater incentive to consider installing such equipment.

A multi-metal CEM was temporarily installed at the facility as a pilot test project. However, attempts to develop an appropriate test method to demonstrate accuracy were unsuccessful. After repeated problems with equipment reliability, VRA/WTI ended their relationship with Thermo Jarrell Ash, the company developing the monitoring system. The equipment was removed from the facility over a year ago.

Please also refer to the document entitled *Response to Comments Received for Issuance of Draft Title V Air Permit for VRA/WTI, Columbiana County, dated September 25, 2003.*

2H) "A five-year study, published in the *New England Journal of Medicine*, has found that lead is harmful to children at concentrations in the blood that are typically considered safe. On April 17, 2003, Cornell University scientists reported that low lead levels, below those once thought safe, pose significant risk to children's cognitive functioning. Scientists say that children suffer intellectual impairment as a blood-lead concentration below the level of 10 micrograms per deciliter (mcg/dl) - about 100 parts per billion - currently considered acceptable by the Centers for Disease Control and Prevention (CDC). "We also found that the amount of impairment attributed to lead was most pronounced at lower levels," says Richard Canfield, lead author of the journal paper and a senior researcher in Cornell's Division of Nutritional Sciences. Most of the damage to intellectual functioning - and the scientists found it to be substantial - occurs at blood-lead concentrations that are below 10 mcg/dl. This is significant new information that is important to consider when setting lead emission limits for Von Roll/WTI, given it's location next door to a 400-student elementary school and in the middle of a neighborhood where these children live and play. The closest home is only 320 feet away. It is also important to consider that 1992 baseline testing of the children in East Liverpool showed that there was already a lead problem. The Clean Air Act requires that the NAAQS must be set to protect public health using an adequate margin of safety." (Tri-State)

"For these reasons: 1) New information shows that even low lead levels present a significant risk; 2) Von Roll/WTI's proximity to a 400-student elementary school; 3) Existing lead problem in the children of East Liverpool prior to Von Roll/WTI operation, and 4) Air inversions which trap lead pollution in the valley, EPA must lower the lead emission limit and must require both ambient air monitoring for lead as well as stack CEM for lead." (Tri-State)

Response to 2H:

See generally, Response to 16B.12 on the lead study.

Regarding 1992 testing that Ms. Swearingen mentioned, we would welcome the

opportunity to review whatever data Ms. Swearingen has available on this matter.

Please see the Response to Comment 2B regarding the request for ambient air monitoring and a stack CEM for lead.

- 2I) "Acid gas emissions like HCL (hydrogen chloride gas) that escapes through the acid gas scrubbing unit must be monitored and accounted for. How much HCl is released in Von Roll/WTI's Emergency Vent (bypass stack) that is 100% uncontrolled release? Have releases from the EV been modeled? What is the maximum ground level concentration for HCl and what were the predicted off-site concentrations? Were they considered in the risk assessment??" (Tri-State)

Reponse to Comment 2I:

Hydrogen chloride (HCl) is monitored at the stack via CEMs. VRA/WTI's incineration system does not include an emergency vent or bypass stack and consequently, no HCl is released via this mechanism.

Based on a maximum HCl emission established during the trial burn (0.032 g/sec) and a dispersion factor (0.91 $\mu\text{g}/\text{m}^3/\text{g}/\text{sec}$) reflecting the meteorology of the area, the risk assessment predicted and evaluated a maximum ground level HCl concentration of 0.029 $\mu\text{g}/\text{m}^3$ and an average value of 0.0093 $\mu\text{g}/\text{m}^3$. From these values and from the Reference Air Concentration value of 0.00175 mg/m^3 , the following hazard quotients were calculated for Subarea E1 (the area of maximum exposure):

Adult: .016

Young child: .06

School Age Child: .035

Since these predicted levels do not approach the hazard quotient value of 1.0 (a widely accepted safe exposure benchmark), the conclusion was that the ground-level impacts of HCl should not create a health threat.

Another way to report maximum ground level concentrations for HCl are as follows. The HCl limit, based on the Permit to Install issued by Ohio EPA, Division of Air Pollution Control, is 4 lb/hr. This value was modeled by the Ohio EPA under a SCREEN program using the actual airflow from stack testing at the facility. In running the model, the maximum expected concentration was 3.908 micrograms/cubic meter ($\mu\text{g}/\text{m}^3$) at a distance of 1416 meters from the facility.

- 2J) "We request more pollution and parameter monitoring conditions for HCl in the Title 5 Permit. We request that the EPA review HCl impacts during inversions and calm wind conditions of less than 5-7 mph. Even low volumes of this dangerous acid gas may pose health and property damage concerns in the immediate neighborhoods downwind of the facility. HCl is an aggressive acid. Such strong acids will attack and destroy human lung tissue resulting in increased infections, including colds, pneumonia, etc. If HCl can eat and corrode metals, you can imagine what it does to human lung tissue. Even low ambient air levels will contribute to adverse health

effects and corrosion-induced property damage. Citizens request that EPA require that the CEM data for HCl (along with all other CEM data) be made available for review by the public. Any and all releases of HCl are unacceptable since it has such a harmful effects on human lung tissue, even at remarkably low concentrations well below 1.0 ppm down to the low ppb range. To allow Von Roll/WTI to release even 17.5 tons (the Ross incinerator Title 5 emission limit) let alone 75 tons (the Von Roll/WTI Draft Title 5 emission limit) is unacceptable and a gross failure of the EPA to protect the public health of the community. We are demanding zero HCl emissions for more protective operation." (Tri-State)

"The emission limit for HCl in the Ross Incinerator Title 5 Permit, which is pretty much out in the middle of a field with no homes in sight, is 17.5 tons per year. On the other hand, the Draft Title 5 emission limit for HCl at the Von Roll/WTI incinerator, which is in the middle of a heavily populated neighborhood and next door to a 400-student elementary school is 75 tons per year. Given the serious adverse health impacts from exposure to this aggressive acid, we are demanding a zero emission limit as the most protective operation." (Tri-State)

Response to 2J:

VRA/WTI has redundant CEMs for HCl in the stack to record emissions and, in addition, has a pH monitor in the facility's Four Stage Wet Scrubber to monitor acid gas removal efficiency. The pH monitor triggers an automatic waste feed cutoff anytime the pH falls below a preset value. This acts as an OPL for HCl and further ensures compliance with emission limits at the stack.

The EPA considered the commenter's request to review HCl impacts during inversions and calm wind conditions of less than 5 to 7 mph. As mentioned in Comment 2I, the Ohio EPA, Division of Air Pollution Control, Central Office, modeled HCl values under a screen program using the actual airflow from the last stack test at the facility. The model takes into consideration various wind speeds and stability classes of the meteorology. This is called a full meteorology option which is in the air modeling program, specifically to address the issues of various wind speeds and conditions, as the worst case is not always light winds. There are five stability classes in the model, with wind speeds from 0 up to 20 meters/second (44 mph). The variations in wind speed did not negatively impact the maximum expected concentration of HCl and consequently would not negatively impact human health and the environment.

Regarding the request for EPA to require CEM data for HCl be made available for review by the public, there are no regulatory requirements for a facility to provide continuous emission monitoring data to the public. Although the Ohio EPA may have access to real time data via the CEMs, the quarterly emission reports which are required by law are how compliance is determined for a facility. These reports are available to the public.

Ross Incineration Services Title V emission limit for HCl is 32.89 lb/hr and 144 tons/year. VRA/WTI's draft Title V emission limit for HCl is 4 lb/hr and 75 tons/year. The lowest

emission rate of any pollutant that could be required would be "no detectable emissions". It is not technically feasible to achieve this value at this time and, it is not required by the regulations governing combustion units.

The impact of HCl on the community was evaluated as part of the risk assessment and not found to be a health concern.

2K) *"Several items in WTI's emissions from the Draft Title 5 Permit raise red flags, even if they are toxic air maximum allowable emission rates that have been approved. The EPA must take into consideration three things: 1.) Von Roll/WTI is in an extremely sensitive location in the middle of a residential neighborhood, 400 yards from a 400-student elementary school and 320 feet from homes; 2.) The 1997 risk assessment was flawed and inadequate, with too many errors, not enough data and too many uncertainties; 3.) We live in a valley with air inversions." (Tri-State)*

"There are air inversions 2 out of every three days that trap any pollutants you allow Von Roll/WTI to release. The 20% opacity is way too high, as are the mass emission rates for metals, PM, HCl and other contaminants. You must consider emission rates at the margin. You must consider existing air quality when establishing emission limits for Von Roll/WTI. It is not as if we live in a pristine environment here in the Ohio Valley. In fact, according the American Lung Association's Annual State of the Air 2003 Report, the Ohio Valley ranks 26th among counties for the dirtiest air in the nation. We are literally marinated in toxic air pollution. Due to the sensitive location of the incinerator, topped off by valley air inversions, health based standards MUST be used in setting permit limits. According to the EPA, "the RCRA permit was modified based on the results of that risk assessment. The RCRA permit, therefore, contains limits which were either verified by or based on the results of the risk assessment." Therefore, emission limits used in the Title 5 Permit must not be allowed to be any higher than in the RCRA Permit. Emission limits must actually be lowered in order to compensate for the inadequacies and flaws in the risk assessment." (Tri-State)

Response to 2K:

While VRA/WTI is required to comply with their Title V permit, the facility is also required to comply with the limits specified in the final renewal permit. In cases where there is a conflict between the two permits, the facility must follow the more stringent emission requirements. Regarding existing air quality for Columbiana County, the Ohio EPA Division of Air Pollution Control (DAPC) auditor for Northeast Ohio reports the quality of data for ambient air monitoring conducted by NOVAA passed all audits while they were the monitoring agency for the county. When the Ohio EPA replaced NOVAA as the monitoring agency, data was valid and passed audits with the exception of data collected between 1999 and 2002. A summary of air quality of Columbiana County per DAPC Central Office indicates that Lead, CO, NO₂, SO₂, and particulate matter less than 10 microns in diameter (PM10) levels are in attainment of the national ambient air quality standards. PM10 is a subset of the former Total Suspended Particulate (TSP) standard and is based on

evidence that breathing smaller particulate matter is more of a health threat than larger particulate matter. PM10 PSD increments were adopted on June 2, 1994. Columbiana County is currently designated non-attainment for the 8-hour ozone standard that went into effect June 15, 2004. VRA/WTI, however, is not a significant contributor to the area-wide emissions of NOx and VOC. Ohio EPA has considered air quality issues and the emission limits in the draft permit are considered to be appropriate and protective. As new information is made available, the director of Ohio EPA may, under Ohio law, modify the hazardous waste permit for cause. For effect of air inversions, please refer to comment 16A.12.

The commenter's allegations of perceived flaws in the 1997 U.S. EPA Risk Assessment are addressed in Category 16.

- 2L) "According to US EPA: "For pollutants such as PCCDs/PCDFs (i.e., "dioxins"), the incinerator is operated during the stack test in a way designed to maximize the emissions, providing an upper bound emission. In the case of WTI, the most important operating parameter affecting dioxin emission is the amount of activated carbon fed into the ductwork. Dioxins adsorb onto the activated carbon. The permit requires that this feed rate of activated carbon be no less than used during the original performance tests for the carbon system." (Tri-State)

Response to 2L:

Regarding the statement in the comment above, "The permit requires that this feed rate of activated carbon be no less than used during the original performance tests for the carbon system.", on May 8, 2003, and July 30, 2003, Ohio EPA and U.S. EPA, respectively, approved a permit modification request to reduce the carbon flow rate that was injected into the incineration train via the Enhanced Carbon Injection System (ECIS). Prior to approving the modification, the Ohio EPA required VRA/WTI to conduct a minburn stack test to demonstrate compliance with dioxin/furan emissions at the reduced carbon feed rates. The test was conducted during the week of October 21-25, 2002. The test results, which were the lowest dioxin emissions ever recorded for VRA/WTI, demonstrated emission levels well below all applicable limits established for hazardous waste incinerators during normal operating conditions. Terms and conditions were required as part of the modification approval. Language was included to require more frequent dioxin/furan testing than MACT requires and additional testing if certain conditions occur. These terms and conditions are in Attachment II of the previous State of Ohio Hazardous Waste Facility Installation and Operation Permit and are in section I (A).3. of the current permit.

As is the case with most incinerator performance testing, the September 2003 testing was conducted while the incinerator's air pollution control system was operated in a "detuned" mode, representing non-ideal operating conditions. Under that mode, dioxin/furan emissions were found to exceed MACT standards in one of the two test conditions, requiring re-testing under a less "detuned" mode of operation. A subsequent test program in December 2003 demonstrated acceptable dioxin/furan emissions when the incinerator was operated in the revised mode. The RCRA permit and new regulations under the Clean

Air Act now require Von Roll to operate the incineration system within the bounds established by the September and December tests in order to comply with the dioxin/furan requirements. In addition, the Clean Air Act regulations limit the actual emissions of dioxins/furans to 0.2 ng/dscm. This limit was also added to the State of Ohio permit on May 8, 2003.

Because further operational changes were still necessary to achieve compliance with required limits on semi-volatile emissions, additional testing was also conducted in March 2004 and April 2004.

2M) *"If the stack test is designed to maximize the emissions, providing the upper bound emission limit, then we request that the results achieved by WTI during their stack test for dioxin and all other toxic emissions be incorporated into their permit as permit emission limits. If they can achieve these emission rates --- and when they do, they brag about them --- then why not incorporate these numbers into their permit as emission limits? The results obtained during the test burn can obviously be achieved, and would be the most protective. Obviously, the lower the emission rates, the more protective of human health and the environment. If they can achieve these numbers, they why not incorporate them as emission limits?"*

Response to 2M:

Trial burns test the operation of the incineration system under worse case scenarios to establish operational parameter limits and conditions to achieve complete combustion of the waste fed and to comply with regulatory standards. The risk assessment examines risk to the community using the information obtained through trial burn testing. The emission limits or feed rates are adjusted when necessary to best protect human health and the environment.

When VRA/WTI conducts a stack test and reports emission limits well below their permit limits, this demonstrates that the incineration system is operating properly and as expected based upon the operational parameter limits and conditions. Stack tests are conducted under what are considered normal operating conditions compared to the worst case scenario of trial burns. If the EPA were to lower the emission limits to those values achieved during the testing, this would not allow for the normal variations in the system. These variations are to be expected considering the nature of the material being incinerated.

2N) *"What conditions will EPA incorporate into the Title 5 Permit to ensure that the amount of activated carbon fed to the ductwork during testing is maintained at the same level to control dioxin emissions during routine operations? How is compliance maintained? How often is the carbon changed? How often are the carbon boxes in the packed bed scrubber changed? How do you know? Without a Dioxin CEM, how do you know that WTI is maintaining the necessary carbon feed rate to control emission? Citizens request the requirement for a Dioxin CEM."* (Tri-

State)

Response to 2N:

Activated carbon is fed to the ECIS using a cascade screw feed system. The carbon is placed in a large feed hopper which discharges the carbon into a smaller metered hopper. The smaller metered hopper is continuously monitored by a load cell (scale). The carbon in the smaller hopper is then injected into the ECIS. The feed hopper has both a high level and a low level probe. The high level probe is the first alarm that the level in the feed hopper is getting low. The low level probe is the second warning. The alarms are both visual and audible.

The system utilized by the ECIS is a continuous monitoring system (CMS) which also continuously records the feed rate of the activated carbon. A load cell, which is part of the CMS, is calibrated monthly according to manufacturer's recommendations. Ohio EPA periodically reviews the operating records maintained by the facility which document the calibration of the load cell. The feed rate of the carbon is based on dioxin testing conducted at the facility and is protective of human health and the environment. If the activated carbon feed rate falls below a pre-set value, an automatic waste feed cutoff occurs and all hazardous waste feeds are terminated.

Activated carbon injected into the ECIS does not get changed. The activated carbon injected into the incineration system is collected by the ash collection system from the various air pollution control units which remove particulate matter from the flue gas stream. The ash is considered treatment residue and managed as hazardous waste.

There are no carbon boxes in the packed bed scrubber. The carbon boxes are used in the facility's vapor recovery system. The scrubber uses a bed of packing material (small plastic rings) to increase removal efficiency of acid gases. The packing is inspected, at a minimum, annually to determine if and when it needs replaced.

Please see Response 2B regarding the request for a dioxin CEM.

- 20) "Have constituents of the purple plume been analyzed more than once? What else is in the purple plume besides iodine? Are there exceedances of any other hazardous constituents during the purple plume? If the problem is iodine, why does the Enhanced Carbon Injection System (ECIS) not absorb the iodine before it has a chance to be released from the stack? If the carbon is not capturing the iodine, as it's supposed to, then perhaps it's not capturing the dioxins or mercury? Has an analysis been conducted to test this theory? I have tried for years, unsuccessfully, to obtain a copy of the 37 page Draft report/analysis NOVAA's Harold Strohmeyer was working on just before NOVAA was disbanded. In a December 1996 report, Mr. Strohmeyer noted an exceedance in mercury associated with the purple plume."
(Tri-State)

Response to 20:

During testing on October 28, 1997, as part of VRA/WTI's quarterly CEM audit, the plume at the stack was observed by Ohio EPA to have a purple tint. Since samples were being taken, VRA/WTI had their contractors analyze the samples for fluoride, bromide and iodine. The samples showed a clear absence of significant fluoride and bromide. However, iodine was detected. This analysis confirmed the theory proposed by the facility that iodine was responsible for the plume coloration. The discoloration of the normally white plume has been described as pink, magenta, and red in addition to purple.

Regarding the question of hazardous constituents analyzed for during the purple plume, the plume discoloration occurred during a CEM audit, testing was not being conducted for hazardous waste constituents. For the commenter's information, halogenated constituents such as fluoride, bromide, and iodine are not regulated as hazardous constituents. The discoloration of the plume is unpredictable and although the facility did try to induce discoloration during a scheduled testing event, they were unsuccessful. There are too many factors involved to artificially induce a purple plume.

As to why the carbon does not remove the iodine, the Enhanced Carbon Injection System (ECIS) is not designed to remove the iodine, but to remove dioxin/furans. The carbon is injected into the flue gas stream and becomes suspended allowing it to adsorb the dioxin/furans from the flue gas. Dioxin/furan removal efficiency of the ECIS is tested currently on an annual basis.

The commenter described a 37 page draft report/analysis that Harold Strohmeyer with the Northern Ohio Valley Air Administration (NOVAA) was working on just before NOVAA was disbanded. Ohio EPA has no evidence this report exists. In a December, 27, 1996 letter regarding plume discoloration signed by Mr. Strohmeyer, the only exceedance that was noted was for opacity. An exceedance in mercury was not mentioned in that letter. Ohio EPA contacted Mr. Strohmeyer by telephone in order to respond to Comment 20. During that call, Mr. Strohmeyer stated to the Ohio EPA that he did not prepare a 37 page draft report/analysis or any other report regarding a mercury exceedance associated with the purple plume.

3) ISSUES RELATED TO HEALTH (CANCER, LEAD, ASTHMA):

3A) "The results of a state funded study showed an existing lead problem in East Liverpool. In August 1992, two thirds of the children tested had high lead levels. The incidence of children with mercury in their urine more than doubled within the first 6 months of WTI's operation. No further medical testing for lead or mercury has been conducted since 1993." (Tri-State)

"In theory, the purpose of the Von Roll/WTI RCRA permit and the Title V Permit is to protect public health under the Clean Air Act and RCRA, but the lead levels in local children's blood raises the issue that health is not being protected. According to the Ohio Department of Health, 2/3 of the children tested during the baseline test

already had high blood lead levels. The lead emission rate must consider the impact of adding additional lead to the environment to further expose the children in the community. As for mercury, within the first 6 months of WTI operation, the number of children with mercury in their urine doubled." (Tri-State)

Response to 3A:

The commenter did not specify which state funded study they were referencing. However, in 1992 the Ohio Department of Health (ODH) and the East Liverpool Health Department (ELHD) began health studies as a result of concerns expressed by the community. The studies were conducted over a two-year period, from August 1992 through December 1994. The Ohio Department of Health, Bureau of Environmental Health and Toxicology, released a report which documented their findings entitled "East Liverpool Health Study", dated August 15, 1995.

To summarize this report, the operation of the WTI incinerator did not cause East Liverpool children to have higher levels of lead or mercury in their bodies, based on blood and urine samples. The comment that two thirds (or 66%) of the children had high blood lead levels is simply not accurate. While approximately 9% of the participants were found to have blood lead levels of concern, there were actually decreases observed over time in the blood lead levels of the consistent participants in the study (page 7). Mercury levels did not change significantly over time (page 14). Soil and air samples collected as part of that study did not show evidence of significant impact by the WTI facility (page 17).

The report discusses the high percentage (66.7%) of houses in the area built before 1950 and associates older homes with lead-based paint. The 66.7 percent of houses in the area which are associated with lead-based paint may be the two-thirds value the commenter is referring to. In relation to blood lead levels that were observed, the report suggested that "many East Liverpool children are being exposed to lead from paint used in and on the home." Of the initial 424 children in the lead study, there were 45 children (~9 %) who tested "high" for lead with blood levels at greater than or equal to 15 ug/dl. Of those 45 children, all but one of their homes were found to contain areas of lead paint. The report concluded that "lead exposure from the home is the most likely source of the lead responsible" for the elevated blood levels, and the "largest contributor to these children's lead levels is lead-based paint" (pages 8, 10).

The same report describes the results of urine testing for mercury, conducted five times over a 24-month period of time. Despite attempts by ODH, repeat participation in testing was poor. 152 children participated in the initial testing, but only 56 children participated in testing at all of the five required times (page 12). There were no detectable levels of mercury found in 90% or ~136 of the initial 152 urine samples. Despite the small number of consistent participants, there was no indication that urine mercury levels had changed significantly over time (page 14). All of the 56 consistent participants had urine mercury levels of less than 9 micrograms per liter (ug/L) throughout the 24-month testing period. Urine mercury levels below 20 ug/L were considered normal.

The commenter questioned the permit emission rate for lead in relation to blood lead levels in children within the community. Permits are written with the intent of protecting public health by setting feed restrictions and emission limits, and by ensuring a facility's compliance with the regulations. Additional comments and responses regarding permit limits and how those limits are developed can be found in the responses to comments in Categories 2 and 16.

A copy of the August 15, 1995 report may be obtained from ODH or the ELHD. Ohio EPA is very supportive of additional health testing. Requests for additional studies and/or testing must be addressed to ODH and the ELHD. Mr. Robert Indian at ODH may be reached at 614-644-7025 and Mr. Gary Ryan at ELHD may be reached at 330-385-7900. The Ohio EPA is providing a copy of this responsiveness summary to each of these individuals.

3B) *" _____, a plaintiff in Judge Aldrich's TRO who fit EPA's profile of the Maximally Exposed Individual (MEI), died of breast cancer at the age of 55 in June, 1998. She believed her cancer was triggered by the presence of WTI in our community. WTI was able to get the court of appeals to dismiss the federal court ruling, based on lack of jurisdiction, not on lack of evidence of risk. _____ was a local subsistence farmer who lived in the vicinity of the incinerator and ate homegrown meat, vegetables and dairy products from her 100-year old family farm. As such, she fit EPA's profile of the "MEI" --- or maximally exposed individual. _____ died of cancer in 1998 at the age of 55."*¹ (Tri-State)

Response to 3B:

Questions regarding cancers in the area are being referred to ODH and the ELHD. It would be difficult to determine with certainty whether the presence of a facility could trigger cancer in an individual. It is also unclear from the comment whether Ms. Allison's cancer was pre-existing and if she felt the operation of VRA/WTI caused her cancer growth to accelerate. Many cancers are known to have a relatively long latency period between the onset of the cancer growth and the discovery. It is also extremely difficult to assess individual experiences or personal exposures which may be related to an individual developing cancer. Because of that difficulty, determining the cause of cancer is often not possible.

When determining risks associated with cancer, the most conservative approach is generally used when calculating values in risk assessments. In addition, the risk assessment conducted for the VRA/WTI facility by U.S. EPA evaluated potential impacts from the facility's operation on several categories of individuals, including subsistence farmers. The exposure estimates for the various categories of individuals are believed to be conservative values, meaning there are layers of protection built into the values as part of the risk assessment calculations. The risk assessment did not indicate significant

¹For privacy reasons, names have been omitted.

cancer risks associated with operation of the facility. More comments related to cancer rates are provided in the Response to Comments in Category 3 and Category 16. See also response 15A regarding Greenpeace versus Waste Technologies Industries, 93CV0083.

3C) "Citizens have documented over 200 new cases of cancer near the incinerator since it began burning in 1992. Donna Danver and the husband of Becky McKinnon, two life-long residents and long-time WTI opponents who live just yards from the incinerator, were both recently diagnosed with cancer. In the past few years, we've seen children suffering from rare forms of cancer. There've been two young boys, both under age 3 at the time of diagnosis, who've been forced to have an eyeball removed because of retinoblastoma, a rare form of eye cancer. The expected incidence rate of retinoblastoma is 1 in 250,000. East Liverpool, with a population of only 13,000, has two cases, both in the vicinity of the incinerator. One of the little boys lives just 800 feet from WTI. There's a young girl with another rare cancer, rhabdomyosarcoma, and four cases of male breast cancer. Last year, a 10-year old girl had a hysterectomy because of uterine cancer. Just this summer, an 11-year-old girl died from a cancer that's never been seen before. On the young girl's street, which is two blocks from WTI, there've been 5 other kids with cancer. Across the river, a young child has a serious case of scleroderma, only one of about 700 in the nation." (Tri-State)

3D) "There was a news story some time ago about 2 children that had a rare kind of eye cancer. It was extremely rare for one child to have this condition let along 2 in close proximity. That also sickened me." (Cuthbert)

Response to 3C and 3D:

Ohio EPA personnel are concerned about the incidents of cancer which the commenter has described. Ohio EPA strongly encourages the commenter to provide the specific details of these cases to ODH and the ELHD. East Liverpool, particularly in the area along the Ohio River, is heavily industrialized with many facilities which could potentially be sources for exposures and emissions to the residents. As always, Ohio EPA will work with ODH and the ELHD to the greatest extent possible in evaluating any of these facilities which are cause for concern.

As part of the permitting process for VRA/WTI, Ohio EPA has set incinerator feed limits and emission limits for the facility. These permit limits were set conservatively to be protective of human health and the environment. Ohio EPA has also placed many restrictions upon VRA/WTI as an operating facility to ensure that exposures are minimized to the greatest extent possible.

3E) "Asthma and respiratory problems appear to be epidemic in the area. While citizens have never collected information on incidence, we have seen more and more folks complaining of respiratory ailments since Von Roll/WTI began operating. _____, son of _____, who lives just 800 feet behind Von Roll/WTI, never had asthma

or sinus problems while growing up until he moved back home after college. He is now so sensitive that he cannot function for a day without taking some kind of allergy/sinus medication. _____'s biology teacher just this week reported the same experience --- she never previously had any kind of respiratory problems, but now she has serious sinus and allergy symptoms."² (Tri-State)

Response to 3E:

It is suggested that ODH and the ELHD be contacted for further information regarding incident rates of asthma and respiratory problems in the area. Ohio EPA has not been provided with any information to substantiate the statement that asthma and respiratory problems appear to be epidemic in the area.

In general, respiratory problems may be associated with ozone levels and fine particulate matter which is airborne. Ohio EPA, DAPC installed and maintains ambient air monitors for fine particulate matter and sulfur dioxide levels in locations in Columbiana County in accordance with federal siting requirements. These ambient air monitors are not facility-specific, but instead collect data which is used to evaluate ambient air quality for the entire county.

Facility inventory data (which is facility-specific) indicates VRA/WTI is a relatively small source for emissions of ozone precursors and airborne particulate matter in comparison to the total amount from all facilities in Columbiana County. Facility inventory data can be accessed from the Ohio EPA web site (www.epa.state.oh.us).

3F) "On a more personal note, I am currently undergoing IV chelation for high levels of lead, mercury and arsenic. Prior to the high levels found during testing in 2000, I have never had high levels in past testing. I do not have any mercury amalgam filling in my mouth where from which mercury could be leaching. We have a reverse osmosis double filter water filtration system in our house for all cooking and drinking. I always carry with me bottled water that has been treated by distillation and reverse osmosis, so I doubt the arsenic is coming from the water I drink. I have had 7 treatments, and need a total of approximately 40." (Tri-State)

Response to 3F:

Ohio EPA personnel are concerned regarding the commentor's treatment for high levels of metals in the blood. Ohio EPA strongly encourages the commentor to contact the appropriate health agency in West Virginia. Ohio EPA also suggests that the commentor have water samples analyzed, both before and after any personal treatment equipment. The West Virginia EPA will be able to provide a list of labs certified to conduct analysis on drinking water supplies. There are many other factors besides the operation of the

²For privacy reasons, names have been omitted.

VRA/WTI facility which could contribute to individual public health issues in the East Liverpool area and surrounding communities.

4) ISSUES RELATED TO ACCIDENT SCENARIOS:

- 4A)** "According to WTI, a worst-case accident, releasing 100,000 pounds of toxic chemicals could threaten the population within 3.9 miles of the facility. The US EPA also failed to take into account additional accident risks posed by the transport through East Liverpool of 20 trucks a day carrying ultra-hazardous substances to be burned at WTI." (Tri-State)

Response to 4A:

The accident analysis referred to is the analysis required under Section 112(r) of the Clean Air Act ("CAA") for most industrial plants. It is different from the 1997 U.S. EPA Risk Assessment that was conducted as part of the RCRA evaluation under the RCRA permit, and follows different protocols. The specific "worst case" protocols required for a CAA 112(r) program risk analysis (also referred to as a Risk Management Plan or "RMP") use very conservative assumptions and frequently result in predictions of impacts extending out to great distances. A number of facilities (> 50) in Ohio have similar and in some cases significantly greater impact distances associated with onsite hazardous substances. The CAA 112(r) program does not use the results of these analyses for the purpose of prohibiting operations at industrial plants. Rather, the results are used to inform and advise the appropriate emergency planners and response agencies, allowing them to prioritize and plan for various industrial accidents at the industrial sites in their geographic areas.

The RMP program requires affected facilities to assess the potential risks posed by an accidental release from the facility, and to develop a plan that minimizes consequences of such a release. This plan is to include hazard assessments, management programs, and emergency response programs.

It is true that Von Roll's Risk Management Plan under CAA 112(r) does not address truck accidents. The protocols currently used for RMPs do not include an evaluation of risks associated with transportation of raw materials, products, or wastes to and from the facility. On the other hand, the site-specific accident analysis conducted as part of the U.S. EPA's 1997 Risk Assessment did evaluate spills and fires associated with truck accidents for wastes en-route to the Von Roll facility (Volume VII - Accident Analysis: Selection and Assessment of Potential Release Scenarios).

5) ISSUES RELATED TO ALLEGATIONS OF WRONGDOING:

- 5A)** "In 1996, three executives of Von Roll, including its former managing director Heinz Frech, were found guilty in Switzerland's highest court for illegally exporting war materials to Iraq believed to be for the construction of Saddam Hussein's "super

gun". The sale of this material occurred in 1990, just months prior to the Gulf War." (Tri-State)

- 5B) "In a 1997 investigation by the Beacon Journal, it was reported that Von Roll/WTI made payments on the side to employees of the North Ohio Valley Air Authority (NOVAA), the regulatory agency responsible for monitoring air emissions from the facility." (Tri-State)
- 5C) "WTI lobbyist, Anthony Fabiano and the V Group." (partial statement in the Tri-State outline, Section II. D.)
- 5D) "Issues relating to conduct of WTI's ultimate parent company, Von Roll, A.G., alleged Von Roll connections with an admitted Mafia Capo, Thomas Petrizzo, decision-makers who approved the relationship with Thomas Petrizzo and their responsibilities involving WTI." (partial statements in the Tri-State outline, Section II. A., A.1., A.1.a)

Response to 5A through 5D:

On February 13, 1998, the Ohio Hazardous Waste Facility Board (Board) authorized the transfer of the hazardous waste permit (originally issued to WTI in 1984) to Von Roll America (VRA). In so doing, it deliberated upon various aspects of VRA's history of compliance with environmental and other laws. During this process, the Board considered information presented regarding alleged or proven illegal dealings between VRA and its sister companies with Iraq and with NOVAA. The Board's decision on this matter was appealed to both the Franklin County Court of Appeals and the Ohio Supreme Court. The Court of Appeals (case # 98AP-220) affirmed the Board's decision on December 28, 1998. The Ohio Supreme Court declined to hear the case (1999).

ORC Section 3734.44 stated then, as it does today, in relevant part that:

"Notwithstanding the provisions of any law to the contrary, no permit or license shall be issued or renewed by the director of environmental protection, the hazardous waste facility board, or a board of health:

- B) If any individual or business concern required to be listed in the disclosure statement or shown to have a beneficial interest in the business of the applicant or the permittee, other than an equity interest or debt liability, by the investigation thereof, has been convicted of any of the following crimes under the laws of this state or equivalent laws of any other jurisdiction:"(21 crimes are listed)*

Under this standard, the Board considered the information relating to Iraq and NOVAA including the 1997 report prepared by the Environmental Background Investigation Unit (EBIU) of the Attorney General's Office. The Board concluded that VRA/WTI, or a sister or parent company, had not been convicted of a disqualifying crime listed in ORC Section 3734.44(B) and no basis existed to revoke VRA/WTI's permit or to deny a modification to

transfer ownership to VRA.

As a result of the Board's decision and subsequent affirmation by the Franklin County Court of Appeals, the 1996 Iraq issue and the 1997 NOVAA issue have been adequately addressed. These issues are not considerations of Ohio EPA action on VRA/WTI's renewal permit.

- 5E) "In July 2002, following an extensive German investigation of corruption involving waste incineration projects, Rene Luthy, one of Von Roll chief executives, was arrested on criminal bribery charges. He was released from jail in August after Von Roll posted a bond of 200,000 Euros. In March 2003, following his resignation from Von Roll, it was reported in Switzerland that René Lüthy was convicted of bribery conducted during the past decade while he was a top Von Roll executive and director of the group's major United States subsidiary that handles waste incineration." (Tri-State)
- 5F) "Issues relating to illegal conduct by Union Bank of Switzerland ("UBS") at a time when UBS held a controlling interest in Von Roll, the alleged laundering of Colombian drug money by UBS vice director Josef Oberholser, the shredding of Holocaust era documents in violation of Swiss law after denying their existence." (partial statements in the Tri-State outline, Section II. B., B.1, B.2)

Response to 5E and 5F:

The draft renewal permit was premised, in part, on the acceptance of a May 2002 EBIU report to Ohio EPA that there were no disqualifying crimes to warrant denying the renewal permit under the ORC 3734.44(B) standard. A subsequent June 2004 EBIU report to Ohio EPA also indicates no disqualifying crimes to warrant denying the renewal permit. To the extent that new disclosures are brought to light, the EBIU will incorporate them into their next update report and provide the Ohio EPA with their findings and recommendations. The Agency will have all its regulatory options available and will take the appropriate action at that time.

- 5G) "Issues relating to Counterclaims by WTI in Hager v. Waste Technologies Industries, No. 97-CV-34, Columbiana County Ct Common Pleas." (partial statement in the Tri-State outline, Section II. E.)

Response to 5G:

The comment refers to an action originally filed in the Columbiana County Court of Common Pleas (Case No. 97-CV-34) against Waste Technologies Industries by neighboring property owners asserting claims of trespass, nuisance, and negligence. In June 2000, the Common Pleas court granted summary judgement in favor of WTI and dismissed the property owner's complaints in its entirety. This decision was appealed to the Seventh District Court of Appeals of Ohio. On June 27, 2002 the Court of Appeals rendered a decision sustaining the lower court decision (2002 WL 1483913 (Ohio App. 7

Dist.)). Ohio EPA was not a party to either proceeding. The Agency is not aware of the issues relating to counterclaims made by WTI in this case and how it may potentially impact the renewal determination. The Court decisions themselves present no justification warranting Ohio EPA denial of Von Roll's renewal application.

6) ISSUES RELATED TO OWNERSHIP:

6A) "Because of legal, ethical and liability concerns, ownership of the facility has been a critical issue in the case of the East Liverpool incinerator. In 1990, the permit was sold. It was then that Von Roll, a multinational Swiss corporation, acquired sole ownership and operational control of the incinerator. Facility construction did not begin until 1991, so the only thing that was sold in 1990 was a permit. It is illegal to sell or trade a permit as a commodity. It violates the heart of federal hazardous waste law. Information about changes in ownership and operational control was not disclosed by Von Roll until inquiries during a 1992 Congressional hearing. In September 1993, after an extensive investigation into WTI's ownership, the Ohio Attorney General's report concluded "WTI's changes of ownership have resulted in unlawful installation and operation of the facility by the current owner, in violation of the three Ohio provisions of law which prohibit ownership and operation without a permit." The EPA fined WTI \$64,900 for failure to notify the US EPA in advance of adding Von Roll (its Swiss owner) to its permit as an incinerator operator." (Tri-State)

6B) "The fairness, Adequacy, and legality of substantive and procedural decisions with respect to the WTI incinerator by EPA and other governmental bodies, issues relating to WTI permit violations:

- 1) regulations and procedures in issuing WTI's RCRA permit to operate without securing the landowner's signature and with full knowledge of the landowner's identity; 2) whether EPA exhibited favoritism to WTI in unilaterally modifying WTI's CRCA permit to include the landowner as a co-permittee and/or defending and litigating such unilateral action even as against the former objection of the landowner; 3) whether the original WTI partnership ceased to exist under Ohio law when WTI made changes in its partnership; 4) whether EPA's decision to modify WTI's RCRA permit by adding Von Roll (Ohio), Inc. as an operator and issuing a modest civil fine rather than revoking the permit when WTI made changes in its partnership without making an advance request to EPA for permit modification; 5) whether Von Roll America, Inc. unlawfully installed and/or operated the hazardous waste incinerator without a valid permit under Ohio law as a result of changes in the WTI partnership; 6) whether the Ohio EPA exhibited favoritism to Von Roll/WTI by failing to revoke WTI's state permit to operate when the Ohio Attorney General formally advised OEPA that "WTI's changes of ownership have resulted in unlawful installation and operation of the

facility by the current owner” (partial statements in the Tri-State outline, Section III., III.A., III.A.1 through III.A.6)

Response to 6A and 6B:

The Ohio hazardous waste rules contain no legal prohibition to the sale and transfer of a hazardous waste facility and/or permit. It is legal to sell a permit, and selling a permit does not violate federal or state hazardous waste laws. Comments relating to the propriety of the original transfer of ownership to VRA, the concerns raised in the Ohio Attorney General's 1993 investigative report, Ohio EPA's actions concerning the WTI partnership's transfer have all been dealt with by Ohio EPA's transmittal of WTI partnership's modification request to the Ohio Hazardous Waste Facility Board and the Board's 1998 decision (as explained in Ohio EPA's Response to comments 5A through 5D and as detailed in Response to comments 6C through 6S). The actions by agencies and the courts of the State of Ohio have addressed the Commentator's question of whether WTI's alleged violation of law (on transfers of ownership) is appropriately addressed or vigorously pursued. As such, comments raising issues that have been addressed in previous state actions are not determining factors in deciding whether to issue a renewal of the hazardous waste permit in the current instance.

- 6C) "The name Enron is now synonymous with corporate corruption, accounting tricks, influence peddling and environmental negligence. Fictional investment partnerships were part of an elaborate accounting shell game used to get around laws and regulations. (CorpWatch, 5/9/02) The Powers Report, an in-house investigation, concluded that about 4,000 partnerships were part of a corrupt shell game. (The Examiner, 2/8/02) A top Enron executive tried to fire one of their attorneys who tried to question all the partnerships. According to the San Francisco Examiner, "Our way or the highway" was the theme of Enron's corporate culture. According to an AP news account, failed Enron Corporation used schemes of dizzying complexity to shrink its tax payments, inflate its income and overwhelm the IRS." (Tri-State)
- 6D) "The many stories about how Enron used a complex corporate shell game to increase profit, skirt the law and to generally stay in business sounded all too familiar to citizens involved in monitoring the activities of Von Roll/WTI." (Tri-State)
- 6E) "In the late '80s and early '90s, corporations obviously got away with this kind of stuff, as exemplified by Enron. Even financial regulators were duped, so it's no wonder environmental regulators might not get it. But today, with all the news of Enron and other companies that have used similar corrupt schemes, there's no excuse for not taking a closer look at companies who are playing fast and loose with corporate rules and engaging in elaborate corporate shell games in order to skirt the law. This kind of activity should be a red flag. One Enron article in the Guardian was titled, "When greed is fact and control is fiction" You, as regulators, cannot believe in the fiction of control and ignore the facts." (Tri-State)
- 6F) "At least 44 different companies were discovered during investigations into WTI's

ownership and operational control. Accounts of the Enron scandal are De Je Vu for citizens familiar with Von Roll/WTI's corporate flow chart. And we are just now learning about more recent changes in the corporate structure of Von Roll/WTI, with the involvement of Heritage as a possible owner/operator. The General Accounting Office (GAO) investigation ordered by Vice President Elect Gore concluded "Under EPA's regulations, the grounds for terminating a permit include noncompliance by the permittee with any condition of the permit." (Tri-State)

- 6G) "Remember the 44 different companies involved with Von Roll/WTI investigated by Ohio Attorney General Lee Fisher? We are just now learning about more recent changes to in the corporate structure of Von Roll/WTI, with the involvement of Heritage as the new owner." (Tri-State)
- 6H) "According to an October 16, 2000 PR Newswire press release issued by Von Roll America, Inc. (VRA), Heritage Environmental would be acquiring an interest in VRA's commercial hazardous waste incineration facility. VRA publicly announced an agreement with Heritage Environmental Services, LLC, whereby Heritage would assume an ownership stake of 51% with Von Roll holding 49%. According to the Von Roll press release, the agreement is subject to Ohio's permit transfer process." (Tri-State)
- 6I) "Also on October 16, 2000, Heritage was announcing their acquisition of the WTI facility on their web site (<http://www.heritage-enviro.com/news.htm#1016>). Heritage announced the agreement this way: "Heritage to acquire Von Roll's Liverpool, OH Facility: Von Roll America, Inc. and Heritage Environmental Services, LLC are pleased to announce the initiation of the permit transfer process administered by the Ohio Environmental Protection Agency which will allow Heritage to acquire a majority interest in Von Roll's East Liverpool, Ohio hazardous waste incineration facility. Heritage President, Dr. Ken Price, expressed his pleasure in the successful closure of this new relationship with Von Roll..."
- 6J) "An October 16, 2000 AP article on the sale of WTI to Heritage quoted Von Roll America, Inc.: "*Indiana company plans to acquire controlling stake in incinerator.* EAST LIVERPOOL, Ohio (AP) - An environmental services company plans to acquire a controlling stake in an eastern Ohio hazardous waste incinerator, operator Von Roll America Inc. said Monday. The deal with Indianapolis-based Heritage Environmental Services LLC is subject to regulatory approval. Heritage Environmental would assume a 51 percent ownership stake in the Columbiana County incinerator, with Switzerland-based Von Roll America holding 49 percent." (Tri-State)
- 6K) "In 1994 the parent company Von Roll and Heritage Environmental Services entered into a joint venture. Together, they created the respondent Von Roll America, Inc., they gave Heritage a 51% controlling interest, and operational control of the new corporation, and of WTI. United States Department Of Labor, Office Of

The Administrative Law Judges, Complainant Donna Trueblood's Pre-Hearing Statement. Page 15. Case No. 2002-WPC-3, 4 and 5. June 2002." (Tri-State)

- 6L) "Within the last two years, Heritage LLC decided to acquire an ownership interest in VonRoll America, Inc. (Zaengerle Dep., 21, 27-28). "Heritage LLC created a separate company called Heritage WTI LLC to "hold" its interest in VonRoll America. (Zaengerle Dep., 27-28). VR USA Holding ultimately sold 51 % percent of its ownership interest in VonRoll America to Heritage WTI LLC. (Zaengerle Dep., 21) United States Department Of Labor, Administrative Law Judge Donna L. Trueblood, Complainant, v. Von Roll America, Inc. D/B/A WTI, Heritage Environmental Services, Respondent Heritage Environmental Services' Post - Hearing Brief December 2002." (Tri-State)
- 6M) "Heritage Environmental Services purchased 51% of WTI. It is rumored that his transaction may have taken place as early as 1994. [See statement above from US DOL case 2002-WPC-3, 4 and 5. Complainant Donna Trueblood's Pre-trial hearing statement.] In announcing the change in ownership, both Heritage and Von Roll acknowledged that the transfer was subject to Ohio's permit transfer process. Originally Von Roll and Heritage had publicly announced that Heritage Environmental Services, LLC was acquiring a 51% controlling interest." (Tri-State)
- 6N) "According to Rudolf Zaengerle, Executive Vice President of VonRoll AG in Switzerland, Heritage LLC decided to acquire an ownership interest in Von Roll America, Inc. sometime in 2000. In his deposition in the Donna Trueblood case, he testified that Heritage LLC created a separate company called Heritage WTI LLC to "hold" its interest in Von Roll America and that VR USA Holding ultimately sold 51% of its ownership interest in Von Roll America to Heritage WTI LLC." (Tri-State)
- 6O) "It is our current understanding that Heritage Environmental Services/WTI, LLC sold 1% of their 51% ownership to Heritage Environmental Services, LLC. In an attempt to get around the regulatory process involving permit transfer, they devised a scheme - a corporate shell game. They created a brand new corporation, so that now there are two Heritage corporations involved. Does any of this sound familiar? Does it harken back to the early '90s when Von Roll played this game before. Even though the Attorney General of Ohio determined that "WTI's changes of ownership have resulted in unlawful installation and operation of the facility by the current owner in violation of three Ohio provisions of law which prohibit ownership and operation without a permit," EPA allowed Von Roll to interpret the law, saying that since no "outside" company was involved, there was no change in ownership. In an August 17, 1995 letter to the Tri-State Environmental Council, EPA Region 5 Administrator Val Adamkus acted as a mouthpiece for Von Roll in stating, "[T]he changes to the WTI partnership did not involve the addition of outside companies into the partnership. ...The point we tried to make in the August 1993 fact sheet is that they are closely related to the original partners rather than outside companies and this fact supports the confusion that the changes to the WTI partnership have

been technical in nature." No less than three times in that letter, Mr. Adamkus argued that it wasn't a change in ownership because there was no addition of an "outside" company." (Tri-State)

- 6P) "Heritage is definitely an outside company. And if the argument about "relatedness" still holds true, then it doesn't matter if two different Heritage corporations each own a piece of the WTI facility, together, they still own 51%, which is a controlling interest. EPA and Von Roll/WTI can't have it both ways. As announced by both Heritage and Von Roll in October 2000, the facility is now owned by Heritage. Heritage should be required to go through the permit transfer process just as they announced they would." (Tri-State)
- 6Q) "And lifted from Heritage's web site in 1997 (three years before the first public report of the sale): Our East Liverpool, Ohio incinerator facility represents the state of the art in the United States and is operated by our detail-driven staff." (Tri-State)
- 6R) "We need to know the truth about who owns the WTI facility. No permit --- not a Title V permit and not the renewal of the RCRA hazardous waste permit --- should be granted until a full investigation is conducted into who really owns this facility. No decision should be made and the process should be halted now until after the Ohio Attorney General releases the results of his updated background investigation into the true owner/operator of the Von Roll/WTI incinerator. EPA should begin the process of rewriting a second Draft Title 5 Permit after the release of the Attorney General's updated background investigation into who really owns the incinerator and who is operating it. Von Roll/WTI is required to disclose in July 2003." (Tri-State)
- 6S) "Von Roll America, Inc., has not made a full and complete public accounting of its ownership and control." (SOC)

Response to 6C through 6S:

These comments raise the concerns about the recent changes in the corporate structure at Von Roll/WTI and the uncertainty of Heritage as a potential new owner as a basis for delaying a decision on the renewal permit until the Ohio Attorney General releases an updated background investigation report "into the true owner/operator of the Von Roll/WTI incinerator."

It is Ohio EPA's understanding that Heritage Environmental Services /WTI, LLC currently owns 51% of the Von Roll America, Inc. (VRA) stock. For purposes of ownership as it relates to the Hazardous Waste Permit, Von Roll America, Inc. is the owner. According to OAC 3745-50-10, an owner is defined as a "person who owns the facility or part of a facility." A facility or hazardous waste facility, according to this same rule, is "all contiguous land, and structures, other appurtenances, and improvements on the land, used for treating, storing or disposing of hazardous waste." Therefore, VRA owns the facility.

Ownership of stock in a company was not contemplated in the regulations. Since the Ohio Hazardous Waste Installation and Operation Permit currently lists VRA as the owner and operator of the East Liverpool facility, no permit modification is necessary.

Heritage Environmental Services/WTI, LLC, however, was looked at by the AGO's Environmental Background Investigation Unit (EBIU), since VRA's facility is an offsite hazardous waste facility. The AGO's EBIU investigation would primarily look at the key employees of Heritage Environmental Services/WTI, LLC to see if they have any potentially disqualifying crimes as listed in Ohio Revised Code (ORC) 3734.44(B). The AGO completed its report on June 30, 2004 and transmitted that to Ohio EPA on July 8, 2004.

Since changes to key employees, e.g. employee retirement, new hires, etc., occur regularly, the Environmental Background Investigation law (ORC 3734.44) requires applicants to submit annual disclosure statements and thus the AGO's EBIU is required to provide the Director of Ohio EPA with annual updates to its original investigative report. If the results of an update indicate action is warranted, the Director will take action as deemed necessary at that time. The AGO-EBIU report covers the 2002-2003 updates and no disqualifying crimes were identified.

6T) "In a 1996 letter, the citizens requested that the U.S. Department of Justice (DOJ) render a determination as to the correctness of Ohio Attorney General (OAG) Lee Fisher's legal conclusion that Waste Technologies Industries (WTI) has no permit and is operating illegally. In their letter to the DOJ, the citizens quoted a letter from the OAG's office which stated "WTI's changes of ownership have resulted in unlawful installation and operation of the facility by the current owner, in violation of the three Ohio provisions of law which prohibit ownership and operation without a permit."

"In their November 27, 1996 response to the citizens concerning the OAG's findings, the DOJ wrote, "The OAG Report concluded that under Ohio partnership law, the WTI partnership transactions resulted in successive dissolution's of the original WTI partnership and ultimately the formation of one new corporate entity. ...[T]he WTI facility is currently owned and operated by one corporate entity which is different from the partnership entity that was issued a permit in 1985."

"As a general rule, the Department of Justice does not second-guess the regulatory decisions of a regulatory agency regarding a program the agency has been authorized by Congress to administer; therefore, we will not review EPA's regulatory determination concerning the effect of the OAG report on the validity of the federal RCRA permit. It would be inappropriate for the Department of Justice to review an opinion of the Ohio Attorney General regarding matters of Ohio state law."

"The DOJ readily acknowledged the OAG's conclusion that the incinerator is owned and operated by an entity that is not the permittee. The DOJ also admitted that it

would be inappropriate to review the OAG's opinion regarding matters of Ohio state law. Who better to interpret Ohio state law than the highest law enforcement officer in the state, the OAG? It does not make sense for those outside the state to interpret state law, especially when the question is one of corporate form and considering that corporations are creations of the state. The DOJ rightly argued that the best person to interpret Ohio law is the Ohio Attorney General. But the federal EPA interpreted Ohio state law, reaching an opinion that is contrary to that of the legal determination of the OAG."

"The U.S. EPA never considered the Coleman memo in their analysis of WTI's ownership changes. As concluded by the OAG, the WTI partnership (the original permittee) no longer exists. Von Roll has built and is operating the incinerator illegally without a permit, as outlined in the OAG's 1993 background report. The November 27, 1989 "Coleman memo" shows that Von Roll was aware of the legal ramifications of WTI partnership changes before they completed those changes. Von Roll appears to have understood that the changes in the WTI partnership (changes that ultimately occurred) would trigger the Ohio legal requirements in the permit modification process which they vigorously sought to avoid. Von Roll made the changes anyway without notifying the regulatory agencies or seeking the legally required agency approval. The memo memorializes the discussions that took place between individuals involved in the WTI project and WTI attorney Chuck Waterman. (See paragraph 1, page 1.) The memo, describing Von Roll's "*wish list*", outlines various ownership options and the "*advantages and disadvantages*" of each. As described in the memo, most advantageous for Von Roll would be for Von Roll to "*buy out other WTI partners*". As stated on page 6 of the memo, as well as in a chart on the final page, the disadvantage of this option was that it would be least satisfying for Von Roll under Ohio law, as it would require a permit modification and new public hearing "*since the owners, and perhaps the 'form', of WTI would change.*" As described in the OAG's background investigation, we now know that Von Roll did "*buy out the other WTI partners*"; but they failed to disclose the changes or provide the required notification to the regulatory agencies for approval."

"Our belief about the Coleman memo is this: To ensure financing for the project, Von Roll/WTI needed written assurance from the OEPA that the company was in good legal standing. On January 24, 1990, Chuck Waterman wrote to the Ohio EPA to secure this comfort letter. But in order to secure the approval which would ultimately be used to secure financing and allow the project to proceed, Chuck Waterman misrepresented the ownership of the facility to the OEPA. The description of ownership and ownership changes provided to the OEPA in Waterman's January 24, 1990 letter were inaccurate. In describing WTI's ownership to the OEPA, Mr. Waterman lists "Von Roll (Ohio) Inc." and "Waste Technologies Incorporated" as two of the "*original partners*." But, according to the OAG's background report, as well as official testimony during the Ohio Hazardous Waste Facility Board (OHWFB) proceedings, Von Roll (Ohio) Inc. was not an original partner, nor could it have been since it was only created in 1986! (OHWFB

transcript, page 338). The same is true of Waste Technologies Incorporated. The original partnership was created in 1981, whereas Waste Technologies Incorporated only came into existence in 1986. Based on the false ownership information provided by Waterman in his January 24, 1990 letter, the Ohio EPA gave the necessary approval that cleared the way for the project to proceed.”

“During the OHWFB hearings in October 1996, representing the Ohio EPA (OEPA) as a stand-in for Director Shregardus was Mr. David Sholtis, Assistant Chief of the Division of Waste Management. Mr. Sholtis testified that the OEPA had accepted as correct the facts and conclusions found in the OAG’s report. (OHWFB transcript, page 306) He testified that the OAG’s report concluded that *“transfers of partnership interests resulted in new persons for purposes of hazardous waste permit law”* (OHWFB transcript, page 309), and that the report states *“that the effect of the transfer — of the transaction — was to transfer ownership of the incinerator to another person without transferring the permit.”* (OHWFB transcript page 314.)”

“The purpose of Mr. Waterman’s January 24, 1990 letter to the OEPA was addressed during the HWFB hearing. When questioned if Waterman was asking for Agency assurance that no formal proceeding [regarding ownership changes] was necessary, and if the agency gave him that assurance, Mr. Sholtis answered, “Yes.” (OHWFB transcript, page 335) Mr. Sholtis also testified that in order for the Ohio EPA to give WTI the assurances they requested, it was critical that information in the letter was accurate in detail. (OHWFB transcript page 336.) When asked if it was an accurate statement by Waterman [in his January 24, 1990 letter] that there were no changes to the partners of WTI, Mr. Sholtis stated, *“No, it doesn’t seem to be.”* (OHWFB transcript page 343.) When questioned further about the integrity of the information in the letter, Mr. Sholtis stated, *“[[I]t doesn’t seem entirely accurate.”* (OHWFB transcript page 349.)

“WTI/Von Roll never revealed to anyone the myriad changes in ownership. It was only after exhaustive efforts by citizens, who had documented them, that appropriate authority (the OAG’s office) confirmed the allegations.”

“Citizens wonder why a clear violation of the law is not being pursued as prescribed by law under ORC 3734.10, which states, “—shall prosecute to termination or bring an action for injunction against any person who has violated, is violating, or is threatening to violate any section of this chapter, rules adopted under this chapter, or terms or conditions of permits, licenses, variances, or orders issued under this chapter.”

Response to 6T:

This comment questions whether the state vigorously prosecuted VRA for the initial transfer of ownership (which by 1990 had Von Roll America owning all the stock of the original WTI corporate partners). A review of the facts supports the conclusion that the state acted appropriately.

On April 27, 1984, the Hazardous Waste Facility Board (HWFB) issued to WTI partnership a hazardous waste permit. The WTI partnership consisted of four corporate partners.

In early 1990, pursuant to R.C. 3734.42, the WTI partnership submitted to the Ohio Attorney General a disclosure statement concerning the compliance history of the WTI partnership. Pursuant to statute, the Attorney General investigated the WTI partnership.

On June 18, 1993, the Attorney General transmitted to the Ohio EPA an investigative report on the WTI partnership. The report showed that by 1990, VRA, one of the original partners of the WTI partnership, owned all of the stock of the four WTI corporate partners. The report concluded that some of the transfers resulted in a new partnership. The report further concluded that the resulting partnership assumed ownership of the WTI facility without first receiving a transfer of the original permit as required by R.C. 3734.05(l) as it existed at the time.

On June 30, 1993, the Ohio EPA requested that WTI submit a permit change request to list VRA as the owner and operator of the facility. Ohio EPA received the permit change request on July 16, 1993. The Ohio EPA determined that the application was complete and appeared to comply with agency rules. Based on this determination, Ohio EPA found the request constituted a modification of the permit and transmitted it to the HWFB.

The Ohio EPA's method of addressing the alleged violation of law was found to be appropriate see Martin v. Schregardus (September 30, 1996), (Franklin County Court of Appeals (No. 96APH02-138)) affirming the Ohio EPA's dismissal of a verified complaint concerning the violations described in the Attorney General's report.

On February 13, 1998, the HWFB acted on WTI's request and transferred the permit to Von Roll America, Inc. The Franklin County Court of Appeals affirmed the Board's decision in December of 1998 (98AP-220). The Ohio Supreme Court declined to entertain the case in 1999.

Comments relating to the propriety of the original transfer of ownership to VRA, the concerns raised in the Ohio Attorney General's 1993 investigative report, Ohio EPA's actions concerning the WTI partnership's transfer have all been dealt with by Ohio EPA's transmittal of WTI partnership's modification request to the Ohio Hazardous Waste Facility Board and the Board's 1998 decision. The actions by agencies and the courts of the State of Ohio have addressed the Commentator's question of whether WTI's alleged violation of law (on transfers of ownership) is appropriately addressed or vigorously pursued. As such, comments raising issues that have been addressed in previous state actions are not determining factors in deciding whether to issue a renewal of the hazardous waste permit in the current instance.

7) **ISSUES RELATED TO PERMITTING (TERMINATION, EXPIRATION, OPERATING CONDITIONS):**

- 7A) "My vote is no even though it will not make a difference....I KNOW YOU WILL LET THEM CONTINUE. When a company understands the do and don'ts of their business and they have any violations it is time to shut them down." (Cuthbert)
- 7B) "Based on Von Roll/WTI's history of operation, (...) and the request to renew the RCRA Hazardous Waste Permit should be denied. Instead, the facility should be closed." (Tri-State)
- 7C) "Why is the EPA considering (...) the renewal of the Hazardous Waste Permit now --- at this particular point in time --- especially when there are so many questions that remain unanswered and so many outstanding issues that need to be resolved. The EPA has acted prematurely." (Tri-State)
- 7D) "Thus, the grounds for terminating WTI's permit or imposing a penalty have been present at many times during its ten-year history of commercial operation, and EPA could have taken either action or both." (Tri-State)

"The brief history of the company's operation for the past ten years is partial evidence that Von Roll/WTI should never have been granted a permit in the first place. It is time for the EPA to accept responsibility for this mistake and act in the public's best interest." (Tri-State)

Response to 7A through 7D:

The permitting process for a hazardous waste treatment facility is described in Ohio Administrative Code (OAC) Rule 3745-50. This rule includes regulations covering permit renewal as well as the continuation of expiring permits. The Ohio EPA must have just cause to not renew a facility's permit to operate. VRA/WTI's history of compliance has been evaluated and their permit has been reviewed and revised to conform with the State of Ohio laws and regulations. Ohio EPA has found no just cause to not renew the VRA/WTI RCRA permit.

By law (ORC 3734.05), the Director will not issue a renewal permit unless he determines that during the term of the existing permit, the owner and operator has maintained a history of compliance with Chapter 3734 of the Revised Code, rules adopted thereunder, the existing permit, and orders entered into to enforce such requirements that demonstrates sufficient reliability, expertise, and competency to operate the facility in compliance with Chapter 3734 of the revised code, rules adopted thereunder and the renewal permit. Additionally, for facilities accepting waste from off-site, the owner/operator must have a history of compliance with environmental laws and must not have been convicted of disqualifying crimes (ORC 3734.44) listed in the statute. As part of the permit renewal process, the Ohio EPA evaluated grounds for termination of the State of Ohio Hazardous Waste Facility Installation and Operation Permit and found no cause for termination. The Ohio EPA evaluated violations cited and determined that, during the facility's ten years of operation, none rose to a level of substantial non-compliance that would justify termination of the VRA/WTI permit. In addition, during the ten years of operation and as part of the return to compliance process when violations were cited, corrective actions were taken

and, when necessary, penalties for the violations were imposed. It is the Ohio EPA's position that VRA meets the requirements of the law and qualifies to receive a hazardous waste permit renewal.

7E) "WTI's operators permit expired in 1995. It has been operating for more than 8 years on interim status." (Tri-State)

Response to 7E:

The VRA facility never operated under interim standards on the state level (OAC 3745-65) or interim status on the federal level (40 CFR 265). The Ohio EPA Hazardous Waste permit was issued to be effective for a period of five years after approval of the trial burn results. The Ohio EPA approved the trial burn results in May of 1997. Accordingly, the Hazardous Waste permit passed its expiration date May of 2002. However, Ohio law (OAC Rule 3745-50-56) allows a facility to continue operating past a permit's effective date until the renewal permit is issued or denied so long as a timely renewal application was filed and, through no fault of the permittee, a new permit has not been issued on or before the expiration date of the previous permit. VRA filed a timely renewal application with the state in 1994. The federal permit became effective in 1985 for a term of ten years. VRA filed a timely permit renewal with US EPA also in 1994, which continued the effectiveness of the permit.

7F) "On October 20th the EPA's National Ombudsman Robert Martin not only recommended an immediate shut down of WTI until critical health and safety issues are resolved, he also found that the permit which allowed WTI to operate was based on failed test burns, corrupted monitoring and tainted data, and a seriously flawed and inadequate risk assessment. He wrote: "it is neither protective of human health nor of public safety to allow the WTI facility to continue unrestricted operations in the face of new information of compromised data and insufficient environmental monitoring data affecting both the WTI trial burn and the risk assessment." He also referred this case for criminal investigation. Under RCRA the EPA can use its omnibus authority, or authorities under other federal statutes such as the Clean Air Act, to end the burning of hazardous waste at the WTI incinerator in East Liverpool, Ohio. But the recommendations of the federal EPA Ombudsman were ignored. He never had the opportunity to finalize his investigation and report and his work was never completed by anyone else in the EPA. They just dropped the ball on it." (Tri-State)

Response to 7F:

The U.S. EPA's "National Ombudsman's Draft Report on Waste Technologies Industries" was responded to by Timothy Fields, U.S. EPA Assistant Administrator, in a memorandum to Robert J. Martin on January 19, 2001. The memorandum disagreed with the findings in the report based on concerns with assumptions used to support the findings and procedural concerns with how the investigation was conducted. However, as a result of the report, U.S. EPA has taken several steps to ensure the best data possible about the facility has been evaluated. These steps were outlined in the January 19, 2001 memorandum which is attached to this document as Attachment B.

The Director's "omnibus authority," as set forth in Ohio Administrative Code (OAC) Rule 3745-50-40 and 50-51, allows the Director to add additional permit conditions that "he determines [are] necessary to protect human health and the environment" as long as the need for the additional conditions can be justified in terms of environmental protection or protection of human health. Additional permit conditions can be justified, on a site specific basis, using the results of a site-specific risk assessment, or other findings that relate to activities at the site. Ohio EPA concludes that there are insufficient findings to support the use of the Director's "omnibus authority" to end the burning of hazardous waste at the VRA/WTI incinerator in East Liverpool.

- 7G)** "There should be no problem in delaying the Title 5/RCRA Hazardous Waste Renewal process until an acceptable Draft Title 5 Permit has been rewritten by the Ohio EPA, taking into consideration ALL comments during this round of public involvement." (Tri-State)
- 7H)** "EPA must deny approval of the Title 5 Permit and renewal of the Hazardous Waste Permit (the RCRA Permit which expired in January 1995). At the very least, this process should be stopped right now until all the issues and objections presented by commenters are resolved. The EPA has reached this point far too early in the process." (Tri-State)
- 7I)** "No decision should be made and the process should be halted now until AFTER the MACT Emission Test scheduled to take place in September 2003. It doesn't make sense to set operating parameters, establish conditions and set permit limits until Von Roll/WTI has been tested under the MACT guidelines. EPA should begin the process of rewriting a second Draft Title 5 Permit after completion and analysis of the MACT Test this September." (Tri-State)

Response to 7G through 7I:

The law requires Ohio EPA to make a decision on a permit renewal application within sixty days after the public meeting or close of the public comment period (ORC Section 3734.05(H)). The Ohio EPA's renewal standard requires the director to "consider the application and accompanying information, inspection reports of the facility, results of performance tests, a report regarding the facility's compliance or noncompliance with the terms and conditions of its permit and rules adopted by the director under this chapter, and such other information as is relevant to the operation of the facility..." In making a determination on renewal, "the director shall not issue a renewal permit unless the director determines that the facility under the existing permit has a history of compliance with this chapter, rules adopted under it, the existing permit, or orders entered to enforce such requirements that demonstrates sufficient reliability, expertise, and competency to operate the facility henceforth under this chapter, rules adopted under it, and the renewal permit"(see ORC Section 3734.05(H)).

The Ohio EPA carefully reviewed the RCRA permit application and EBIU reports regarding the facility's compliance or noncompliance with the hazardous waste rules and with the conditions of its hazardous waste permit. Using the state renewal standard, the Ohio EPA

also carefully considered the public comments and concerns received during the comment period for the draft RCRA renewal permit; the body of this responsiveness summary and the final permit is evidence of this fact.

Additionally, for facilities accepting waste from off-site, the owner/operator must have a history of compliance with environmental laws and must not have been convicted of disqualifying crimes (ORC 3734.44) listed in the statute. The most recent AGO-EBIU reports presented to Ohio EPA (dated May 2002, and June 30, 2004) contain no revelations that would support denial of the VRA renewal application.

The information discussed above forms the basis for Ohio EPA's determination to renew the VRA permit.

There were numerous steps prior to the issuance of the final Title V air permit, dated February 2004. The RCRA permit has remained in effect since the Title V permit was approved. The two programs remain separate. Ohio EPA is required to issue permits if the facility meets the applicable standards.

Once the MACT CPT is approved, the facility may request that redundant operating conditions and permit limits included in the Title V permit be removed from the RCRA permit. Ohio EPA will evaluate the facility's request as a permit modification and determine which conditions and limits may be removed.

7J) "We request that no requirement or condition currently in Von Roll/WTI's RCRA Permit or Conditional PTO be weakened in any way, and that if anything, additional restrictions and limitations are made rather than decreasing protection. For example, the following are now required at Von Roll/WTI":

- "Von Roll's permits require it to operate certain continuous monitors which record combustion gas emissions, process flow rates, and other parameters related to the incinerator's emissions and overall performance. If these monitors detect that process upsets are resulting in operation outside of the permit limits, the feed of hazardous waste to the incinerator must immediately cease. Von Roll is required to operate continuous emission monitors which measure carbon monoxide, total hydrocarbons, opacity, hydrogen chloride, oxides of sulfur ("SOx") and oxides of nitrogen ("NOx")."
- "In response to recommendations in the engineering study and discussions with the Ohio EPA, Von Roll submitted a proposal for a proprietary design system intended to reduce the occurrence of fugitive emissions of combustion gas from the kiln seals. The system Von Roll proposed included a shroud designed to hold the flue gases in the kiln. Since the violation for the fugitive emissions was included in the enforcement action, the installation of the shroud became part of the settlement agreement. The system is currently in place and based on preliminary observations by Ohio EPA, while it does not appear to completely prevent fugitive emissions from the largest

pressure excursions in the secondary combustion chamber ("SCC"), it nonetheless appears to be preventing approximately 90% of the previous fugitive emissions."

- "The SCC is normally operated under negative pressure, which causes the kiln to also operate under a negative pressure. The shroud applies a positive pressure at the discharge end of the kiln (where the rotating kiln joins the stationary SCC). If the SCC experiences a positive pressure less than the pressure exerted by the shroud, the fugitive emission is prevented. However, if the positive pressure in the SCC is greater than that exerted by the shroud, a fugitive emission can still occur."
- "The Ohio EPA has also, as a result of an April, 2000, fugitive emission event described below, required the following additional preventive measures at the facility: As a result of Von Roll maintenance activities directed at cleaning out the spray dryer while still "on waste", an ash fall occurred which blocked the outlet to the spray dryer. This blockage produced a very significant fugitive emission from the incinerator system (not just the kiln seals). Von Roll was cited for violating Ohio's hazardous waste rules and its permit. To return to compliance, the Ohio EPA required that Von Roll (1) evaluate all maintenance activities that could result in blockage of the flue gas and a pressure excursion in the SCC; (2) once these activities were identified, Von Roll was required to stop feeding solid waste if maintenance activities were going to be performed which could potentially block the flow of the flue gas; and (3) Von Roll was to document the evaluation of the maintenance activity as well as the cessation of solid waste to the kiln. In addition, Von Roll installed "vibrators" in the spray dryer to help prevent the build up of ash on the walls. Von Roll is also investigating the feasibility of putting the spray dryer on scales so the operators can monitor the build up of the ash and more accurately determine when clean out of the unit is complete."
- "Von Roll currently operates a continuous emission monitor which monitors and records concentrations of *total hydrocarbons* in the combustion gases. Since not all organic emissions are volatile, there is no reason to believe that a volatile organic carbon monitor would yield results which are any more useful than the results of the total hydrocarbon monitor."
- "Valves, flanges, pumps, etc., are required to be tested for leaks on a routine basis as dictated by EPA regulation. If one of these items is found to be leaking, WTI must repair it within a specified amount of time. This program includes the testing of approximately 29 pumps, 746 valves, and 1688 flanges at WTI."
- "Additionally, we request that the above programs be maintained and strengthened."
- "Additionally, we request that all areas of the facility where waste is handled

or stored by placed under negative pressure to prevent the escape of fugitive emissions." (Tri-State)

Response to 7J:

The RCRA operating conditions in the previous permit have not been weakened in the renewal permit. Some examples include:

- *Monitors that read process operating conditions associated with the incinerators performance which are tied to waste feed cut-offs (Permit application pages D-102-103).*
- *The shrouds to the incinerator kiln seals which helps to control fugitive emissions by exerting a positive pressure on the seal (Permit application pages D-116-117).*
- *Prior to conducting maintenance on the spray dryer which could lead to a blockage in the spray dryer the incinerator will come off solid waste prior to commencing maintenance (Facility standard operating procedures).*
- *Operation of a continuous total hydrocarbon monitor in combustion gas stream (Permit application page D-102).*
- *Inspections and maintenance against leaks of all pumps, piping, valves, tanks and containers associated (Permit application page F-3-8, Attachments F1, F2, & F4).*
- *The February 2004 Title V restates some of the RCRA requirements such as the requirement to maintain a leak detection system.*

Although most of the air emissions issues are addressed in the February 2004 Title V permit, the RCRA renewal permit will retain limits that are risk based. The MACT program, which is under the Clean Air Act, is technology based. The renewal permit is as restrictive as the previous permit and also more comprehensive. The renewal permit includes additional permit operating conditions and corrective actions."

7K) "Remedies for resolution of the Von Roll/WTI case: Denial of Title 5 Permit and denial to renew RCRA hazardous waste permit. Revocation of all operating permit. Close the Von Roll/WTI incinerator. If the EPA refuses to protect the health and welfare of citizens in the Ohio Valley with complete closure of the incinerator, at a minimum:

- Von Roll/WTI cannot operate during periods of busing or during school time.
- Von Roll/WTI cannot emit any dioxin at all.
- Von Roll/WTI cannot emit any organochlorines.
- Von Roll/WTI cannot emit any endocrine disrupting chemicals.
- Von Roll/WTI cannot emit any lead or mercury at all.
- Any child who attends East Elementary school who develops any condition

that may or can be attributed to any environmental cause, WTI must be responsible for their medical expenses.

- WTI must provide medical insurance for each child in East Elementary.” (Tri-State)

Response to 7K:

The permit is protective. In addition, restrictions posed on a facility can only be those that are required by regulations and mandated by law in order to protect human health and the environment. Suggestions made by the commenter, such as zero emissions, are not technically feasible nor required by law to protect human health and the environment.

8) ISSUES RELATED TO COMPLIANCE:

- 8A)** “The federal EPA has recorded roughly 40 fires, 2 explosions and numerous other release incidents since WTI began operation.” (Tri-State)
- 8B)** “We’ve been forced to endure repeated violations, including roughly 40 fires, two explosions and numerous toxic release incidents.” (Tri-State)
- 8C)** “The US EPA has recorded 110 equipment/procedural failures and incidents. On many occasions, the entire community has smelled of a pungent, cat-urine odor. There’ve been leaks where the odors from WTI can be smelled some 30 miles away. In addition, WTI has been cited for over 130 violations and was labeled by the EPA as a “Significant Non-Complier.”” (Tri-State)

Response to 8A through 8C:

As part of the renewal process, the facility’s history of compliance was evaluated. At VRA/WTI, each incident is investigated by Ohio EPA to determine its significance relative to the facility’s permit and Ohio laws and regulations. In every case, after an incident is evaluated, corrective actions are taken in order to prevent the incident from recurring in the future. If appropriate, a violation is cited which may or may not lead to escalated enforcement. The record of incidents at the VRA/WTI facility has been evaluated and the Ohio EPA has determined that the state renewal standards for compliance have been met. VRA/WTI is not currently classified by the Ohio EPA as a Significant Non-Complier.

- 8D)** “How many strikes before a company is out? I have dealt with other issues needing EPA approval. Much to my chagrin, it seems you can issue permits but you’re power to protect the environment exists only on paper issuing violations and many companies are able to continue their arrogant unlawful practices through numerous loopholes, appeals thus generating a meaningless long-term paper trail. Maybe if we are lucky in the end after years of pollution and a stack of violations, you may get the AG’s office to file some kind of action—then again maybe not. Then you find ways of dealing with the ruins to limit the affect on the environment.” (Cuthbert)

Response to 8D:

Findings of violations are issued for instances when the facility is not in compliance with

state rules and regulations. In response to those findings, the facility takes corrective measures and, if appropriate, pays a penalty in order to return to compliance. In the past, there have been situations in Ohio when a notice of intent to deny the permit has been issued to a facility as a result of poor compliance history. During the permit renewal process, a facility's history of compliance is evaluated to determine if they have a record of compliance or non-compliance. In the case of VRA/WTI, although violations of non-compliance have occurred, their overall history is one of compliance with the State of Ohio rules and regulations. The State of Ohio would not issue a permit if the facility did not have an overall history of compliance.

- 8E) "You are fully aware that compliance has mostly to do with data the company records itself --- from the manifests, to accidents, to setting the parameters of detection monitors, to reporting. What gives you're your confidence in the honesty and integrity of Von roll/WTI. Von Roll/WTI is only interested in profit. They don't care about public health. We wonder whether the EPA does. We no longer have confidence that the EPA is acting in the public's best interest." (Tri-State)
- 8F) "VonRoll America, Inc., does not have the character of honesty required for lawful operation of an environmental facility, as demonstrated by its pattern of retaliating against employees who report violations, and then using false testimony and evidence to evade responsibility for its actions. This company cannot be trusted to make honest reports." (SOC)

Response to 8E and 8F:

Compliance evaluations of hazardous waste facilities are based on site inspections and review of the facility's operating record. This applies to all facilities in Ohio. Comprehensive Compliance Evaluation Inspections (CEIs) are conducted at VRA/WTI bi-annually. The CEIs are conducted by the two on-site inspectors and several other hazardous waste inspectors and have included inspectors from the U.S. EPA on occasion. These inspections, which typically take three to four days, include a visual inspection of the facility as well as review of operating records. The document review includes inspection records, training records, manifests, lab reports, control room operations, river bank surveys, and other documents generated during the operation of the facility. Cross-comparisons of data and documents are conducted to check for discrepancies and provide confidence in VRA's data. Discrepancies which may be observed are investigated and, if appropriate, non-compliance with Ohio's rules and regulations are cited. In addition to the comprehensive CEIs, the on-site inspectors have daily contact with facility personnel and conduct frequent visual inspections of operations and plant procedures and activities. Open dialogue occurs regularly between the Ohio EPA inspectors and facility personnel about the day to day operations and management of hazardous waste.

- 8G) "No decision should be made and the process should be halted now until after the US and Ohio EPA have fully investigated the issues raised by VonRoll/WTI employee Donna Trueblood. US and Ohio EPA have failed to adequately address Ms. Trueblood's allegations or to take them into account for compliance purposes. EPA should begin the process of rewriting a second Draft Title 5 Permit after the violations/problems cited by Ms. Trueblood have been fully investigated and

addressed." (Tri-State)

- 8H) "After reading the article (Article from Post-Gazette Newspaper about the whistle blower case), I can't for the life of me believe that OEPA would grant WTI any kind of permit to continue burning hazardous waste." (Cuthbert)
- 8I) "The applicant's pattern of retaliating against whistleblowers reveals that they seek to intimidate their employees to stifle the free flow of information. The March 26, 2003, findings by the Administrative Law Judge of the U.S. Department of Labor reveal both the pattern of retaliation, and the pattern of straying from the truth to cover it up. VonRoll's expressions of animus, dishonesty, and failure to follow normal procedures, reveal a lack of trustworthiness. VonRoll's refusal to obey Judge Morgan's order, even after he issued the May 6, 2003, Preliminary Order on Remand, belies VonRoll's claim that it is fully compliant with the law." (SOC)
- 8J) "Heritage's and VonRoll's record of environmental violations constitute a breach of the public trust, sufficient to justify denial of permits. Much of the recent evidence cited in this objection arises from the public hearing in the case of Trueblood v. VRA, an environmental whistleblower proceeding pending before the U.S. Department of Labor. The hearing lasted from September 10 to November 20, 2002 (consisting of 11 days of hearing during these dates). On March 26, 2003, Administrative Law Judge Richard A. Morgan issued a 60-page Recommended Decision and Order Granting Relief (RD&O). App.72. The applicant, of course, petitioned for review to appeal to the U.S. Department of Labor's Administrative Review Board (ARB). Nevertheless, as Judge Morgan found that the facts of retaliation violated the Energy Reorganization Act (ERA), 42 U.S.C. Section 5851, he issued a Preliminary Order requiring VRA and Heritage to follow his order while the appeal is pending. App. 134. Through counsel, VRA refused, in writing, to obey an order for Trueblood's reinstatement. App.140. VRA has chosen to become an outlaw, rather than take back a known whistleblower or even just pay her the outstanding wages she is due. By identifying Trueblood as a whistleblower, expressing open hostility toward her protected activity, and conveying that management no longer could trust her, VRA had already violated the employee protections before posing their first question. By retaliating against Trueblood, management demonstrated that it wants to punish the messengers who report compliance issues. Therefore, this management cannot be trusted with any public environmental permit. If employees are coerced and intimidated into remaining silent when they should speak out, the result can be catastrophic. *Rose v. Secretary of Department of Labor* (6th Cir. 1986), 800 F.2d 563, 565." (SOC)
- 8K) "Knowing the kind of opposition and fear that surrounded this facility from the beginning, this company should have handled it's hazardous waste impeccably at all times. That would have given them credibility and proved the residents were wrong. Instead, if it is true, and I believe her story to be true, the residents proved their fears were valid." (Cuthbert)

Response to 8G through 8K:

The case before federal Administrative Law Judge Richard Morgan dealt with the unlawful termination of a VRA/WTI employee. The ruling was based on the treatment of the employee by VRA/WTI and not on the allegations of illegal waste handling practices indicated by the employee. The allegations were investigated by the Ohio EPA on-site inspectors as they were presented by the employee and mitigated accordingly. It must be noted that some allegations made by the employee could not be substantiated by the Ohio EPA despite thorough evaluation.

In the renewal process, Ohio EPA considers the application, inspection reports, and the facility's history of compliance with the present permit, and Ohio's hazardous waste laws. Ohio EPA has found that the facility has a history of compliance that demonstrates sufficient reliability, expertise, and competency to operate the facility. Our record of incidents at the VRA/WTI facility has been evaluated and the Ohio EPA has determined that state renewal standards for compliance have been met. Additionally, for facilities accepting waste from off-site, the owner/operator must have a history of compliance with environmental laws and must not have been convicted of disqualifying crimes (ORC 3734.44) listed in the statute. Ohio EPA has determined that VRA/WTI qualifies to receive a hazardous waste permit renewal. It is Ohio EPA's task to ensure that as long as VRA/WTI continues to operate, they continue to do so safely and in a manner consistent with compliance with environmental regulations.

VRA/WTI may be required to disclose the US Department of Justice decision to the Attorney General's Environmental Background Investigation Unit (EBIU). To the extent that new disclosures are brought to light, the EBIU will incorporate them into their next update report and provide the Ohio EPA with their findings and recommendations. The Agency will have all its regulatory options available and will take appropriate action at that time.

One of the comments regarded the handling of hazardous waste at the facility. VRA/WTI has standard operating procedures in place for most activities involving the handling and processing of hazardous waste on-site. Those procedures are intended to allow for the handling and processing of hazardous waste as safely and efficiently as possible. A majority of the received waste is handled safely and without incident. Evaluations of incidents include a review of the response actions taken and suggestions for improvements. VRA/WTI conducts daily safety meetings to review the waste which is expected each day and the handling instructions.

- 8L) "No decision should be made and the process should be halted now until all of the issues raised in former Von Roll/WTI employee Terry Lancaster's letter to US EPA. Ms. Lancaster's June 2002 letter raises 11 areas of concern which must be addressed by the US and Ohio EPA. US and Ohio EPA have failed to adequately address Ms. Lancaster's allegations or to take them into account for compliance purposes. EPA should begin the process of rewriting a second Draft Title 5 Permit after the violations/problems cited by Ms. Lancaster have been investigated and addressed." (Tri-State)

Response to 8L:

The letter you are referring to is actually dated January 7, 2002 and is addressed to Mr. Gary Victorine of U.S. EPA. Upon receipt of the letter, Mr. Victorine contacted the author of the letter (the complainant) and verbally verified that the author wished to remain confidential. The U.S. EPA provided the letter to Ohio EPA with the understanding that the complainant would be kept confidential by Ohio EPA as well. Ohio EPA and U.S. EPA have treated the complainant as a confidential source throughout the course of the investigation and still do to this day. It is unclear how the commentor obtained a copy of this letter with a June 2002 date. If it was received via e-mail, the computer program utilized by the commentor may have automatically re-dated the letter with the date the letter was printed.

The January 28, 2002 letter is written in a narrative format. For the investigation, the content of that letter was enumerated into 11 allegations. A formal investigation into the allegations was conducted during the week of February 25, 2002, by both U.S. EPA and Ohio EPA personnel. A copy of the letter containing the results of that investigation is presented as Attachment J of this responsiveness summary. Ohio EPA has concluded that no issues rise to the level of a violation of the state hazardous waste rules. For 9 out of the 11 allegations, evidence was not found to substantiate the allegations.

9) ISSUES RELATED TO THE REQUEST TO FUND AN INDEPENDENT STUDY:

9A) "No decision should be made and the Title 5 Permit process should be halted now until EPA is able to help citizens secure funding to hire an independent external expert to 1) review and comment on the new Draft Title 5 permit that will be written by the Ohio EPA; 2) review the MACT test plan and comment on it prior to the test; 3) observe the MACT test as it is conducted; 3) review and analyze the results of the MACT test, and 4) review the test protocol/test burn plan before any stack testing or other environmental monitoring is conducted. In US EPA's recent Response to Comments from citizen's comments in November 2000, the Tri-State Environmental Council requested such funding. EPA responded by stating that a TAG grant was not available, "[h]owever, there is another program available to provide similar assistance known as the Technical Outreach Services for Communities (TOSC) that would be appropriate. TOSC is complementary to the TAG program, but is different in two aspects. One, TOSC is available to communities with hazardous-substance issues that cannot receive help from a TAG. In other words, TOSC is not limited to NPL Superfund sites. Second, because TOSC is not a grant program, it is easier to access since there are no federal or incorporation requirements. The purpose of TOSC is to provide independent technical information and education based on science and engineering. The services are provided through regional Hazardous Substance Research Centers. EPA's Office of Solid Waste (OSW) is currently looking into initiating the TOSC grant process on behalf of the community." We are again requesting help in securing funding for an independent expert to review technical information, however we want the option to choose our own independent experts who have no connection to the EPA, other federal agencies or the chemical or hazardous waste industry."
(Tri-State)

Response to 9A:

Technical Outreach Services for Committees (TOSC)

The U.S. EPA provided initial information to Ms. Swearingen about TOSC assistance (e-mailed June 24, 2003). However, as explained below, U.S. EPA approved the CAA Comprehensive Performance Test Plan on August 19, 2003, and the RCRA Trial Burn Plan on August 22, 2003. As of the date the test plans were approved, such technical assistance had not yet been secured.

MACT Comprehensive Performance Test Plan

Regulations at 40 CFR 63.1207(e) require that a regulated facility submit its Comprehensive Performance Test ("CPT") Plan one year before the test is scheduled to begin, and specifies that the appropriate regulatory agency approve or notify of intent to deny within 9 months.

Von Roll submitted the initial version of its CPT Plan via e-mail on June 22, 2001. This initial test plan was reviewed by a national workgroup which included representatives of the U.S. EPA's Office of Air Quality Planning and Standards, the Environmental Response Team in Edison, New Jersey, representatives of Ohio EPA- NEDO, and Region 5. Following this review, a letter dated August 30, 2001, was sent to Von Roll requesting additional information. Von Roll responded to the above information request by submitting an entirely new CPT Plan, referred to as RCRA Trial Burn Plan Revision 0, dated December 12, 2001. The test plan constituted both a CPT Plan and a RCRA Trial Burn Plan.

Revision 0 was reviewed by the Ohio EPA, U.S. EPA Region 5, and TechLaw under a Region 5 work assignment. Comments and questions generated from this combined review were sent to Von Roll on September 11, 2002. Von Roll responded by submitting Revision 1 on February 17, 2003. In response to several additional issues communicated to Von Roll by Region 5, Von Roll submitted revised pages to create Revision 2 on May 6, 2003. Von Roll later e-mailed several "Redacted" pages to Region 5 on May 21, 2003, to address information which was to be claimed as confidential under 40 CFR Part 2. Updated pages which incorporated minor changes to expected operating parameters were e-mailed by Von Roll on July 2, 2003, creating Revision 3.

U. S. EPA reviewed the test plan, including all changes through Revision 3, and determined that it satisfied the requirements of the regulations. In order to give VRA the opportunity to run the CPT before the compliance deadline of September 30, 2003,³ U.S. EPA approved the CPT on August 19, 2003.⁴

Because the September test did not demonstrate compliance with all the requirements of the HWC-MACT Rule, additional testing was conducted in December 2003, March 2004,

³ Many facilities like VRA that are subject to the MACT requirements for hazardous waste combustors were required to comply by September 30, 2003.

⁴ In a letter dated May 29, 2003, VRA requested an extension of time, as allowed under the regulations, to delay compliance with the entire HWC MACT rule if the CPT were not approved by July 16, 2003.

and April 2004. Please see the response to Comment 2L.

While Ms. Swearingen's comment requested help in securing funding to hire an independent external expert to review the MACT test plan and comment on it prior to the test, we believe approval/denial could not be delayed any further given the compliance deadline and regulatory restrictions on review time.

As indicated above, the test plan approved by U.S. EPA fulfilled the requirements of two different regulatory programs. These requirements are the Comprehensive Performance Test under the Clean Air Act regulations found at 40 CFR 63 Subpart EEE (the "MACT" Rule), and the Trial Burn under RCRA regulations found at 40 CFR 264 Subpart O. Because the Trial Burn Plan is part of the RCRA permit, the RCRA permit had to be modified to incorporate the approved revised Trial Burn Plan in accordance with 40 CFR 270.42(b), i.e., a Class 2 permit modification. VRA requested this required permit modification on April 25, 2003, and provided public notice on May 1, 2003, opening a public comment period which ended on June 30, 2003. The permit modification was approved on August 22, 2003.

10) ISSUES RELATED TO THE PUBLIC PARTICIPATION PROCESS:

- 10A)** "It also makes me ill that the notices for this important hearing are posted in the most obscure place in the paper. To my knowledge many people missed it. I found out by accident." (Cuthbert)
- 10B)** "EPA did not follow proper procedure for public participation. We object to the way citizens were brought into the Title 5/permit renewal process." (Tri-State)
- 10C)** "The required notice, to be published in the local newspaper, was published in the Morning Journal in Lisbon, Ohio. Most citizens living in the vicinity of the Von Roll/WTI toxic waste incinerator subscribe to the local East Liverpool paper, The Review, which is published right in East Liverpool, Ohio, where the incinerator is located. Many citizens in the local community were unaware of the hearing because they do not subscribe to the Lisbon paper wherein the notice was published." (Tri-State)
- 10D)** "Even if review of these documents at Carnegie Public Library was convenient and/or practical, most citizens were unaware of their availability there. The January 24, 2002 public notice did not state that the draft permit was available at Carnegie Library (at the time, it was not), and even if it did, the notice was not published in the most widely circulated paper in the vicinity of WTI, which is the Review, published in East Liverpool, Ohio, where Von Roll/WTI is located. Instead, the public notice was published in the Morning Journal, in Lisbon, Ohio." (Tri-State)
- 10E)** "It is not realistic for EPA to schedule 30 minutes prior to the actual hearing to provide citizens with information about the Title 5 permit (as well as the permit renewal issue) and then expect citizens to comment on that information in the same

session immediately following." (Tri-State)

- 10F)** "From the time of receipt of the February 13 notification, the EPA allowed roughly 14 days to review and prepare comments on all the issues that EPA has scheduled for the hearing. The required protocol for public hearings is to notify the public at least 30 days in advance." (Tri-State)
- 10G)** "We, too, believe that the EPA wants this facility as much as Von Roll/WTI and that they will do anything to keep it up and running, regardless of the consequences to the health and safety of area residents. In the past, our comments have either been ignored or used as a roadmap to get Von Roll/WTI where they want to go. Why should we be convinced that EPA will now seriously consider our concerns and recommendations in the Title 5 Permit issuance and RCRA hazardous waste permit renewal process?" (Tri-State)

Response to 10A through 10G:

Ohio EPA followed the proper procedures for public participation as required by Ohio's hazardous waste laws. On January 24, 2003, Ohio EPA issued a draft renewal Hazardous Waste Facility Installation and Operation Permit (Draft Renewal Permit) to Von Roll America, Inc., for its facility in East Liverpool, Ohio. On January 25, 2003, the Agency issued a public notice of the issuance of the Draft Renewal Permit in a newspaper having general circulation in the county in which the facility is located and over a local radio station. The public notice gave the locations where the permit application and Draft Renewal Permit could be reviewed and the notice was published in the Lisbon "The Morning Journal" newspaper. A public service announcement was aired on WOHI Radio Station. These public notices were given at least thirty days prior to the public meeting held on February 25, 2003. Lisbon is the Columbiana County seat and Ohio EPA typically uses "The Morning Journal" for issuing public notices for actions occurring in Columbiana County. Ohio EPA has received "Proof of Publication" from "The Morning Journal".

Additionally, the East Liverpool "The Review" carried a front page article on the draft permit renewal on February 14, 2003. "The Morning Journal" also carried an article about the proposed renewal on February 14th. These newspaper articles were not required by Ohio's hazardous waste laws. One commenter mentions a February 13th notification. Ohio EPA is not aware of a notification issued on that date.

Additionally, the public notice was sent to over 100 persons or organizations on the mailing list. To be added to the mailing list, contact Ohio EPA, Division of Hazardous Waste Management, Attn: Regulatory and Information Services, P.O. Box 1049, Columbus, Ohio 43216-1049, telephone number (614) 644-2977, fax number (614) 728-1245, e-mail: dhwmcomments@epa.state.oh.us.

Also, the Division of Hazardous Waste Management has an electronic news service to provide interested persons with quick and timely updates on events and news related to hazardous waste activities in Ohio. Members of this service can sign-up to receive updates about each of the following topics: permitting, rulemaking, enforcement, guidance, annual reports, The Notifier, and the Cessation of Regulated Operations program. To sign up for

this service visit this Web address: <http://www.epa.stae.oh.us/dhwm/listserv.html>. On January 24, 2003, Ohio EPA notified service members via e-mail that Ohio EPA had issued the Von Roll Draft Renewal Permit that day. At that time, the public notice, the Fact Sheet and the Draft Renewal Permit were available electronically on Ohio EPA's Web site.

Ohio EPA scheduled a public information session prior to the public hearing to provide an overview of the permit. The public hearing gives the public an opportunity to ask questions or give comments on the permit and/or permitting process. Written comments are accepted during the public comment period, which lasts for sixty days in accordance with Ohio hazardous waste rules.

As a result of requests, from the public and to coincide with the Title V air permit comment period, Ohio EPA extended the public comment period for the hazardous waste draft permit renewal an additional 45 days to May 9, 2003. Ohio EPA issued this public notice on February 28, 2003, in the East Liverpool "The Review" and the Lisbon "The Morning Journal".

Even though the requirements imposed by Ohio law were met by issuing the public notice in the Lisbon "The Morning Journal", Ohio EPA will, in response to your comments, issue future public notices in both the East Liverpool "The Review" and the Lisbon "The Morning Journal".

In response to the commenter's question, "Why should we be convinced that EPA will now seriously consider our concerns and recommendations in the Title V Permit issuance and RCRA hazardous waste permit renewal process?," Ohio EPA did consider public comments before the final decision was made. After carefully considering public comments, Ohio EPA reconsidered the draft renewal permit, making any necessary changes prior to issuing the final permit. Ohio EPA also issued this Responsiveness Summary, specifying changes made to the draft permit. The Responsiveness Summary and final permit have been sent to all individuals and organizations that provided comments on the draft permit. Ohio EPA and U.S. EPA invested a considerable amount of time in carefully considering and responding to every comment submitted during the public comment process. The Agencies have prepared the detailed responses in this Responsiveness Summary to address the concerns of all those who participated in this process.

11) ISSUES RELATED TO CONSTRUCTION (EMERGENCY VENT, STACK HEIGHT):

11A) "Regulations indicate a stack should comply with Good Engineering Practice (GEP). The Von Roll/WTI stack does not meet GEP."

- "September 10, 1991 -- Four Nines, Inc. Dispersion Modeling and Risk Assessment prepared for Waste Technologies Industries. Page 7 states, The minimum and maximum GEP stack heights were determined to be 170 feet (51.8 meters) and 213 feet (65 meters), respectively. The minimum GEP height was determined using the Incinerator Feed Building which is the

controlling building. The actual stack height is 150 feet. This height is slightly below GEP criteria."

- "March 29, 1994 -- DRAFT: See under February 10, 1995. U.S. EPA "Reports to U.S. EPA Region 5 about downwash from WTI" by U.S. EPA Engineer Gary Victorine. From October 1, 1993 to February 27, 1994, there were 13 episodes of "severe downwash" reported at WTI."
- "March 29, 1994 -- Letter from the North Ohio Valley Air Authority (NOVAA) Director Pat DeLuca to Mike Walton. Concerning the plume downwash at WTI, Mr. DeLuca wrote, NOVAA is very sure of the plume downwash occurrence at the WTI facility in East Liverpool. We have made this known to OEPA and USEPA."
- "April 19, 1994 -- Letter from Environmental Supervisor for the Division of Hazardous Waste Management, Paul Anderson, to Mike Walton. Responding to questions regarding stack height at WTI, Mr. Anderson wrote, Since construction of the facility, significant public concern has arisen regarding "down wash" of the stack plume from the WTI facility caused by air currents across the site. The U.S. EPA found no unacceptable risk from air emissions from its 1992 study entitled "Preliminary Risk of Inhalation Exposures to Stack Emissions from the WTI Incinerator." However, the issue of appropriate stack height is again being addressed in the "Phase II" risk assessment currently being conducted by U.S. EPA which will look at direct and indirect risk from the site. The Ohio EPA will await the results of this study to determine if any additional changes to the WTI permit are necessary to ensure safe operation at the facility. See the letter for detailed discussion of the WTI stack height."
- "April 26, 1994 -- U.S. EPA document titled "Analysis of Potential WTI Permit Modification Discrepancies." The document examines potential inconsistencies between the state permit issued by the Hazardous Waste Facility Board and the federal RCRA permit issued by the U.S. EPA. Concerning the WTI stack height, page 8, point number 11 stated, c. Once Phase 2 of the U.S. EPA's risk assessment regarding this facility has been completed, the issue of whether stack height requirements need to be incorporated in the permit will be revisited. Since stack height has a significant effect on the calculated dispersion of pollutants and the resulting potential risks determined by such a risk assessment, it is presently believed that the permit should specify the stack height(s) used in the assessment."
- "July 25, 1996 -- U.S. EPA Response to Comments from April 24, 1996 Public Meeting in East Liverpool, Ohio, with U.S. EPA Assistant Administrator of Research and Development, Dr. Robert Huggett. See pages 4 and 5 of the report. The type of downwash described by Ms. Barnhart and many other citizens is commonly referred to as "building-induced downwash," where a wake created by nearby structures drives part

or all of the emission plume quickly down toward the ground. The air dispersion models used in the detailed risk assessment did take into account the type of "building -induced downwash" which is predicted to occur from the specific configuration of buildings, stack height, meteorology at the WTI site. However, in considering WTI's application for renewal of the RCRA permit, the State of Ohio might still want to consider the frequency and duration of reported plume downwash events and evaluate whether additional measures might be called for. In conducting the risk assessment, supplemental air dispersion modeling was performed to evaluate how a GEP stack height of 72.7 meters (about 240 feet) would affect the impacts. This second modeling, with the hypothetical GEP stack, did predict near-field average pollutant concentrations approximately 13 % percent lower. Although the predicted average concentrations were lower with the GEP stack model, the model did not predict a significant reduction in the deposition of pollutants from the plume. (See also U.S. EPA's footnote to this comment.)" (Tri-State)

11B) "We request that Von Roll/WTI be required to meet the minimum Good Engineering Practice (GEP) for stack height. We feel that the 13% reduction in the concentration of pollutants over the area would result in at least a small reduction of risk. If even slight reductions in risk are made incrementally in several different areas and ways, the overall risk reduction will be much more significant and well worth it to the citizens." (Tri-State)

11C) "WTI's stack is only 150 feet high --- not even the minimum for Good Engineering Practice --- so that dispersion from the stack is decreased. According to US EPA's Gary Victorine, to increase Von Roll/WTI stack height to the minimum GEP would reduce the concentration of pollutants by 13%." (Tri-State)

Response to 11A through 11C:

The commenter is equating "Good Engineering Practice" (GEP) with "minimum design requirements" to forward the position that the stack height does not meet minimum requirements for good engineering practice. In fact, the term "Good Engineering Practice" for stack height is not a stand-alone design requirement for actual stack height but is a term developed (under Section 123 of the CAA) for use when addressing compliance with National Ambient Air Quality Standards. Regulations were developed to insure that the degree of emission limitation required for the control of any air contaminant (under an applicable State Implementation Plan) is not affected by that portion of any stack height which exceeds GEP, or by any other dispersion technique. The GEP was used in standard/validated air models to accurately predict ambient concentrations and appropriately credit sources for their contribution while avoiding distortion caused by excessive dispersion based on taller than GEP stacks.

The overall concern raised by the commentor is whether the current stack height at WTI is adequate to be protective of human health and the environment. As indicated by the commentator, this issue was raised and reviewed by US EPA in its comprehensive 1997 Risk Assessment and the Peer Review process that followed. The air modeling of the

emissions from this site was based on the actual stack height (of 150 feet); it was acknowledged to be less than GEP for air modeling purposes thus necessitating consideration of downwash effects from structures near the stack. One of the primary conclusions of this review indicate that the estimated average total cancer risk and non-cancer hazard index were sufficiently low that adverse cancer and non-cancer health effects would not be anticipated as a result of exposure to routine WTI emissions. Also, since 1997 there have not been reports of incidents of excessive downwash at the facility. Accordingly, there does not appear to be a need to require WTI to raise its stack height at this time.

11D) "How often does Von Roll/WTI make use of the Emergency Vent (EV)? How do you know? How is compliance maintained? Are emissions released from the Emergency vent regulated and accounted for?" (Tri-State)

Response to 11D:

VRA/WTI does not have a Emergency Vent System from the incinerator.

12) ISSUES RELATED TO CITIZEN ACCESS TO MONITORING DATA:

- 12A)** "EPA should require public availability of all monitoring data from Von Roll/WTI. The OEPA had 24-hour access to Von Roll/WTI's CEM data. We are requesting that the same information be made available to citizens via computer access, as it is with the Ohio EPA. If a special computer program is required, the system can be installed at the Carnegie Public Library, so that at any time, citizens can access information about what is being released from the stack at WTI, including from the dioxin and mercury CEMs, when they are added. In addition, a web site should be established within the Ohio EPA's on-line data system whereby citizens can access information about all releases and other information about the operation of Von Roll/WTI, similar to the Toxic Release Inventory (TRI) program. The information could easily be made available on-line and would help reduce the number of Open Records Act Requests at the state level and Freedom of Information Act Requests at the federal level." (Tri-State)
- 12B)** "We request that the EPA require the same on-line data provided to the Ohio EPA is also made available to citizens. If it is not possible for citizens to access this information individually on home computers, a computer system could be established at the Carnegie Library." (Tri-State)
- 12C)** "In their recent Response to Comments made by citizens in November of 2000, US EPA responded to citizens request for access to data and information from Von Roll/WTI: We will be requesting that Von Roll consider methods of allowing interested members of the community more access to information such as waste inventories and emissions. Von Roll maintains extensive computer records both on waste which is on-site and on waste which has been burned. These records are constantly electronically updated, via the computer system, for utilization in daily operations and for permanent record keeping." (Tri-State)

Response to 12A, 12B, and 12C:

Commentors have requested that certain monitoring data collected and used by VRA/WTI be made available to the public. Some of the requested data is contained in the Bailey Distributed Control System (DCS). The DCS is used by VRA/WTI to maintain process parameters and operating conditions within the permitted range, e.g., feed rates, combustion zone temperature, and process flow. Waste inventories such as waste approved for delivery, waste on-site, and waste treated are maintained on a VRA/WTI database. The data collected is used by VRA/WTI to ensure compliance with permit limits and conditions and to compile monthly, quarterly, and annual reports which are submitted to Ohio EPA and which are available to the public. Examples of reports submitted by VRA/WTI are the quarterly excess emissions report and the hazardous waste annual report.

The Bailey Distributed Control System (DCS) was not created to carry out a function of Ohio EPA. As stated above, the DCS functions in many capacities to assist VRA/WTI in day to day operations. Ohio EPA has the ability to observe information electronically that

is extracted from the DCS on a near real time basis. On occasion, Ohio EPA may retrieve data from the DCS database and this information, once collected, would be considered a public record. Ohio EPA has no regulatory authority to require public availability of the monitoring data or the VRA/WTI database. To reiterate, the DCS is not kept nor controlled by Ohio EPA and consequently, the DCS data is not a public record. As a private entity, VRA/WTI is free to share whatever information with citizens they desire and the facility has expressed an interest in setting up public access to the database. Ohio EPA encourages interested citizens to contact Raymond Wayne at VRA/WTI (330-385-7336) to pursue this option.

13) ISSUES RELATED TO LAB PACKS:

13A) "Even though Von Roll/WTI had requested approval to handle lab pack on at least three earlier occasions, approval was not granted by the EPA until just AFTER the risk assessment was released." (Tri-State)

Response to 13A:

The chronology for approval of the permit modification for VRA/WTI to handle lab packs is a separate issue from release of the risk assessment for the facility. The initial Waste Analysis Plan (WAP) approved as part of the VRA/WTI permit application did not include a description of the management procedures for lab packs. In addition, a particular section of the WAP (at that time, section C-2e) stated that VRA/WTI could not accept lab packs until the WAP was modified (with Ohio EPA and U.S. EPA approval) to include language describing the management procedures.

VRA/WTI followed the permit modification process by submitting several requests between 1993 and 1998 to both Ohio EPA and U.S. EPA. The modification requests proposed that VRA/WTI be allowed to accept, handle, and incinerate lab packs. These requests were reviewed and comments were provided to VRA/WTI by both agencies. Ultimately, VRA/WTI submitted modifications dated August 29, 1997 and September 11, 1997 to Ohio EPA and U.S. EPA, respectively. Both agencies reclassified this permit modification as a "Class 3" modification, which required a second public comment period (held November 14, 1998 through January 6, 1999) and a regulatory hearing (held December 14, 1998).

A document entitled "Responsiveness Summary For Comments on VRA Modification Request" dated March 24, 1999 provided agency responses to a total of 43 comments from various citizens (including 8 from Ms. Swearingen) regarding the modification proposal to accept lab packs at the VRA/WTI facility. In April 1999, this document was provided to Tri-State Environmental Council and other parties on the Ohio EPA's mailing list maintained for actions pertaining to the VRA/WTI facility. The modification allowing VRA/WTI to accept lab packs was approved by Ohio EPA on April 8, 1999.

13B) "Why did the EPA wait until AFTER the risk assessment was complete to approve the handling of lab packs? (So that the handling of lab packs --- which have caused problems at other incinerators, including an explosion that closed the Chicago incinerator --- would not have to be considered in the risk assessment?)

The risk assessment did not take into consideration the handling of lab packs at WTI. Why not? If a credible risk assessment is performed, the handling of lab packs must be considered." (Tri-State)

Response to 13B:

As explained in the response to Comment 13A, the chronology for approval of the permit modification for VRA/WTI to handle lab packs is a separate issue from the release of the risk assessment for the facility. The document entitled Risk Assessment for the Waste Technologies Industries (WTI) Hazardous Waste Incineration Facility (East Liverpool, Ohio) was prepared by U.S. EPA Region 5 and dated May 1997. The risk assessment included evaluations of worst-case incidents at the VRA/WTI facility. As such, while the handling of lab packs as a particular waste stream may not have been specifically evaluated, the evaluations of worst-case incidents would have been more than inclusive of any waste processing activities at the facility, including those involving lab packs.

Volume I, the Executive Summary, part I.B.3 Accident Analysis, describes the performance of an accident analysis as part of the risk assessment, in order to evaluate the likelihood and potential off-site consequences of accidents that may occur during normal operations. Those operations would include the handling and processing of all waste received at VRA/WTI. This section states (page I-10) that "Three general classes of on-site accidents (spill, fire, and mixing of incompatible wastes) and two general classes of off-site accidents (spill and fire) are evaluated."

Volume VII describes the Accident Analysis in detail, and explains the rationale behind evaluating the on-site and off-site scenarios. The on-site spill scenarios evaluate credible events that, if they were to occur, would be expected to result in the most potentially significant off-site consequences (Vol VII, page II-7). Of the various possible events evaluated, an outdoor spill involving a tanker truck in the Truck Unloading Station was selected for quantitative evaluation (Vol VII, page II-8) as the worst-case scenario. Other on-site spills would be expected to have lower off-site consequences (Vol VII, page II-9). In general, lab packs range from 5 gallon to 55 gallon containers. By comparison, a tanker truck contains approximately 7,000 to 8,000 gallons (sometimes more) and consequently would pose more risk than the handling of lab packs. As stated previously, the risk assessment evaluated risks associated with possible on-site and off-site worst-case scenarios. The worst-case scenarios that were evaluated would have been more significant than any waste processing activities at the facility.

In addition, concern by Ohio EPA and U.S. EPA regarding the handling, processing, and storage of lab packs at VRA/WTI resulted in the inclusion of several pages in the permit application. These pages describe in detail the procedures and restrictions regarding lab packs. Please also see the response to Category 16.

14) ISSUES RELATED TO PERMIT-SPECIFIC COMMENTS FROM VRA/WTI:

14A) "Please revise the table of contents. It is not numbered correctly."

Response to 14A:

A Table of Contents was not included in the draft renewal permit.

14B) B.14- "This page is worded differently than VRA's current approved contingency plan. The wording is important because the current contingency plan allows the facility and OEPA to jointly classify incidents. This language was added to VRA's contingency plan at the agency's request in 1999. At the time it followed the guidance for contingency plan implementation, which could and was interpreted to mean as long as the incident was minor and posed no threat to human health and the environment, a contingency activation was not necessary. The DHWM now presumes that any fire involving hazardous waste would constitute contingency plan activation. It does contain a phrase that allows a facility to modify their contingency plan to include information that the unique nature of the hazardous waste would not be a threat to human health and the environment under certain emergency situations. VRA would have a very difficult time predicting this information and prefers working with on-site inspectors on a case-by-case basis. Page 23 now contradicts VRA's contingency plan and would require contingency activation for every fire involving hazardous waste. VRA believes that contingency activation is not warranted in all cases because all fires do not impact human health and the environment. VRA would like to follow the current contingency plan by either referencing it in the permit or including identical language on page 23. VRA provides their on-site inspector with a weekly list of minor incidents and works with the inspectors to determine if a contingency plan should be activated. This allows the on-site inspector the freedom to rule out minor fires that posed no threat to human health or the environment."

Response to 14B:

Ohio EPA interprets OAC Rule 3745-54-51, Purpose and implementation of contingency plan, to assume any fire, explosion, or release of hazardous waste or hazardous waste constituents will threaten human health or the environment unless the facility can demonstrate to the contrary. Von Roll has demonstrated the ability to control fires through extensive emergency response and fire brigade training. The facility possesses adequate resources on-site to respond to such emergencies when the need arises. In addition, automated systems for detection and suppression of fires are in place should a fire occur.

If VRA would like to change the wording in the permit regarding specific criteria to be utilized in the determination of implementation of the contingency plan, a permit modification request should be submitted to address such changes. Specifically, a permit modification to Section G, the Contingency Plan, of the Part B permit application would be necessary. In addition to the specific criteria to be added, VRA may want to provide common scenarios when the contingency plan would not be implemented based on available resources, training, and/or past experiences. If the request is approved, the language in the permit would then be changed to reflect the permit application.

There were no changes to the permit as a result of this comment.

14C) C.14) - "This page contradicts written agreements VRA has developed with on-site

inspectors. VRA believes that the container staging requirements contained on this page were entered in error. C.14 (b) should be struck out because in a letter dated March 6, 2002 VRA responded to a notice of violation for improper storage. Although VRA was not storing hazardous waste, the issue of staging vs. storage was discussed. VRA proposed to submit a diagram mapping out where, and for how long wastes would be staged. The diagram allows for an unlimited time to complete the splitting process in the splitting area. This is due to the rate at which certain materials can be fed. Spilt material cannot be placed back into the warehouse and may take several days or up to a week in some cases to incinerate. Item C.14(d) is also incorrect. It only allows 24 hours for the staging of direct tankers. The March 6, 2002 letter stated "Additionally, as per our verbal agreement on February 14, 2002, the time allotted for holding direct tankers on site prior to processing will be 72 hours."

Response to 14C:

Ohio EPA realizes that circumstances arise when the processing of waste at the facility must be delayed, e.g., unexpected outages, mechanical problems, problems with waste feed, etc. In many of these situations, staging of the waste rather than returning it to storage is the best option. This is applicable to those situations when the staging period is of relatively short duration and it is safer to stage the waste rather than transport it back to storage. The criteria used to make the safety determination is (1) the staging areas have secondary containment; (2) the majority of the staging areas have automatic fire detection and suppression systems; (3) the majority of the staging areas are under canopy or in enclosures. The Permittee is responsible for informing the Ohio EPA on-site inspectors, in advance, of situations when the permitted staging times are exceeded.

If VRA/WTI would like to change the wording in the permit regarding Container Staging, a permit modification request should be made to add the specific staging requirements to the permit application. If the permit modification is approved the language in the permit would be changed to reflect the modified "Part B" permit application.

There were no changes made to the permit as a result of this comment.

14D) D. (c) "General Wastewater Treatment System-- The water in Tank W-4 is used as recycle water and may be used for any plant processes. Page 49 limits VRA to using the water only in the scrubber or in the DeNOx system."

Response to 14D:

In response to this comment, Section D of the permit was revised as follows:

D. TANK STORAGE, TREATMENT AND MANAGEMENT

(c) General Wastewater Treatment System

The sentence, "The water in Tank W-4 is used as recycle water and may be used as make-up for the four-stage wet scrubber or in the DeNOx system."

has been revised to read, "The water in Tank W-4 is used as process water at the facility and may be used as make-up water in the four-stage wet scrubber or in the DeNOx system."

- 14E)** I(A).2.(ii)– "The OEPA states that VRA cannot burn waste that has a heat of combustion lower than carbon tetrachloride. This statement should be removed on the basis that the U.S. EPA now recognizes that the thermal stability table is more representative of successful treatment of such chemicals. There should be no limits because VRA demonstrated that it can successfully burn a class 1 compound on the thermal stability table."

Response to 14E:

Ohio EPA agrees with VRA/WTI's comment and has adopted the position that if a facility selects a principal organic hazardous constituent (POHC), ranked Class 1 on the thermal stability ranking index, and achieves the required destruction and removal efficiency (DRE), that demonstrates the facility can burn chemicals characterized as Class 1 or greater. Because Class 1 contains the most difficult to incinerate organic hazardous constituents, the Permittee would not be restricted from feeding organic hazardous constituents listed in the Appendix to OAC Rule 3745-51-11 to the incinerator. VRA/WTI has used monochlorobenzene (MCB), a liquid, Class 1 compound, as the POHC for their annual performance tests for the past several years and successfully achieved DRE of greater than 99.99%. In addition, MCB is a compound with a low heat of combustion which means it is difficult to incinerate as determined in the Heat of Combustion System.

Ohio EPA revised this permit condition based on the comment and suggests the facility submit a permit modification request to revise the language in Section C of the Part B permit application accordingly. The new permit language is as follows:

I(A).2. Identification Criteria for Permitted and Prohibited Waste

- (A) *The Permittee shall not feed any hazardous waste containing any organic hazardous constituents listed in the Appendix to OAC Rule 3745-51-11 of the Administrative Code unless the constituent has a thermal stability class ranking equal to or higher than Class 1.*

- 14F)** I(A).2.(v)– "Currently some waste codes only exist federally so the statement "shall not incinerate or treat any hazardous waste whose current Ohio EPA hazardous waste code does not appear in the approved Part A permit application..." should be revised to include any federally approved codes that Ohio has not yet promulgated."

Response to 14F:

The Ohio Hazardous Waste Facility's Installation and Operation permit can not include waste codes that have yet to be promulgated by the Ohio EPA. Any change in the federal regulations that subject a facility to immediate compliance will need to be added to the Federal permit. Those portions of the Federal permit that apply to this situation will remain in effect. When, and if, the State of Ohio promulgates the regulation, the facility will be required at that time to take action at the state level to make the appropriate modifications to the State permit. The permit language was revised to reflect that this condition applies

to state recognition of RCRA hazardous waste. The new permit language is as follows:

I(A). INCINERATION

I(A).2. Identification Criteria for Permitted and Prohibited Waste

(a)(v) The Permittee shall not incinerate or treat (1) any State-recognized hazardous waste whose current Ohio EPA hazardous waste code does not appear in the approved Part A permit application or (2) any waste listed in Section C of the approved Part B permit application categorized as being prohibited from incineration or (3) any waste for which the facility is not designed to receive, handle, store or treat.

14G) I(A).2.(c)(iii)- "This limits VRA from receiving dioxin-bearing waste that is below the treatment standard. Please clarify this statement to read dioxin waste exceeding the treatment standard."

Response to 14G:

Ohio EPA agrees that the language can be interpreted to prohibit acceptance of any dioxin-bearing waste. It is the Agency's intent that the Permittee not take wastes that are listed specifically because of dioxin/furan content (F020 through F023, F026 and F027) or waste that contains dioxin/furan concentrations above applicable LDR treatment standard. For clarification, dioxin-bearing wastes are defined as waste requiring specific treatment technology, that is, destruction and removal efficiency (DRE) of 99.9999%. Examples include waste assigned federal hazardous waste codes F020 through F024, F026, and F027. In addition to certain criteria for permitted and prohibited waste, section I.(A).2 also includes restrictions on wastes assigned federal hazardous waste codes which are required to meet LDR treatment standards for dioxins and furans, such as F032, F039, K043, and K099. To reflect these changes to the permit, the Ohio EPA is requiring that VRA submit a permit modification to revise Section C of the Part B permit application. Therefore, in response to this comment, several changes were made.

The new permit language is as follows:

I(A).2. Identification Criteria for Permitted, RESTRICTED, and Prohibited Waste

- (c) Wastes, in accordance with Section C of the approved Part B permit application, that are prohibited from acceptance on-site include:
 - (iii) dioxin bearing waste: waste requiring specific treatment technology, i.e., destruction and removal efficiency (DRE) of 99.9999%; waste assigned federal hazardous waste codes F020 through F024, F026, and F027;
- (d) "Wastes that are restricted at the facility are described in Section C of the approved Part B permit application. Examples of restricted wastes include:

- (i) wastes that may require special handling and/or storage requirements;
- (ii) wastes with treatment restrictions; and
- (iii) wastes that carry any of the federal hazardous waste codes which are required to meet LDR treatment standards for dioxins and furans, such as F032, F039, K043, and/or K099.

A description of restricted wastes are listed in Section C-1a(2), Category 2 - Restricted Wastes of the Part B permit application."

14H) I(A).3.(I)– "Atomization fluid pressure is given for steam and air combined. Air pressure will be monitored by a pressure switch and will not be recorded. The switch will cause an alarm to sound. The fluid pressure will vary and should not be in the permit."

Response to 14H:

The feed lance atomizers at the front wall function to reduce the waste to a spray and to project the waste away from the front wall into the combustion zone which optimizes incineration. During the initial trial burn, the atomization fluid pressure (e.g., steam, air) to the front wall lances was recorded at 45 psig. This then, shall be the pressure required as a permit limit until and unless additional testing demonstrates that complete combustion can be achieved at atomization pressures other than 45 psig.

Upon further evaluation, the permit has been modified to include the following language:

"The limit of 45 psig was recorded during the Permittee's initial trial burn and will be maintained until and unless additional testing demonstrates that complete combustion can be achieved at atomization pressures other than 45 psig.

If the atomization pressure for any of the feed lances at the front wall fall below 45 psig, the feed for that lance will be cutoff until such time the pressure can be maintained."

14I) "Attachment 1, Critical Process Control Parameters (page 101) – This table represents operating parameters in which VRA typically operates. These parameters however are not limits that cannot be exceeded. In contrast, VRA periodically may operate outside of the ranges identified in this table. These conditions were not considered critical in the approved trial burn plan with the intent of becoming limiting parameters."

Response to 14I:

Ohio EPA has evaluated this comment. Considering the process control parameters listed in the table in Attachment 1 are not operating parameters for the combustion of hazardous waste and are not currently permit conditions, Ohio EPA acknowledges the validity of this comment. The removal of these process control parameters from the permit will not impact

human health and the environment. In response to this comment, Ohio EPA has modified the permit by removing the table in this attachment.

- 14J) "VRA is requesting that the front wall lance pressure identified in Attachment 3 be modified to represent how the facility currently operates. Attachment 3 identifies that the atomizing steam pressure is 45 psi when it should be 20 psi."

Response to 14J:

This comment is the same as Comment 14H.

- 14K) "VRA is requesting that "sundowner" language be entered into the permit to aid in the transition out of RCRA oversight for incinerator operations and into Title V oversight when it is demonstrated that the facility complies with the HWC MACT Rule 40 CFR part 63 subpart EEE."

"In addition, 40 CFR 264.340 (b) discusses the integration of the HWC MACT standards by stating the following: "(1) Except as provided by paragraphs (b)(2), (b)(3), and (b)(4) of this section, the standards of this part no longer apply when an owner or operator demonstrates compliance with the maximum achievable control technology (MACT) requirements of part 63, subpart EEE, of this chapter by conducting a comprehensive performance test and submitting to the Administrator a Notification of Compliance under §§ 63.1207(j) and 63.1210(b) of this chapter documenting compliance with the requirements of part 63, subpart EEE, of this chapter. Nevertheless, even after this demonstration of compliance with the MACT standards, RCRA permit conditions that were based on the standards of this part will continue to be in effect until they are removed from the permit or the permit is terminated or revoked, unless the permit expressly provides otherwise."

"To aid in this transition, the USEPA's Office of Solid Waste issued a fact sheet (document number 5305W – see attached) which discusses how the transition should work for a facility in the process of renewing a RCRA permit. In following this guidance document and following the regulatory basis for this transition, VRA is requesting that certain sections of this permit be revoked upon verification of compliance with the HWC MACT Rule. With the above in mind, VRA requests that language be added to the permit which states that after VRA provides OEPA DAPC with the required written documents including the Start-up, Shutdown and Malfunction Plan (SSMP), and the Notice of Compliance (NOC) following completion of facility will be authorized to operate without adhering to the following sections in the permit: I(A)1, I(A)2(a)(ii), I(A)2(a)(iii), IA2(a)(vi), I(A)2(d), I(A)2(e), I(A)2(f), I(A)3, I(A)4 I(A)5, I(A)6, I(A)8, I(A)9, I(A)11, Attachment 1, Attachment 2 with exception to the annual metals feed limits because they are risk based, all of attachment 3 and all of section D-5 of the application."

Response to 14K:

The OAC rules, equivalent to the citations in the comment, HWC MACT Rule 40 CFR part 63 subpart EEE and 40 CFR 264.340, are not under the Ohio EPA Division of Hazardous Waste Management's regulatory authority. That said, Ohio EPA can not include sunset

language in the State of Ohio RCRA permit. Once the facility submits their Notice of Compliance to the U.S. EPA and certifies their compliance, a permit modification will be required to remove relevant sections from the State RCRA permit. No change was made to the draft permit in response to this comment.

- 14L) "The inclusion in a hazardous waste facility renewal permit of corrective action requirements for historic groundwater and/or soil contamination resulting from infrequent and catastrophic spills of petroleum products from product storage tanks which once occupied a portion of the hazardous waste facility site before the permitted facility was constructed is unlawful."

"The draft permit recites the known history of the Charter Oil contamination: as many as three (3) catastrophic spills occurred when the site was used as a petrochemical storage facility/tank farm prior to the construction of (and wholly unrelated to the operation of) the WTI facility. These spills were from above-ground storage tanks used to hold product. There is no information in the record to suggest that the storage tanks from which the releases occurred were ever used for the management of solid waste."

"Under pertinent Ohio regulations, corrective action is required at permitted TSD facilities "for all releases of hazardous waste or constituents from any waste management unit at the facility." OAC 3745-55-011. A "waste management unit" is "any discernible unit at which solid waste, hazardous waste, infectious waste, industrial waste, or other waste has been placed at any time Such units include any area at a facility at which solid waste, hazardous waste, infectious waste, construction and demolition debris, industrial waste, or other waste has been routinely and systematically released." OAC 3745-55-10(A)(128)."

"The Ohio Administrative Code definition of "waste management unit" is based upon the analogous U.S. EPA definition of "solid waste management unit" pertinent to the RCRA corrective action regulations at 40 CFR §§ 264.100, 101. A SWMU must be a discernible waste management unit at a RCRA facility from which hazardous waste or its constituents have migrated or could migrate in the future; thus, the definition does not include accidental spills. *Horsehead Industries v. St. Joe Minerals Corp.*, 1996 U.S. Dist. LEXIS 22493 (N.D. Oklahoma). Moreover, a solid waste must have been intentionally placed into such discernible unit before the unit becomes a SWMU under corrective action regulations. *Cytec Industries v. B.F. Goodrich Co.*, 232 F. Supp. 821 (S.D. Ohio E.D. 2002). A tank used to store product or raw material is not a SWMU. In *re Amerada Hess Corp.*, 1989 RCRA LEXIS 25 (1989). Thus, the petroleum product storage tanks operated by River Services and Charter Oil did not meet the definition of a SWMU, and the accidental spills of product from those tanks do not constitute a release of a hazardous waste or constituent from a SWMU."

"It is important to note that the draft permit discussion references one document as the basis for the corrective action portion of the permit. That document, the Preliminary Assessment/Visual Site Inspection Report performed by PRC

Environmental Management, Inc., under contract to U.S. EPA ("PAVSI"), identified 18 SWMUs at the VRA facility, and concludes that there are no documented releases from any of those SWMUs. The PAVSI also discusses the Charter Oil contamination as an "area of concern," but does not characterize that historic contamination as emanating from or related to any SWMU."

"Therefore, because the Charter Oil contamination did not emanate from and is wholly unrelated to any SWMU at the VRA facility, inclusion in the permit of any corrective action requirements applicable to the Charter Oil contamination is unlawful."

"The inclusion of corrective action requirements for the Charter Oil historic contamination in the VRA hazardous waste facility permit is unnecessary and inappropriate."

"The Charter Oil contamination is the subject of a consent order entered by the Director of the Ohio EPA and the Port Authority of Columbiana County in November 1991. That order required characterization of the nature and extent of the contamination, and the development, approval and implementation of a remedial plan to contain and abate that contamination. VRA assumed the Port Authority's obligations under that order when it purchased the facility property in 1992, and work under that order continues today. There is no information in the record that the scope of the Charter Oil contamination problem or any risks to human health or the environment associated with the contamination have changed since 1992, nor is there any information to suggest that continued implementation of the Ohio EPA-approved remedial plan will not contain and abate the contamination. That order was based upon CERCLA and the Director's statutory authority to investigate and address suspected contamination in the State of Ohio. The order is not based upon, nor does it reference, corrective action under RCRA. Moreover, although it was issued after the Hazardous and Solid Waste Amendments to RCRA became law, the original RCRA permit issued by U.S. EPA to WTI in 1985 likewise does not include any RCRA corrective action requirements applicable to the Charter Oil contamination. Thus, the Charter Oil contamination has been and continues to be appropriately addressed without reference to or reliance upon RCRA-based authority."

Response to 14L:

Corrective action in Ohio is intended to address "all releases of hazardous waste or constituents from any waste management unit at the facility, regardless of the time at which waste was placed in such unit.", Ohio Administrative Code ("OAC") rule 3745-55-011(A). While the commenter properly notes the existence of this rule, he offers the argument that historic contamination may not be addressed. In that he edited his citation to exclude the qualifying phrase "regardless of the time at which waste was placed in such unit," his argument is unsupported. In furtherance of his argument, the commenter also selectively cites the definition of "waste management unit" contained in OAC rule 3745-50-

10(A)(128)⁵, but again includes only a portion of the definition in his argument. The full definition reads as follows:

"Waste management unit" means any discernible unit at which solid waste, hazardous waste, infectious waste (as those terms are defined in Chapter 3734. of the Revised Code), construction and demolition debris (as defined in Chapter 3714. of the Revised Code), industrial waste, or other waste (as those terms are defined in Chapter 6111 . of the Revised Code) has been placed at any time, irrespective of whether the unit was intended for the management of solid waste, hazardous waste, infectious waste, construction and demolition debris, industrial waste, or other waste. Such units include any area at a facility at which solid waste, hazardous waste, infectious waste, construction and demolition debris, industrial waste, or other waste has been routinely and systematically released. (Emphasis added)

By eliminating the italicized phrase above, the commentor continues to argue that the intent to place waste in the waste management unit is a necessary element of the definition of such a unit. Based on the plain language of the Ohio definition of "waste management unit," however, this conclusion is incorrect. Further, of the case law cited to support the commentor's position, only *Cytec Industries v. B.F. Goodrich Co.*, 232 F. Supp 2d 821 (S.D. Ohio E.D. 2002)⁶ could be located, despite extensive searches in legal databases. A careful reading of this case reveals nothing which supports the proposition for which it is cited, to wit, "a solid waste must be intentionally placed into such discernible units before the unit becomes a SWMU under corrective action regulations." Further, as this case does not interpret the Ohio rules cited above, its relevance is at best extremely limited.

Clearly, areas of contamination resulting from spill events may meet the definition of "waste management unit" and may be included in the corrective action required pursuant to a hazardous waste installation and operation permit. The plain language of the rules supports no other result. The commentor notes that the Preliminary Assessment/Visual Site Inspection report identified the Charter Oil contamination as an "area of concern." As its title indicates, this report is preliminary, and is merely an overview of the facility based on what was known in 1993, when the report was produced. Waste management units subject to corrective action may be identified at any point during the life of the facility, and the designation as such is not dependent on being so named in a preliminary assessment of the facility. Nothing in the analysis provided supports the commentor's conclusions that to address an area of historic spill contamination through corrective action is unlawful, and no changes have been made to the draft permit in response to this portion of the comment.

15) MISCELLANEOUS COMMENTS:

⁵ This definition was improperly cited the comment as "OAC rule 3745-55-10(A)(128)." The correct citation is noted above.

⁶ This case was improperly cited as "*Cytec Industries v. B.F. Goodrich Co.*, 232 F. Supp 821 (S.D. Ohio E.D. 2002." The correct citation is noted above.

- 15A) "Federal District Court (Judge Ann Aldrich) ruled in March, 1993 that WTI met the Resource Conservation and Recovery Act's (RCRA) standard of "imminent and substantial endangerment," 42 U.S.C. SS 6972(a)(1)(B) and 6973(a) and was found to be too dangerous to operate for even one year resulting in a temporary restraining order (TRO)." (Tri-State)

Response to 15A:

The following response to this issue was provided in an August 17, 1995, letter from V. Adamkus of the U.S. EPA to Ms. Swearingen:

Judge Aldrich's March 5, 1993, Memorandum and Order in that case (later dismissed for lack of subject matter jurisdiction⁷) was, for the most part, based on the results of a U.S. EPA screening⁸ analysis of cancer risks from stack emissions of dioxin and furan compounds. That analysis was not intended to be an in-depth exposure assessment using site-specific information regarding locations of key exposed individuals. It covered the first year of operation of the facility and assumed continuous operation. Since the facility had not yet started operations, estimated air concentrations of dioxin and furan compounds from the Phase I risk assessment were utilized. Further, a number of aspects of the fate, transport, and food chain modeling were intentionally very conservative.

Lifetime cancer risks resulting from the one-year uninterrupted operation, followed by residual risks from soil impacts, were estimated for four different exposure scenarios: a subsistence farmer who ate only beef raised on his farm, a "high-end" farmer who ate beef both from his farm and from other sources, a resident with a home garden, and a child with schoolyard exposures. Since the analysis was for screening purposes, it was also conservatively assumed that the subsistence farmer lived at the point of maximum impact of the stack emissions.

For the residential and schoolyard exposures, no risks exceeded 10^{-7} . For both farm scenarios, the only risk which exceeded the 10^{-7} level was the beef ingestion risk, which was in the 10^{-5} range. From this highly conservative screening analysis, the Agency concluded that a one-year period of uninterrupted operation of the incinerator would not result in unreasonable risk to the population in the environs of the facility.

This analysis was updated in the Fall of 1994 based upon site-specific data which became available after the completion of the initial analysis. Such data included one-year meteorological data from the site, actual emissions data from the

⁷ The U.S. EPA believes that the Court of Appeals would have overturned Judge Aldrich's findings regarding the risk from the facility had it reached the issue. In particular, Judge Aldrich mistakenly determined that the risk from one year of post trial burn operation was "...likely to result in an increased cancer risk of at least 4×10^{-5} ." It is important to keep in mind that the conservative, hypothetical exposure scenarios in any screening analysis refer to plausible but unlikely conditions. The actual risks are likely to be less than the upper bound risk predicted by a screening.

⁸ A screening analysis of risk is a simplified exercise, which, due to its conservative assumptions, tends to overstate potential risks. It is only meant to be used as a first step to determine whether a more detailed risk assessment is called for.

performance tests and trial burn conducted subsequent to the installation of the enhanced carbon injection system, and actual percentages of time that the facility had been operating since the start of the period of limited commercial operations. Further, it utilized updated dioxin fate and transport parameters, consistent with the Agency's dioxin exposure reassessment document. All of the exposure scenarios and assumptions were unchanged from the initial screening analysis.

For the residential and schoolyard exposures, no risks exceeded 10^{-6} . For both farm scenarios, the only risk which exceeded the 10^{-6} level was the beef ingestion risk, which was 1×10^{-6} for the subsistence farmer and 5×10^{-7} for the high-end farmer.

U.S. EPA's screening risk analysis was the basis of the decision to perform a second, more detailed, phase of risk assessment. The primary conclusions of the detailed risk assessment were as follows:

- For incinerator stack emissions, polychlorinated dioxins and furans (PCDD/PCDF) were identified as the primary constituents of concern. The consumption of meat and eggs from locally raised livestock, and the consumption of milk and dairy products from locally exposed cows were identified as principal pathways of exposures to PCDD/PCDF. For these pathways, the estimated average total cancer risk was 1 in 1 million (1×10^{-6}) or less.
- Estimated average noncancer hazard index (HI) values were below 1.0, indicating that noncancer health effects associated with stack emissions would not be anticipated.
- For fugitive emissions, average cancer risks were estimated to be less than 2 in 1 million (2×10^{-6}) for all fugitive emissions sources. The estimated noncancer HI values associated with exposure to fugitive emissions were substantially below 1.0, indicating that noncancer health effects would not be anticipated.
- Based on an evaluation of site-specific, incremental risk across the entire population in the vicinity of the WTI facility, it was not anticipated that any individual in this population would develop cancer as a result of exposure to routine WTI emissions.
- Predicted off-site air concentrations of U.S. EPA- regulated "criteria pollutants," such as sulfur dioxide, nitrogen oxides, hydrogen chloride, particulate matter, and lead were determined to be less than National Ambient Air Quality Standards.

15B) "Von Roll/WTI continues to operate. What's so sad are the real-world consequences of WTI's 10 years of operation. Sandy Estell, who lives with her 5 children on the bluff 800 feet away, provides a personal glimpse of what it's like to live next door to an incinerator. "Our home sits on a bluff overlooking WTI, only 800 feet away. I am not some hysterical housewife with nothing better to do. Over the last few years, I have learned as much as I could about this most unwelcome neighbor. I've done a lot of reading about mercury and dioxins, things I knew

nothing about before WTI. We have experienced the terror of being evacuated, pulling our children out of school and out of harm's way. We have also been chased from our neighborhood because of noxious fumes from a chemical spill. Just imagine your entire town smelling like strong cat urine! Or even better, imagine driving toward your home, across the Ohio River and seeing the flashing red lights of the fire trucks just below your house. Imagine it taking forever to drive that last mile. Fire trucks are everywhere around the incinerator. Panic sets in at that point because you have no idea what is happening and there is nowhere to call, no one to ask for an explanation. Your little ones are all excited over the commotion but your older ones are looking at you with that familiar look as if to say, "Are we going to have to leave home again?" I'm tired of this science experiment. I don't want to play anymore. The stakes are too high. I want my family to be a safe distance away from what is potentially the world's largest commercial toxic waste incinerator. For me, moving is not an option. This is my home. I am an American citizen, not some wealthy multinational corporation." (Tri-State)

Response to 15B:

VRA/WTI remains one of the most stringently monitored facilities in Ohio, both out of regulatory interests and out of respect for citizens' concerns regarding this facility. As a result, Ohio EPA staff conduct facility compliance inspections two to four times each week, respond to numerous phone calls and letters requesting information, investigate complaints, participate in emergency incident training exercises and work with VRA/WTI to promote safe operation of the facility. Comprehensive Compliance Evaluation Inspections are conducted on a semi-annual basis to inspect and review VRA/WTI's operating records. Incidents are investigated to determine significance relative to the facility's permit and Ohio laws and regulations. If appropriate, violations are cited which may or may not lead to escalated enforcement. The Ohio EPA works with VRA/WTI to implement corrective actions as part of the incident evaluation process. During the years of operation, VRA/WTI has responded to situations as they arose to prevent their reoccurrence.

One of the examples the commentor mentioned was the evacuation in 1991 of people in the vicinity of VRA/WTI. It should be clarified that the evacuation incident was due to the rupture of a natural gas line in the area, and was not due to VRA/WTI operations.

In response to the commentor's concern regarding noxious fumes and the strong cat urine smell, the facility did have odor problems associated with the various mercaptan wastes received on site. These sulfur-containing organic compounds have very low odor thresholds, on the order of parts per billion (ppb). The facility instituted a number of changes to mitigate or eliminate this problem. The changes include enclosing the tanker unloading bays where waste was off-loaded and adding vapor recovery. Also, to avoid problems with handling this and other problem waste streams, the facility installed direct tanker unload stations. These units are in an enclosed building with vapor recovery and the waste is pumped directly to the kiln rather than to a tank. The last odor incident associated with the mercaptan odors that Ohio EPA is aware of occurred several years ago. This was related to a problem with the tanker transporting the waste and was not the result of waste management at VRA/WTI. There have been other odor complaints from the citizens since then, but the odors which resulted in those complaints were traced to

another company nearby.

- 15C) "Von Roll/WTI should not be allowed to continue to operate. They do not possess the credibility or trustworthiness to own and operate a toxic waste incinerator, especially in the middle of a residential neighborhood, 1,100 feet from a 400-student elementary school and 320 feet from homes. Von Roll/WTI is unsafe, unnecessary and unwanted. It should be closed immediately. If EPA truly wants to protect citizens in the community and the surrounding areas, they would stop the incinerator from operating. But if past is prologue, EPA will do everything in it's power to see that WTI continues to operate, no matter what the consequences are to people who live here or to future generations." (Tri-State)

Response to 15C:

In the renewal process, Ohio EPA considers the application, inspection reports, and the facility's history of compliance with the present permit, and Ohio's hazardous waste laws. Ohio EPA has found that the facility has a history of compliance that demonstrates sufficient reliability, expertise, and competency to operate the facility. Our record of incidents at the Von Roll America facility has been evaluated and the Ohio EPA has determined that state renewal standards for compliance have been met. Additionally, for facilities accepting waste from off-site, the owner/operator must have a history of compliance with environmental laws and must not have been convicted of disqualifying crimes (ORC 3734.44) listed in the statute. Ohio EPA has determined that VRA qualifies to receive a hazardous waste permit renewal. It is Ohio EPA's task to ensure that as long as VRA/WTI continues to operate, they continue to do so safely and in a manner consistent with compliance with environmental regulations.

The commenter states that the VRA/WTI facility is unnecessary and unwanted. Some people may not approve of the location of the VRA/WTI facility (see category 1 for comments regarding siting). However, facilities which provide proper treatment of both hazardous and non-hazardous waste are necessary. At this time, incinerators are an integral part of the overall national waste management system. We, as human beings, create all types of waste either on the manufacturing end or on the consumer end. Ensuring proper treatment, storage, and/or disposal of hazardous, and in many cases, non-hazardous waste is the responsibility of the EPA. The EPA is also tasked with ensuring that such facilities follow the applicable regulations.

The commenter also states that the consequences of VRA/WTI's operations on people who live here now and on future generations do not matter to EPA. This is not true. Ohio EPA and U.S. EPA are deeply committed to ensuring the health and safety of the citizens surrounding the facility as well as the citizens in other localities. Facilities such as VRA/WTI provide appropriate treatment, storage and/or disposal of materials which might otherwise harm people's health or the environment if improperly disposed. Balancing the concern of citizens and the need for proper waste disposal while ensuring proper operation and maintenance of such facilities can be difficult. That is why it is critical to the EPA to ensure that treatment, storage, and/or disposal facilities comply with the regulations, to ensure that human health and the environment in all locations is protected.

- 15D) "Additional comments, concerns and recommendations: 1) By reference, we would

like to incorporate into our comments, the entire ***Petition Requesting Denial of Permit Renewal, Termination or Revocation of the WTI Permit***, filed by the Tri-State Environmental Council, filed in March 1995 after WTI's RCRA Permit expired and no action was taken by the regulatory agencies." (Tri-State)

Response to 15D:

The Petition Requesting Denial of Permit Renewal, Termination or Revocation of the WTI Permit ("petition") was initially received by U.S. EPA on April 5, 1995. U.S. EPA responded to the most significant issues in a letter to Terri Swearingen dated August 17, 1995. This August 17, 1995 letter is included as Attachment G. The comments and information presented in the petition were considered during the draft permit renewal process. With respect to your request for termination or revocation of the permit, U.S. EPA did not believe at the time that the points raised in the petition warranted those actions.

The petition addressed the permit renewal, compliance issues and the procedures for citizen participation in the renewal process. U.S. EPA, in their letter responding to the petition, clarified state and federal responsibilities in the permit renewal process. Ohio EPA provided information on the procedure for citizen participation in the permit renewal process in the "Public Notice", the Agency issued on January 25, 2003. For issues and further information related to the public participation process, please refer to Ohio EPA response to comments 10A through 10G. The basis for Ohio EPA's determination to renew the hazardous waste permit is covered in our response to comment 15C. Issues related to permitting including, termination, expiration and operating conditions are considered in Ohio EPA's response to comments 7A through 7K. Compliance issues are considered in comments 8A through 8I. Concerns regarding noxious fumes and the strong cat urine smell were addressed in the response to comment 15B.

The petition also deals extensively with changes in the WTI partnership and ownership issues. It states that "the current entity in control of WTI has no permit to own or operate an incinerator". U.S. EPA, in their letter responding to the petition, addressed many of these issues. Ohio EPA has further responded to issues related to ownership, please refer to Ohio EPA response to comments 6A through 6E. On February 13, 1998, the Ohio Hazardous Waste Facility Board (Board) authorized the transfer of the hazardous waste permit (originally issued to WTI in 1984) to Von Roll America (VRA). In so doing, it deliberated upon various aspects of VRA's history of compliance with environmental and other laws. The Board concluded that VRA/WTI or a sister or parent company had not been convicted of a disqualifying crime listed in ORC Section 3734.44(B) and no basis existed to revoke VRA/WTI's permit or to deny a modification to transfer ownership to VRA: The Board's decision on this matter was appealed to both the Franklin County Court of Appeals and the Ohio Supreme Court. The Court of Appeals (case#98AP-220) affirmed the Board's decision on December 28, 1998. The Ohio Supreme Court declined to hear the case (1999). For additional information on this subject, please refer to Ohio EPA response to comments 5A through 5C.

The petition also focuses on public health concerns and the findings of federal district Judge Ann Aldrich as reasons for terminating the permit or for denying the permit renewal application. The findings of Judge Ann Aldrich were initially addressed in U.S. EPA's letter responding to the petition and is discussed further in Ohio EPA response to comment 15

A. Issues related to public health, including mercury exposure, cancer, and respiratory problems are considered in Ohio EPA response to comments 3A through 3G. The site-specific accident analysis conducted as part of the U.S. EPA's 1997 Risk Assessment evaluated spills and fires associated with truck accidents for wastes en-route to the Von Roll facility as well as accidental spills or releases on the facility grounds.

U.S. EPA, in their letter responding to the petition, addressed assertions in the petition that the WTI permit should be terminated because it was issued in violation of Executive Order 11988, regarding flood plains. The U.S. EPA did consider that Executive Order in promulgating its location standards in 1980 (see 40 CFR 264.18), and the WTI permit was issued in compliance with those standards. Issues related to Ohio EPA's siting of the incinerator are addressed in Ohio EPA response to comments 1A through 1D. Siting the facility was a valid decision that was made almost twenty years ago and the facility has been constructed and operating for more than ten years. The renewal standard (ORC Section 3734.05(H)) does not allow the Agency to resite the facility.

15E) "By reference, we would like to incorporate into our comments, the comments of Teresa Mills and the Buckeye Environmental Network (BEN)." (Tri-State)

Response to 15E:

The comments of Teresa Mills on behalf of the Buckeye Environmental Network were directed toward the draft Title V permit. These comments have been addressed by Ohio EPA's Division of Air Pollution Control in conjunction with issuance of the Title V permit.

15F) "By reference, we would like to incorporate into our comments, the 2000 Preliminary Report of National EPA Ombudsman Robert Martin, and all comments and information received by Mr. Martin in conjunction with his preliminary report. In addition to consideration of the Ombudsman Preliminary Report and Recommendations, the EPA must address all issues raised in the body of work completed by the ombudsman, including that of all commenters." (Tri-State)

Response to 15F:

The U.S. EPA's "National Ombudsman's Draft Report on Waste Technologies Industries" was responded to by Timothy Fields, U.S. EPA Assistant Administrator, in a memorandum to Robert J. Martin on January 19, 2001. The memorandum disagreed with the findings in the report based on concerns with assumptions used to support the findings and procedural concerns with how the investigation was conducted. However, as a result of the report, U.S. EPA has taken several steps to ensure availability of the best data possible about the facility. These steps were outlined in the January 19, 2001 memorandum which is Attachment B of this Responsiveness Summary.

15G) "By reference, we would like to incorporate into our comments, the objections raised by Attorney Richard Renner, on behalf of Save Our County (SOC)." (Tri-State)

Response to 15G:

The comments from Attorney Richard Renner on behalf of Save Our County are being addressed in Category 8 of this Responsiveness Summary.

- 15H) "By reference, we would like to incorporate into our comments, the testimony and entire trial transcript from the legal cases involving Von Roll/WTI employee Donna Trublood and others involved in the case. Additional information can be found at the U.S. Department of Labor Administrative Law Judges web page." (Tri-State)

Response to 15H:

This issue was addressed in Category 8 of this Responsiveness Summary.

- 15I) "By reference, we would like to incorporate the comments of former Von Roll/WTI employee Terry Lancaster, in her June 8, 2002 letter to US EPA's Gary Victorine, outlining problems and possible violations at Von Roll/WTI."

Response to 15I:

This issue was addressed in Category 8 of this Responsiveness Summary.

- 15J) "By reference, we would like to incorporate into our comments, the comments in the attached outline discussion of issues that need to be considered in relation to the Title 5 Permit/RCRA hazardous waste permit renewal. These issues/questions need to be answered/resolved before the EPA moves forward on Title 5 Permit issuance/RCRA hazardous waste permit renewal." (Tri-State)

Response to 15J:

The "attached outline discussion of issues" was located at the end of the comments provided by Tri-State Environmental Council. The outline included phrases and partial sentences. When those phrases were included in the body of the letter, the Agencies addressed them as part of the Responsiveness Summary. Where portions of the outline were not expanded upon in the body of Tri-State Environmental Council's comments, the Agencies placed those portions of the outline as a comment in the appropriate category. The portions of the outline are acknowledged as (Tri-State). Where incomplete or unclear statements were included in the outline, the Agencies have attempted to interpret the meaning of those statements and provide a response where possible.

16) ISSUES RELATED TO RISK ASSESSMENT:

[Note: Because the U.S. EPA conducted the risk assessments and accident analysis, the following responses in Category 16 were prepared by U.S. EPA Region 5 together with Ohio EPA.]

16A) COMMENTS FROM DOCTOR HALSTEAD HARRISON

(Letter dated May 8, 2003, submitted electronically May 9, 2003):

16A.1) Dr. Harrison commented:

I judge the "Peer Review" process to have been deeply flawed, and I recommend that it not be cited further in support of present decisions to re-license WTI. Specifically, in EPA's recent "Response to public comments regarding WTI", Comment 1, it is asserted that

"WTI's emissions have been checked via an EPA-conducted peer-reviewed risk assessment, which failed to reveal unusual risks associated with the operation of the incinerator." For reasons extensively discussed [below] I strongly dissent from this incorrect assertion.

Response to 16A.1:

While we are indebted to Dr. Harrison for his participation in the original peer review panel for the U.S. EPA's 1997 detailed risk assessment, and while we appreciate his input at this time, we must respectfully disagree with his characterization of the peer-reviewed risk assessment for the VRA/WTI facility. Dr. Harrison submitted many specific comments about that risk assessment, about the peer review process, and about U.S. EPA's risk assessments in general, which we discuss in detail below.

Before we list and respond to Dr. Harrison's specific comments, however, we believe it appropriate to discuss the basic regulatory framework under RCRA and the manner in which risk assessments have been used within that framework for hazardous waste incinerators.

Regulatory Background: *The U.S. EPA's permitting responsibilities regarding RCRA-regulated facilities, including hazardous waste incinerators like VRA/WTI, are established by statute and regulation. RCRA Section 3004(a) of the Resource Conservation and Recovery Act ("RCRA"), 42 U.S.C. § 6924(a), requires the Agency to develop regulations establishing performance standards applicable to RCRA-regulated facilities for the protection of human health and the environment. Final RCRA regulations are generally presumed to be protective of human health and the environment, and permits that implement these regulations are also generally presumed to be protective.*

While RCRA and the RCRA regulations are the primary means of ensuring protectiveness at RCRA-regulated facilities, both RCRA and the RCRA regulations recognize that additional permit restrictions beyond the requirements of the statute and regulations may sometimes be necessary. The "omnibus provision" (codified in RCRA § 3005(c)(3) and 40 CFR 270.32(b)(2)) directs the RCRA permitting authority to include terms and conditions in the RCRA permit as necessary to ensure adequate protection of human health and the environment. (The Ohio Administrative Code includes a similar provision at OAC § 3745-50-40(D)(6).) If the U.S. EPA concludes that additional permit terms and conditions are necessary to ensure adequate protection of human health and the environment, the omnibus authority allows the Agency to impose them in a facility's permit.

The Agency must be able to provide adequate justification for such a conclusion, however, in order to impose permit terms that go beyond the requirements of the RCRA regulations. A risk assessment is one of the main tools the Agency uses to evaluate whether additional permit terms are necessary to protect human health or the environment. If the risk assessment indicates that additional permit terms are necessary, the risk assessment documents the justification for requiring them.

Use of Risk Assessments: *Risk assessments enable the U.S. EPA to evaluate in a systematic manner risks posed by hazardous waste activities. While individual perceptions*

of the magnitude of risk from regulated activities, including hazardous waste incinerators, are to some extent subjective and inevitably vary among individuals, risk assessment techniques allow the U.S. EPA to develop, evaluate, and integrate objective information about risks posed by a hazardous waste incinerator to assist U.S. EPA and state risk managers in making decisions about whether additional requirements are necessary to help ensure that a permit is protective. To the extent possible, the development, evaluation and integration of such information is based on principles and techniques generally accepted by the scientific community.

Risk assessments are used, for example, to uncover and evaluate conditions unique to a specific facility, such as environmental factors (e.g., valley topography or meteorology) and/or facility configuration (e.g., short stack) , that might cause the facility to have a greater impact on its environment than would be expected under the assumptions on which the regulations were based. They are designed to reveal potentially significant risks from common pollutants that are known to frequently be associated with a particular operation, such as hazardous waste combustion.

No risk assessment can achieve a perfect assessment of risks, since there are inevitably gaps in the scientific understanding of the nature of risks (e.g., information gaps in chemistry or toxicology for certain substances) and limitations in risk methodologies. In response, the U.S. EPA uses conservative risk assumptions to provide a margin of safety and ensure that risks are not underestimated. While risk assessments cannot guarantee safety, they can be conducted in a manner which provides a sound basis for risk management decisions regarding the protectiveness of permits and permit terms. To the extent a risk assessment uncovers risks that might not be addressed adequately by the RCRA regulations and permit, action can be taken to reduce potential health impacts and help ensure that the RCRA permit is protective.

The U.S. EPA's risk assessment techniques rely extensively on peer review by independent experts, to ensure that the techniques parallel those routinely accepted in the larger scientific community. The risk assessment for the VRA/WTI incinerator was carefully prepared and extensively reviewed by an independent peer panel of scientific experts. The U.S. EPA significantly revised the risk assessment in response to comments from the peer panel, resulting in a better and more useful document.

The nature of the risk assessments themselves is not prescribed or otherwise addressed in the regulations. In order to achieve consistent regulation of all potentially affected owner/operators of hazardous waste burning incinerators, boilers, and industrial furnaces, nationally consistent guidance on risk assessment was necessary. In response to this need, a national workgroup of U.S. EPA staff developed a draft guidance manual on how to conduct reasonable yet effective hazardous waste combustor risk assessments. That guidance grew out of national conference calls, risk assessment work done in Region 6 and many other Regions, and to a certain extent, the detailed "Phase 2" VRA/WTI risk assessment, which served as a prototype for risk assessments that followed it. The 1998 draft guidance that grew from this effort was the subject of its own independent peer review, and it is currently being used by the U.S. EPA and facilities that opt to conduct their own risk assessments.

Combustion Strategy: In 1993, Carol Browner, the Administrator of the U.S. EPA at that time, published the draft Strategy for Combustion and Waste Minimization (later finalized in November 1994), which, in part, called for a re-evaluation of the RCRA regulations that applied to hazardous waste combustors (including hazardous waste incinerators) to help ensure that permits issued by the Agency were protective and wouldn't allow unacceptable risks. In the interim, Administrator Browner called for risk assessments as an additional or supplemental part of the process of permitting these facilities under RCRA, until such time as new regulations were in place. Risk assessments were to be used to assess the potential health impacts of pollutants or exposure pathways not necessarily addressed in the regulations. Problems identified by the risk assessment could then potentially be addressed in the permit process for the individual facility.

Risk Assessment for VRA/WTI: Region 5 utilized two phases of risk assessment (one phase before operations were first allowed, and one phase after site-specific testing could be performed) to evaluate the protectiveness of VRA/WTI's RCRA permit conditions. The results of these assessments were issued on July 9, 1992, and May 8, 1997, respectively. The risk assessment allowed Region 5 to evaluate in a systematic manner public concerns that VRA/WTI's location and configuration could create unusual risks, and to examine the nature of the connection between the source and the possible impacts of emissions.

Risk Assessments in the Future: In the last few years, site-specific risk assessments for hazardous waste combustors have become less important. The new hazardous waste combustor regulations that Administrator Browner called for in 1993 were promulgated under the Clean Air Act in September 1999. Although the new regulations are based on what is technologically feasible as opposed to what might cause unacceptable risk, the U.S. EPA conducted a "national risk assessment" as part of the rulemaking process to ensure that the new regulations would be protective. Because this national risk assessment has verified the protectiveness of the new regulations, the preamble to the new regulations suggests that site-specific risk assessment may not routinely be needed, once facilities comply with the new standards. The VRA/WTI facility was required to begin complying with the new standards as of September 30, 2003.

16A.2) Dr: Harrison commented:

"DRE" hides fluxes of toxic materials that are not destroyed, but passed into land-fill operations for later, slow release into the environment. I am skeptical that a DRE of 99.99% is routinely achieved, as stated. That number is cited from limited test-burns conducted under near-ideal conditions. Further, DRE numbers refers to mass, not toxicity. You can get a high-sounding DRE with a feed-stock containing innocuous junk, and the number hides "removals" by spills and fugitive emissions. Destruction efficiency numbers [DE] should be itemized for a speciated list of toxic feedstocks.

Response to 16A.2:

We agree that wastes are not totally destroyed during incineration. Accordingly, the U.S. EPA regards incineration as a treatment technique, to be used for reduction in the mass of waste which is sent to hazardous waste landfills, rather than disposal. Residue from the incineration of hazardous waste must be sent to a hazardous waste landfill, albeit in smaller quantities than if the waste had not been incinerated.

As to the routine achievability of 99.99% DRE, we disagree with Dr. Harrison. The tests which are used to measure DRE are generally conducted on specific chemicals that have been demonstrated to be the most difficult of the regulated hazardous waste constituents to burn. This allows the conclusion that virtually all other organic hazardous constituents, even the most toxic, will be destroyed at least as effectively, if not more effectively. The trial burn tests which demonstrate these DREs are conducted at the minimum combustion temperature and burn time, which are far from ideal conditions, and the minimum average temperature recorded during the trial burn becomes the permit limit for minimum temperature. Because of this and because VRA/WTI's trial burn tests and many following tests have demonstrated DREs sometimes approaching 99.9999%, we think it is reasonable to believe that 99.99% is routinely achieved at VRA/WTI during incineration.

Dr. Harrison is correct that the DRE doesn't address pollution released to the air from fugitive emissions and spills. The DRE addresses only the effectiveness of the incineration device at reducing the amount of organic material in wastes that are incinerated. However, the VRA/WTI RCRA permit together with applicable regulations help reduce fugitive emissions and spills. In addition, risk assessments can be performed to evaluate such emissions. For example, the VRA/WTI risk assessment addressed fugitive emissions such as those from waste handling.

16A.3) Dr. Harrison commented:

"Comment: EPA and/or Von Roll should provide public availability of all data including monitoring data." I agree emphatically: digital formats, please.

Response to 16A.3:

We have made representatives of Von Roll aware of the public's interest in greater availability of data.

16A.4) Dr. Harrison continues:

Regarding the risk assessment peer review process:

The reviewers were first assembled to evaluate "Phase I" output from contracting firms who were responding to task definitions set earlier by staff at EPA. We were narrowly charged to address technical questions on the accuracy and relevance of documents prepared by those contractors. My colleagues and I divided into panels for special topics, responded with comments on the work thus far performed and with suggestions to consider additional aspects of the risk assessment.

My panel was chaired by Walter Dabberdt of NCAR, Boulder, Colorado, and charged with reviewing material associated with atmospheric dispersion and accidents. Among the comments and suggestions from this panel, were:

-Steady-state air-quality models, such as the COMPDEP-ISC model that was exercised by the contractors, are of dubious merit in the complex, river-valley terrain of the WTI facility. We recommended that CALPUFF, INPUFF or other time-dependent model be exercised with locally observed winds, modified where necessary by a terrain-sensitive, mass-conserving wind algorithm. We further

recommended that such models be exercised with assumptions for extraordinary conditions, such as might be expected with severe and sustained stagnation events.

-We recommended that impacts from stack and fugitive emissions should not be considered "from base zero" [that is, as if there were no other pollution sources affecting the community] but as superimposed on top of the existing air quality in the valley. Implicit in this is that data describing the present air-quality "base line" should be presented, and that estimates should be made of the likelihood and severity of exceedances of Federal standards.

-The accident records of comparable installations should be presented and evaluated, and specifically so for a similar toxic-waste incinerator at Biebesheim, in Germany.

In the second or "Phase II" round of the WTI Risk Assessment [Dec. '95] we commended the contractors for responding .. in part .. to concerns for accidents and non-steady state pollutant dispersion, with data at the local site. Phase II did not, however, respond to our concerns about "base zero" accounting, nor to worst-case meteorology, nor to our panel's request for accident records at comparable installations. We further questioned some optimistic estimates of the frequencies of emergency incidents involving accidental releases of hazardous waste materials.

Somewhat outside of our panel's central competence, we judged the Phase II discussion of non-cancer effects to be excessively compressed in to an obscuring "Hazard Index", and that no discussion was included of chronic and acute respiratory effects of particulate inhalation, which have been demonstrated in city populations at low thresholds.

We recommended:

-Additional simulations with CALPUFF under conditions when the air is calm and stable.

-A re-examination of accident risks, based upon experiences with comparable facilities.

-A survey of present measurements of air-quality in the valley and a re-examination of air-quality impacts from WTI "at the margin" rather than from "base-zero".

-Concern for incremental effects of particulate emissions affecting respiratory distress in the elderly, and with asthmatic children.

In May of 1997 I and subset of the full peer panel again reviewed contractors' material responding to Phase II recommendations concerned with off-normal plant operations and accident risks. In this last review I noted that the assessment process had responded in varying degrees to our earlier recommendations for additional dispersion modeling, with an emphasis on stagnation events, and I expressed sympathy to the contractors and to EPA staff for what must seem to have been an interminable task.

I further noted, however, that:

The assessment did NOT discuss the ambient air-quality in the valley as a whole, nor did it address the "base-zero" question. I judged this to be a serious omission.

Response to 16A.4:

Recommendation to Evaluate Air Quality Impacts "at the margins": In a risk assessment that evaluates air impacts "at the margins", concentrations of toxic compounds due to one facility's smoke stack are evaluated as being cumulative with the already-existing concentrations of toxins in the local air. We did not use the "at the margins" method (although see the discussion regarding lead, below), but we believe the method we used to evaluate the impact of air emissions from VRA/WTI was protective, as explained below.

For potential non-carcinogenic hazards due to regulated toxic metals (other than lead) and organic compounds, the VRA/WTI risk assessment did not specifically take into consideration the actual ambient air concentrations. U.S. EPA's guidance on conducting risk assessments for hazardous waste combustors currently does not incorporate this technique. However, Region 5 used a safety threshold that assumes there are other nearby sources of the same metals and organic compounds that contribute up to three times the amount of pollutant as the facility being evaluated. The U.S. EPA recommends (see U.S. EPA's April 1994 Draft Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities) that when calculating an air concentration resulting from an emission source for toxic compounds, one should not only compare the calculated air concentration to hazard quotient⁹ ("HQ") values of 1.0 (i.e., a widely accepted safe exposure benchmark) in making risk management decisions, but should also compare the calculated air concentration to an HQ value of 0.25 – to account for the fact that other facilities in the area might be emitting those same toxic compounds in even greater quantities, and that those emission will be additive. In the case of the VRA/WTI, the results of the risk assessment (See Table V-4 of the Executive Summary) were compared to the recommended benchmarks of HQ = 0.25, and U.S. EPA used these results to reduce permitted annual emissions of the metals mercury, barium, silver, thallium, nickel, selenium, and antimony to achieve calculated HQ values of 0.25. Please also see the responses to Comments 16B.22 and 16 B.31.

We believe the technique described above is just as protective, much simpler, and a much less resource intensive way of addressing the concern over additive emissions.

For the non-carcinogenic effects of lead¹⁰, Region 5 used a human exposure model which

⁹Note that the terms Hazard Quotient (HQ) and Hazard Index (HI) are frequently used interchangeably, but actually have different meanings. An HQ is the numeric ratio obtained by comparing the estimated intake of a specific chemical to its individual threshold toxicity criterion, such as a Reference Concentration. The term HI, on the other hand, is generally used to reflect the sum of the HQs for chemicals having similar toxic impacts.

¹⁰Although lead was found to have carcinogenic effects in some laboratory animal studies, the cancer risk of lead at the concentrations and exposure levels usually encountered in the environment are very small compared to the documented neurotoxicity and developmental toxicity from human exposure to lead. Therefore, risk assessments focus only on the toxic effects of lead.

did include measured ambient air background concentrations of lead in its calculations, yielding an analysis of total lead exposure instead of incremental exposure. Later, when some questioned the validity of the ambient lead air values, we confirmed our analysis by replacing the measured value with a conservative default value typically used in these calculations. Thus, for the non-carcinogenic effects of lead, we believe we did use a technique which falls into the category of "at the margins".

For carcinogenic risks due to regulated toxic metals (other than lead) and organic compounds, the results of the VRAWTI risk assessment were compared to an increased lifetime cancer risk = 1 in 100,000 (or .00001 or 10^{-5}). This benchmark for potential increased cancer risk is insignificant when compared to a "base zero" lifetime cancer risk range of 0.20 to 0.33 (i.e., overall lifetime cancer risks in the United States have typically been stated as ranging from one in five to one in three). All sensitive subgroups evaluated by the VRAWTI risk assessment were projected to have a potential increase in lifetime cancer rate less than this benchmark of 1 in 100,000.

Several reports have highlighted the usefulness of understanding and addressing the accumulation of risks from multiple environmental stressors. These include the National Research Council's (NRC) 1994 report "Science and Judgment in Risk Assessment" and the 1997 report by the Presidential/Congressional Commission on Risk Assessment and Risk Management entitled "Risk Assessment and Risk Management in Regulatory Decision-making." In addition, recent legislation, such as the Food Quality Protection Act of 1996, directed the U.S. EPA to move beyond single chemical assessments and to focus, in part, on the cumulative effects of chemical exposures occurring simultaneously. Further emphasizing the need for U.S. EPA to focus on cumulative risks are the cases filed under Title VI of the 1964 Civil Rights Act. These cases have demanded a population-based approach to assessing human health risks from environmental contaminants.

The U.S. EPA's recently released "Framework for Cumulative Risk Assessment" (U.S. EPA EPA/600/P-02/001F. 01 Jan 2003) is the first step in a long-term effort to develop cumulative risk assessment guidance. Building on U.S. EPA's growing experience with cumulative risk assessment, the Framework identifies the basic elements of the cumulative risk assessment process and provides a flexible structure for conducting and evaluating cumulative risk assessment, and for addressing scientific issues related to cumulative risk. Although this Framework report will serve as a foundation for developing future guidance, it is neither a procedural guide nor a regulatory requirement within U.S. EPA, and it is expected to evolve with experience. The Framework is not an attempt to lay out protocols to address all the risks or considerations that are needed to adequately inform community decisions. Rather, it is an information document, focused on describing various aspects of cumulative risk.

This document has benefitted from extensive peer input. Earlier drafts of the documents served as background pieces for peer consultations with state, federal, and other peer groups. An external peer review, open to the public, was held in June 2002. The document was revised based on input received during the peer consultation and review processes, and from public review and comment. To see the document go to: <http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=54944>

Recommendation for Additional CALPUFF Simulations: In response to the suggestion of the peer review panel on which Dr. Harrison served to use air dispersion models similar to CALPUFF, and to incorporate terrain effects and stagnation events, the U.S. EPA recognized in the 1997 Risk Assessment that the location of the VRA/WTI facility presented several challenges for atmospheric dispersion modeling. Volume IV of the 1997 Risk Assessment stated these challenges as:

-Due to complex topography in the vicinity of the WTI facility, site-specific meteorological measurements indicate strong channeling of winds at lower elevations within the Ohio River Valley that are not present above the valley.

-The dispersion and buoyant rise of plumes released from short stacks may be significantly modified by the presence of buildings or other obstacles to the flow. A particular phenomenon, building-induced downwash, may result in increased concentrations in the near-field.

-The Ohio River Valley has a high incidence of stagnation and inversion conditions. Onsite measurements indicate that calm conditions prevail locally in the valley approximately 20 to 25 percent of the time. These conditions may potentially limit dispersion and transport of facility emissions, and may result in the accumulation of pollutants in the immediate vicinity of the facility.

-Under moderate-to-high wind conditions, terrain-induced downwash (contaminants being drawn downward near the ground surface as air flows over an abrupt drop in terrain elevation) may result in increased concentrations in the vicinity of the WTI facility.

Volume IV of the Risk Assessment documented that these concerns were considered through (1) the development and application of a refined atmospheric dispersion/deposition model (ISC-COMPDEP); (2) performance of sensitivity tests using the advanced non-steady state models (CALPUFF and INPUFF), and (3) in the case of terrain downwash, a separate wind tunnel simulation of conditions in the vicinity of the VRA/WTI facility.

Regarding Dr. Harrison's comment on the use of Hazard Index ("HI"), the HI is a typical and accepted way of evaluating potential chronic low dose impacts, including potential respiratory effects.

Regarding Dr. Harrison's suggestion to use accident information from comparable facilities, including the Biebesheim facility, please see the response to Comment 16A.6, below.

Regarding Dr. Harrison's comment concerning the impact of particulate emissions affecting respiratory distress, please see the response to Comment 16A.5.

16A.5) Dr. Harrison commented:

The assessment did NOT discuss effects of air pollution on bronchio-pulmonary distress, likely to be the most acute community impacts from WTI.

Response to 16A.5:

Ozone and particulate matter are the two major air pollutants which appear to be associated with acute respiratory health effects in the general population. These health effects include inflammatory responses in the lungs, reduced lung function, and exacerbation of asthma symptoms. Recent epidemiological and public health studies have shown a positive correlation between hospitalization rates and elevated levels of ozone and particulate matter. The most sensitive population groups are the elderly, people with asthma, and persons with pre-existing respiratory illness.

Dr. Harrison has previously suggested that one indicator of the overall health of the East Liverpool community would be the rate of emergency room admissions for asthma. The local rate could be compared to similar figures for the State and for the United States (which are generally understood to be increasing). We believe that any such study must be spearheaded by a State or local governmental health board that can access such medical information. We would be happy to work with the health board(s) on this matter.

Because of the potential relationship between respiratory health and the ambient air concentrations of ozone and fine particulate matter, it can be useful to evaluate the "attainment" status of the air in the area in which the VRAWTI facility is located. Attainment status is a measure of whether or not a location attains the U.S. EPA's national ambient air quality standards ("NAAQS") in the area. At the time of the risk assessment it is our understanding that (i) for ozone (the 1-hour standard in effect at that time) Columbiana and Jefferson Counties were in attainment, and Hancock County was "unclassifiable / attainment," (ii) for NO₂ (the major precursor for ozone) all three counties were "cannot be classified or better than national standards," and (iii) for PM10 Columbiana County was unclassifiable, Jefferson County was in part "nonattainment" and in part "unclassifiable", and Hancock County was in part "nonattainment (for certain areas in and around Steubenville and Weirton) and in part "unclassifiable." Beaver County was nonattainment for ozone at that time, but later became attainment for ozone (one-hour standard) in October 2001. In addition, Beaver County was "unclassifiable" for PM10 and "cannot be classified or better than national standards" for NO₂.

More recent attainment data for Columbiana County, summarized from 40 CFR Part 81, is as follows:

Ozone (1-hour)	Attainment
Ozone (8-hour)	Non-attainment (new standard as of 2004)
PM10:	Unclassifiable
NO ₂ :	Cannot be classified, or better than national standards
Lead:	Not designated
CO:	Unclassifiable / attainment
SO ₂ :	Better than national standards

Information listed in the 2004 Code of Federal Regulations at 40 CFR 81.336, 339, and 349, and on the U.S. EPA's "Green Book" web site at <http://www.epa.gov/oar/oagps/greenbk/anay.html>, indicate that (i) for ozone (1-hour standard) Jefferson and Beaver Counties are in attainment, while Hancock County is

"unclassifiable / attainment," (ii) for NO₂ all three counties are "cannot be classified or better than national standards," and (iii) for PM₁₀ Jefferson County is in part attainment and may in part be "unclassifiable," Beaver County is "unclassifiable," and Hancock is in part "nonattainment"(for certain areas in and around Weirton) and in part "unclassifiable".

As part of a continuing federal-state effort to make the nation's air healthier to breathe, on April 15, 2004, the U.S. EPA named areas in the United States that will now be required to reduce emissions of ozone-causing pollution. These designations implemented the U.S. EPA's revised ozone ambient air standard which was originally promulgated in July of 1997. The new 8-hour standard will provide additional protection for the most sensitive population subgroups by lowering the allowable concentrations of this pollutant and will present specific target levels and time frames which the states must achieve in order to be in compliance with the new standard.

To achieve compliance with this new ozone standard, an area must attain an eight-hour average concentration of 0.08 ppm (as compared with the former standard of 0.12 ppm on a one-hour average). Under the new standard, which went into effect on June 15, 2004, many counties in the United States which had previously been considered to be attainment for ozone, including Columbiana, Beaver, Hancock, and Jefferson, were re-designated non-attainment as of that date. Therefore, even though these counties had by 2001 achieved compliance with the 1-hour ozone standard, the new and more restrictive ozone standard has now caused these counties to be re-designated as non-attainment. As such, they will have to make additional efforts to reduce ground level ozone.

Regarding the potential for VRA/WTI to contribute to the downwind synthesis of ozone, VRA/WTI appears to be a relatively minor contributor to the area-wide emissions of NO_x, the major precursor of ozone. Recent information indicates that the VRA/WTI facility is allowed to emit 28.4 lbs/hr of NO_x, which would represent only about 0.2% of the amount of NO_x emissions coming from one of the coal-burning electrical power plants that are located within 10 miles of VRA/WTI, according to information in the U.S. EPA's National Emissions Inventory. For additional information on the National Emission Inventory, please visit <http://epa.gov/air/data/>.

Because ozone is formed in the environment from the interaction of NO_x and Volatile Organic Compounds ("VOCs"), we also used the National Emission Inventory to determine whether the VRA/WTI facility is a significant source of VOC in the area. VRA/WTI was not listed as a significant source of VOC.¹¹

Regarding particulate matter, which also can have negative impacts on branchia-pulmonary health, the U.S. EPA intends in the near future to implement a new ambient air particulate matter standard to address fine-particulate matter. Fine particulate pollution represents one of the most significant barriers to clean air facing our nation today. These tiny particles - about 1/30th the diameter of a human hair - have been scientifically linked to serious health problems. At the time of this writing, most of the counties in the area around VRA/WTI are slated to be listed as non-attainment for the new PM-2.5 ambient air

¹¹Annual Emissions of VOCs were 18.26 tons per year (2002).

standard. Designating these areas as non-attainment, as well as other measures such as recently proposed rules requiring the reduction of pollution from power plants, will help achieve cleaner air.

In conducting the VRA/WTI risk assessment, Region 5 also looked at the Toxic Release Inventory ("TRI") emission inventory of nearby industry, to compare VRA/WTI's emissions of toxic materials to nearby emissions. This showed that VRA/WTI's contribution to the total is insignificant for all TRI-reported pollutants except mercury and ethylbenzene. When we then went back to the risk assessment and looked at these two pollutants, we found that the risk assessment did not predict that VRA/WTI's emissions of those compounds would be close to a level which would produce a significant health impact.

In summary, (1) we do not believe that VRA/WTI is a major contributor to ozone precursors or particulate matter in the surrounding area, (2) the U.S. EPA has recently implemented new ambient air ozone standards as part of its continuing efforts toward reducing ozone and its precursors even further, and (3) the U.S. EPA is developing new ambient air standards for fine particulate, as well as rules governing emissions of these from power plants. These new ozone and particulate matter measures are intended to address and reduce effects of air pollution which can cause bronchial-pulmonary distress, likely to be the most acute community impacts in this area.

16A.6) Dr. Harrison commented:

The material presented to me did NOT include the plant operations history at the Biebesheim facility, as had been requested by both previous reviews. [I have since learned, however, that these data were presented in an appendix.]

Response to 16A.6:

Dr. Harrison is correct that we did not seek or obtain information from the appropriate German governmental body until fairly late in the risk assessment process. In the VRA/WTI risk assessment, the U.S. EPA attempted to use either VRA/WTI-specific or industry-wide information, wherever possible, instead of information from individual sites and plants operating under different rules. Because there are so many unique variables at any one specific hazardous waste facility, we thought it more objective and useful to use industry-wide information.

The U.S. EPA does not believe that events at the Hessische Industriemüll GmbH ("HIM") facility in Biebesheim, Germany, create an appropriate model for predicting events at the VRA/WTI plant. For example, a number of fires have occurred in the solid waste bunker at the HIM facility, but we do not have detailed information regarding the regulatory standards for the waste bunker at HIM-Biebesheim (and how these compare to United States standards), the nature of the waste streams, or the actual extent and nature of any emissions from the reported events. Furthermore, although our comparison of drawings of the two facilities implies that overall storage configurations do have similarities, we were not able to compare operating practices, waste specifications, waste sampling frequencies/procedures, analytical requirements, or equipment details (such as fire prevention and protection equipment). These were thought to be more important than the

overall configuration of the plant. Comparing the waste analysis protocols for the two facilities would seemingly be very important, for example, since the HIM information implies that incomplete characterization of the waste (i.e., operating differences as opposed to equipment differences) could be the most common underlying cause of these fires.

Nevertheless, as the peer panel suggested, the U.S. EPA did subsequently consider information from the HIM facility in Biebesheim, Germany, as well as from other active hazardous waste incineration facilities in the U.S., in conducting the Accident Analysis. The U.S. EPA wrote to the appropriate German governmental body regarding fires and other accidents which had been observed at HIM-Biebesheim. The information provided by the Hessen government contains 75 entries spanning the period from September 1985 through July 1995. Many of these entries describe mechanical or electrical/electronic breakdowns, as opposed to accidents. There were approximately 15 bunker fires reported (note that in the first ten years of operation, VRA/WTI has had many more), but only one of these was in the second five years of operation. In addition, the report indicates several electrical fires, one fire in the "funnel" (assumed to be analogous to the internal solid waste hopper at VRA/WTI), and seven "explosions" in the slag quench tank ("Naßentschlacker"), assumed to be the type of rapid steam expansions commonly experienced when large pieces of hot slag fall into the slag tank. The cover letter states that there were no recorded injuries either on-site or off-site¹², but that there were some emissions in some cases.

Given the reports of solid waste fires in bunkers at the HIM facility, and in response to Peer Review Group comments, an evaluation of the risks associated with a large fire in the VRA/WTI solid waste pit was conducted and is included in the April 1998 Addendum to the risk assessment.

16A.7) Dr. Harrison continues:

The Summary: As I have mentioned, the Executive Summary of the EPA's Risk Assessment Forum was issued in May of 1997, concurrently with the last review, and, consequently without opportunity for response to that review. While this summary makes no explicit recommendation to Ohio State with respect to a pending decision to extend a provisional operating license for the WTI facility, its tone is that the risks of operating the plant are small.

The Summary asserts that:

- Lifetime-exposure cancer risks are estimated to be 1:1,000,000 from the stack, and 2:1,000,000 from fugitive emissions. "It is not anticipated that any individual in this population would develop cancer as a result of exposure to routine emissions".
- "Non-cancer health effects associated with stack emissions would not be anticipated".

¹²Note that there are few residences located in the area around the HIM plant.

- Predicted off-site air concentrations of US EPA regulated "criteria pollutants" [SO₂, NO_x, HCl, Pb, and particulate matter] "are determined to be less than National Ambient Air Quality Standards."

- "Neither fish species [or any other listed species] is likely to be adversely impacted by routine facility emissions."

- "For on-site accidents, only events with minor off-site consequences are considered likely to occur at the WTI facility, and only events with minor or potentially moderate off-site consequences are determined to be reasonably likely to occur."

It is impractical here to enter into detailed discussions of these conclusions, excepting briefly that:

- The estimated cancer risks are driven by dioxins. They are sensitive to perhaps unrealistic estimates that citizen exposures are limited to 9 years and that plant operations are "normal", with 99.99% efficiency of feed-stock conversion from complex hydrocarbons into carbon dioxide. Conspicuous in this lifetime cancer exposure risk [3:1,000,000] is that no estimate is made of uncertainties.

Response to 16A.7:

Dr. Harrison's assumptions that (1) exposures were only calculated at nine years; and that (2) uncertainties were not addressed, are incorrect, as explained below. We also disagree with Dr. Harrison's contention that WTI would not routinely achieve 99.99% destruction and removal efficiency, as discussed previously in the response to comment 16A.2.

Exposure Duration: *The U.S. EPA recognizes that the East Liverpool community includes a wide variety of individuals, each with different behavioral patterns and each from different locations with respect to the facility. Therefore, the U.S. EPA evaluated the risks to a number of different lifestyle/activity types, including residents (children and adults), school children, farmers (children and adults), and subsistence farmers (children and adults). While not every individual is expected to fit precisely into one of these lifestyle/activity categories, these groups provide an indication of the typical risks faced by people in the area surrounding the VRA/WTI facility to the stakeholders and the decision makers evaluating the VRA/WTI permit renewal.*

Human exposure to substances emitted during routine operations of the VRA/WTI facility may occur as a result of inhalation, ingestion, or dermal contact. To estimate the magnitude of the dose received through each of these routes of exposure, the environmental media concentrations estimated by using the fate and transport models are combined with exposure factors reflecting behavior and activity patterns. U.S. EPA guidance calls for estimating the "high-end" exposure, which is an estimate of the exposure of individuals in the upper end of the population exposure distribution. Conceptually, U.S. EPA guidance defines high-end exposure as within the upper 10% of the exposure distribution, but not higher than the expected highest value in the true distribution of the population. The guidance also recommends the development of "central tendency" exposure estimates to reflect exposure experienced by "typical" individuals in the exposed

population (i.e., those approximately at the median of the exposure distribution).”

In the case of the VRA/WTI risk assessment, we analyzed both the central tendency and high end exposures.

The following points should be noted for the VRA/WTI risk assessment:

a) For adult non-farming residents, the central tendency assumption for the exposure duration was nine years. In evaluating stack emissions, this was the only¹³ scenario in which the nine-year exposure duration assumption was employed. For non-farming residents, the high end assumption for exposure duration was 30 years;

b) For adult farming residents, the central tendency and high-end exposure duration assumptions in the VRA/WTI risk assessment were 20 years and 40 years, respectively. The latter two values are significant because the farming population subgroup was found to have the highest potential exposure to stack emissions from the VRA/WTI facility; and

c) In addition, the 40 year estimate of exposure duration for the farming subgroup was combined with high-end estimates of food consumption rates for the major food groups that are likely to be home grown, including meat, eggs, milk, vegetables, and fruit. The combination of high-end exposure duration and high-end food consumption rates was then used to calculate high-end risk estimates (cancer risk and hazard index) for a farmer. These risk estimates would be expected to account for the upper 10% (i.e., 90th percentile or higher) of the risk distribution for the farming population. Even under these hypothetical long-term high-end exposures, the projected risks and health impacts were below the risk management benchmarks of 1 in 100,000 and HI = 0.25.

The only area where a nine-year exposure was used as the sole exposure duration assumption in calculating potential cancer risks, without also looking at longer-time high-end exposures, was the section of the risk assessment which addressed risks from volatile fugitive emissions escaping at near-ground level, such as vapors escaping from storage tanks impacting nearby residents. However, in this situation, the risk assessment also assumed that the receptor would be located at the point of maximum inhalation exposure concentration for 24 hours a day, 350 days per year. This would be unrealistic and represents a worst case exposure.

Hence, the assertion that the VRA/WTI risk assessment used only the unrealistic estimate that all citizen exposure durations are limited to 9 years is incorrect.

The exposure estimates presented in the VRA/WTI risk assessment are believed to be conservative (i.e., tend to overestimate potential risks) for most individuals in the vicinity of the VRA/WTI facility. Even under the high-end scenarios evaluated in the VRA/WTI Risk Assessment, which might apply to a very small fraction of the community (if any), risks

¹³ Applicable U.S. EPA guidance recommended (and still recommends) a child exposure duration of six years due to the fact that exposure parameter values specific to young children (e.g., body weight and soil ingestion rates) change after six years.

were found to be below the risk management benchmarks of cancer = 10^{-5} and HI = 0.25. Please also see the discussion in the response to Comment 16C.2.

Adding Cancer Risks: In his comment, Dr. Harrison appears to add the one-in-one-million potential lifetime cancer risk from stack emissions to the two-in-one-million potential lifetime cancer risk from volatile fugitive emissions, to arrive at a total cancer risk of three in one million. However, we don't believe such addition is appropriate because (1) the stack emissions would impact a different area than the ground level emissions of volatile compounds, and (2) the maximum potential cancer risk from stack emissions would be to residents of subsistence farms (via indirect pathways such as uptake into cattle feed and subsequent consumption of the meat from that cattle), while the potential cancer risks from volatile fugitives would tend to have the greatest impact on the closest residents where there are no subsistence farms.

Even if it were appropriate to add these cancer rates, the sum of three in one million would still be well within the typical risk management benchmark of 10^{-6} .

U.S. EPA's Handling of Uncertainties. There are many different factors that are used in estimating risks associated with the VRA/WTI incinerator. These factors include, for example, the emission rate, dispersion factors, physical/chemical parameters, and exposure assumptions. In some cases, there is uncertainty associated with the values used for these parameters, due to a lack of complete information. To provide an indication of the potential impact of this uncertainty on the estimated risks, an uncertainty analysis was conducted (See Volume V of the Risk Assessment, Chapter IX: "Uncertainty Analysis", pages IX-1 through IX-29). The uncertainty analysis¹⁴ used a methodology referred to as variance propagation to ascertain the cumulative effect of the uncertainties associated with the many individual assumptions used in the assessment. The process used in the uncertainty analysis required the development of distributions of possible values for each parameter in the risk assessment. Thus, a distribution of possible risks was developed, based on the uncertainty of the input parameters used in the assessment. The distributions were developed to cover the entire range of expected values for the uncertain parameters. It would not be appropriate to extend these ranges further to include even more conservative values, because such values would have a very low likelihood of occurring and, thus, would not affect the results of the uncertainty analysis. See also the discussion in the response to 16C.5 regarding uncertainties in applying risk principles to diverse groups.

The sensitivity analysis, on the other hand, was a part of the VRA/WTI risk assessment which focused on a smaller portion of the risk assessment, the estimation of exposure. The factors used in estimating exposure may vary between individuals within a specific group of the population (e.g., residents); however, the risk assessment assumes only a single value for each parameter for a specific group. Therefore, the sensitivity analysis

¹⁴Note that these are the meanings of the terms "uncertainty analysis" and "sensitivity analysis" when used in the reporting of overall results of the risk assessment. These terms can have slightly different meanings within other specific scientific fields. For example, these two terms have slightly different meanings in the area of air dispersion modeling.

was conducted to evaluate this variability within population groups.

For a discussion of the representativeness of the 99.99 % destruction and removal efficiency, please see the response to Comment 16A.2.

Finally, in response to Dr. Harrison's comment about there being no explicit recommendations to the State of Ohio, please see Attachment H, which is a letter transmitting the results of the U.S. EPA's risk assessment to the Director of the Ohio EPA.

16A.8) Dr. Harrison continues:

- An EPA memorandum from Henry Habicht II, Deputy Administrator, included as Appendix B of the National Research Council report "Science and Judgment in Risk Assessment", 1994, specifically directs as "effective immediately, that .. regarding exposure and risk characterization, it is Agency policy to present information on the range of exposures derived from exposure scenarios and on the use of multiple risk-descriptors (i.e., central tendency, high-end of individual risk, population risk, important subgroups, if known) consistent with terminology in the attached Appendix and Agency guidelines". This directive was conspicuously not followed in the WTI assessment.

Response to 16A.8:

We disagree. All of this information is presented in Volume 5 (the detailed human health exposure assessment) of the risk assessment report.

Please also see the discussion in 16A.7 (regarding the development of high-end and central tendency estimates for farming and non-farming residents) and 16C.2.

16A.9) Dr. Harrison continues:

- Of non-cancer health risks, nowhere does the Executive Summary mention childhood or adult asthma, likely the most acute health impact of the WTI facility.

Response to 16A.9:

VRA/WTI is a very small source of particulate matter and ozone precursors in this area, as explained in the response to 16A.5, above.

16A.10) Dr. Harrison continues:

- The Summary's assertion that off-site air concentrations of U.S. EPA regulated "criteria pollutants" [SO₂, NO_x, HCl, Pb, and particulate matter] "are determined to be less than National Ambient Air Quality Standards" was NOT estimated as superimposed on the existing air quality in the East Liverpool valley. No information was presented about the present levels of these pollutants and the frequency of their exceeding federal standards. No estimates were made on the downwind contribution to O₃ synthesis from the NO_x increments from the WTI plant.

Response to 16A.10:

Superimposition of VRA/WTI's criteria pollutant emissions upon the existing levels:
Regarding NOx, SOx, and particulate matter ("PM"), page VIII-10 of Volume V of the U.S. EPA Risk Assessment contains the following language:

c. Potential Health Effects Associated with Inhalation of NOx, SOx, and Particulate Matter

Chronic toxicity criteria have not been established by U.S. EPA for SOx, NOx, or particles less than 10 microns in diameter (PM10). Thus, an evaluation of the risks posed by emissions of these substances is performed by comparison to annual average National Ambient Air Quality Standards (NAAQS). U.S. EPA has developed annual average NAAQS values for NO₂, SO₂, and PM10 of 100, 80, and 50 µg/m³, respectively. The maximum and average ground-level air concentrations of these substances estimated in each subarea are presented in Table VIII-5. As shown in Table VIII-5, the average predicted concentrations of SOx, NOx, and PM10 in the subareas are at least 100 times less than the NAAQS, with maximum predicted concentrations at least a factor of 10 below the NAAQS in all subareas. ...

...Using the NAAQS as a guideline, inhalation exposure to SOx, NOx, and PM10 emissions from the WTI facility stack is, therefore, not expected to pose a significant health risk. [Emphasis added]

From the above, it can be seen that the risk assessment found that potential increases in SOx, NOx and PM10 due to VRA/WTI would not be significant when compared to the NAAQS. Therefore, the U.S. EPA would not expect these emissions to pose a significant increase in potential health effects, whether or not they are superimposed on existing ambient levels.

Regarding lead, page VIII-13 of Volume V contains the following language:

4. Estimation of the Potential Health Effects Due to Lead

The evaluation of risks associated with exposure to lead requires the use of U.S. EPA's Integrated Exposure Uptake Biokinetic (IEUBK) model for lead in children, a computerized model that predicts blood lead concentrations in children exposed to lead through a variety of media. The model is designed to estimate blood lead levels using a combination of default exposure assumptions and site-specific exposure information, where available.

The assessment of risks associated with exposure to lead from the WTI facility is conducted using version 0.99d of the IEUBK model, which is calibrated for children from one-half to seven years of age (U.S. EPA 1994e). Uptake of lead from five media (air, drinking water, soil/dust, food, and paint) is evaluated by the model. For this assessment, blood lead levels for children in the one to seven year-old age range are modeled. The default input values used in the IEUBK model are presented in Table VIII-16. Two site-specific exposure values (background lead concentrations in air and child inhalation rates) are substituted for the model default values for the WTI site

analysis. The default air lead concentration of $0.1 \mu\text{g}/\text{m}^3$ is replaced with an estimated background air lead concentration of $0.065 \mu\text{g}/\text{m}^3$ (OEPA 1993). This concentration is estimated from air sampling conducted at the East Elementary School in East Liverpool, which was compiled by Ohio EPA. Monthly samples were collected from this monitoring station during late-1992 and early 1993, prior to full operation of the WTI facility. None of the samples indicated the presence of lead in air above the detection limit (which ranged from 0.075 to $0.188 \mu\text{g}/\text{m}^3$). The lead concentration in air is estimated as the average of one half the detection limits for the seven monthly samples.

In addition, the default age-specific inhalation rates for one to seven year-old children, which ranged from 2 to $7 \text{ m}^3/\text{day}$, are changed to $16 \text{ m}^3/\text{day}$ for all ages to be consistent with the inhalation rate for children used elsewhere in this risk assessment. This change likely results in an overestimate of the potential for adverse health effects in children due to inhalation of lead.

From the above, it can be seen that the U.S. EPA's assessment of potential lead impacts did indeed consider background air concentrations. In addition, further analysis was conducted at a later date which replaced the site-specific air Pb concentration of $.065 \mu\text{g}/\text{m}^3$ with the higher "default" value of $0.1 \mu\text{g}/\text{m}^3$, with the resulting calculated impacts continuing to be small.

Hydrochloric acid (HCl) is not considered to be a criteria pollutant. While the summary of the risk assessment incorrectly stated that HCL was a criteria pollutant, the risk assessment did address HCl health impacts. We discuss HCl in the response to comment 16A.16.

Present levels of criteria pollutants

As to information regarding the present levels of criteria pollutants in the East Liverpool area, we agree that the risk assessment document did not publish this information. The U.S. EPA's Risk Assessment focused on potential impacts of emissions of chemical constituents that are generally regarded as being more highly toxic/carcinogenic, and especially associated with the incineration of hazardous wastes, including such constituent as PCDD/Fs and mercury. However, we have included below a summary of criteria pollutant status information from the July 1, 2004, edition of 40 CFR Part 81 for Columbiana County, and for the adjoining Counties:

	<i>Columbiana OH</i>	<i>Jefferson OH</i>	<i>Beaver PA</i>	<i>Hancock WV</i>
<i>SO₂</i>	<i>better than national standards</i>	<i>better than national standards</i>	<i>better than national standards</i>	<i>City of Weirton incl. Butler & Clay Magisterial Districts, and New Manchester-Grant Magist. District: does not meet primary standards; better than national standards in rest of County</i>
<i>CO</i>	<i>unclassifiable / attainment</i>	<i>unclassifiable / attainment (by operation of law)</i>	<i>unclassifiable / attainment</i>	<i>unclassifiable / attainment (by operation of law)</i>
<i>PM10</i>	<i>unclassifiable</i>	<i>attainment in part; unclassifiable in part</i>	<i>unclassifiable</i>	<i>City of Weirton is non-attainment (moderate), rest of County unclassifiable</i>
<i>Total Suspended Particulate</i>	<i>not applicable</i>	<i>not applicable</i>	<i>Lower Beaver Valley Air Basin: does not meet primary standards in Aliquippa, Baden and Midland Boros; does not meet secondary standard in rest of Air Basin</i>	<i>Steubenville-Weirton-Wheeling AQCR: does not meet primary standards</i>
<i>NO₂</i>	<i>cannot be classified, or better than national standards</i>	<i>cannot be classified, or better than national standards</i>	<i>cannot be classified, or better than national standards</i>	<i>cannot be classified, or better than national standards</i>
<i>O₃ (1-hour)</i>	<i>attainment</i>	<i>attainment</i>	<i>attainment</i>	<i>unclassifiable / attainment</i>
<i>O₃ (new 8-hour standard)</i>	<i>non-attainment as of June 15, 2004</i>	<i>non-attainment as of June 15, 2004</i>	<i>non-attainment as of June 15, 2004</i>	<i>non-attainment as of June 15, 2004</i>

Downwind contribution to O₃ synthesis from the NO_x increments from the WTI plant
Please see the response to Comment 16A.5.

16A.11) Dr. Harrison continues:

In my judgment, the risk-assessment process, as it operated on the WTI facility, was seriously flawed. Specifically:

-It did not consider what is likely to be the most serious community impact: childhood asthma.

-It did not consider risks "at the margin", that is, above existing baselines for environmental effects on air-quality and health.

Response to 16A.11:

See responses to Comments 16A.5 (on asthma) and 16A.4 (regarding cumulative risk).

16A.12) Dr. Harrison continues:

-It did not consider the climatology of meteorological stagnation events, and the historical record of severe pollution events at the East Liverpool site, or at comparable sites.

Response to 16A.12:

Volume IV of the 1997 Risk Assessment recognized that the chosen air dispersion models did not fully address low-wind speed stagnation ("calm") events and plume fumigation. According to Volume IV (see p 167), the steady-state plume model could not fully treat calm conditions or plume fumigation during inversion break-up conditions. However, sensitivity tests with two non-steady-state puff models (INPUFF and CALPUFF) were conducted, and these indicated that these conditions would not have a significant effect on the peak impacts from the VRAWTI incinerator.

The peer review panel made the following comments regarding the limitations of the Agency's CALPUFF analysis pertaining to calm/stagnation events :

"Comment: The CALPUFF analysis was limited to "simple terrain" and a greatly simplified meteorological data set due to data limitations. The work group recommends performing the CALPUFF analysis using a realistic four-dimensional wind field over a reasonable period of time to assess concentrations under adverse dispersion conditions such as a calm/stagnation event. These results should then be compared with ISCCOMPDEP to better understand the impact of calm/stagnation conditions on predicted concentrations."

Although the U.S. EPA had conducted CALPUFF modeling to address the issue of calm/stagnation events, the peer panel was, in their comment, requesting that this be re-run in a more complex manner.

The following response is provided in Volume VIII of the Risk Assessment:

In December, 1993, several recommendations were made by the Meteorology/Air Dispersion peer review work group, one of which was to include an analysis to

realistically consider the adverse effects associated with plume fumigation events and calm wind conditions. These results were to be compared to the concentrations predicted by the ISC-COMPDEP model which the Agency had selected for use in the indirect risk assessment. Hourly concentrations predicted by straight line Gaussian plume models, such as ISC-COMPDEP, are inversely proportional to the wind speed which can result in unrealistically high predicted concentrations for low wind speed conditions. For this reason, the ISC-COMPDEP uses the U.S. EPA calm wind procedures for light wind speed events. In these procedures, winds below the instrument detection limit are considered calm. Hours with calm winds are ignored in the calculation of multi-hour average concentrations. Hours with winds less than 1 meter/sec but greater than the instrument detection threshold are reset to 1 meter/sec for modeling purposes, but are included in the modeling as a non-calm hour. In addition, ISC-COMPDEP is a steady-state model which does not allow it to adequately model fumigation events. In response to the peer reviewers comments, the Agency agreed to look at alternative models which would be better able to model calm/fumigation conditions to quantify the uncertainty in the ISC-COMPDEP predictions. The CALPUFF model is a non-steady-state puff model which allows the plume to grow as a function of time as well as distance and therefore is better able to model low wind speed conditions. Additionally, it offers better modeling of plume fumigation. These characteristics make CALPUFF a good candidate for addressing the uncertainty associated with the ISC-COMPDEP estimates. CALPUFF was run for receptors only in flat terrain using a one-year meteorological database from the 30-meter on-site tower rather than generating a three dimensional wind field.

The Agency analyzed the peer group's suggestion and determined that rerunning CALPUFF as suggested by the peer reviewers was unnecessary for the following reasons:

A. A reassessment using a three dimensional wind field model will not alter the conclusions from the assessment. The flow within the river valley, where maximum impacts were predicted to occur, is controlled by the surrounding terrain. The meteorological data from the 30-meter tower is representative of conditions and prevailing wind flows in the vicinity of the WTI incinerator and therefore was used in the modeling. For these relatively short travel distances, the computed wind field would be dominated by the on-site tower and would predict essentially the same flow pattern.

B. The inclusion of complex terrain receptors in the CALPUFF run does not increase the concentration estimates over those from ISC-COMPDEP. Concentrations due to plume impaction are typically greater than those due to plume fumigation. While an analysis including the wind field may change the pattern of concentration, the conservative screening level complex terrain algorithm in ISCCOMPDEP will still produce higher concentration estimates than CALPUFF [resulting in more conservative estimates of potential risk].

C. The U.S. EPA conducted an analysis of this issue and determined that the

annual concentrations predicted by the calm wind analysis would have to increase by a factor of eight above the routine emissions to pose a human health risk. The calm wind analysis showed annual concentrations far less than this. Thus, the inclusion of a wind field analysis would not change this result.

In summary, while running CALPUFF with a three dimensional wind field would improve the assessment, it would not change the conclusions of the assessment.

Based on the above information, we believe that the VRA/WTI Risk Assessment did properly consider meteorological stagnation events.

Dr. Harrison mentions a failure to consider a historical record of severe pollution events at the East Liverpool site, or at comparable sites. While we are aware of historical instances of severe pollution in the Ohio River valley, and while we are also aware of the unusual meteorology of the East Liverpool area of the River valley, we are not aware of a history of severe pollution events in East Liverpool itself. However, the meteorological data does indicate a history of calm/stagnation events in the area, and this information has been considered in the air dispersion modeling, as discussed above.

16A.13) Dr Harrison continues:

-It did not consider the incidence and severity of "off-design" operations at WTI.

Response to 16A.13:

The U.S. EPA disagrees. The risk assessment took into consideration common types of process upsets. As discussed in the risk assessment, a variety of process upsets may be expected during normal operation of the VRA/WTI facility or any hazardous waste incinerator. Several different situations were identified that could lead to process upset emissions and were considered in evaluating emission rates for the risk assessment, as described below:

Interruptions in Water Supply to the Scrubber System: The packed bed and venturi scrubbers installed at the VRA/WTI facility are used for control of hydrogen chloride (HCl) and additional fine particle control, which is primarily controlled by the electrostatic precipitator. The scrubber system would not be expected to contribute significantly to the control of organic emissions. Under the RCRA permit for the VRA/WTI facility, any failure of the scrubber system would trigger an instantaneous automatic waste feed cut-off. Pumpable wastes would rapidly cease burning and would, therefore, no longer represent a source of emissions. Solid-form wastes, such as drummed wastes and bulk wastes, may continue to burn in the kiln for several minutes (up to perhaps 30 minutes). However, because the frequency of scrubber water failure is expected to be low, because there are redundant scrubber water feed systems at the VRA/WTI plant, and because of the relatively minor reduction in overall control efficiency expected during a scrubber water failure, this type of event is unlikely to significantly affect overall facility emissions.

Emergency Vent Stack Releases: Unlike most rotary kiln incinerators, the VRA/WTI facility does not have an emergency relief vent stack. Therefore, no emergency vent stack

emissions will occur.

Interruptions in Air Flow: An induced draft ("ID") fan operates in the incineration train prior to entry of flue gases into the stack. Fan failure due to catastrophic mechanical failure or due to power failure would be expected to result in positive pressure in the combustion chamber. Pumpable wastes would be cut off immediately and would not create any further emissions. If solid waste had been charged to the kiln shortly before such an event, emissions of partially burned organics could be emitted through the kiln seals, since this would generally be the path of least resistance to the atmosphere once the kiln is under positive pressure. An emergency generator is present as backup in the event of a power failure, and this generator can keep the ID fan running, although at reduced speed, to keep the system under negative pressure. In response to ID fan failures at the facility in the past, VRA/WTI has taken measures to eliminate situations which might result in the ID fan completely tripping off. Under these circumstances, releases from interruptions in air flow are anticipated to be infrequent events.

Kiln Overpressure Events: Events which cause the kiln to "overpressure," that is, to be held at higher than atmospheric pressure for more than a few seconds can result in the release of partially burned waste material through the kiln seals. Kiln overpressures may be caused by chunks of hot ash falling into the slag quench tank, which is located directly beneath the secondary combustion chamber. This causes a sudden release of steam to travel back into the secondary combustion chamber, causing an overpressure event. In addition, drums and other containers of highly volatile wastes can occasionally overload the negative pressure in the kiln for brief periods of time. Kiln overpressure events trigger automatic waste feed cut-offs; consequently, emissions associated with these events are not expected to occur over extended durations. Since emissions associated with kiln overpressure events occur from the kiln seals, dioxin/furan emissions are unlikely¹⁵ to be associated with these releases.

In addition, the VRA/WTI incinerator is equipped with an automatic waste feed cut-off system that does not allow waste to be fed to the incinerator during major upset conditions. If the unit is outside of the operating parameters allowed in the RCRA permit, waste feed must cease. Despite the presence of the automatic waste feed cut-off system, however, it is possible that residual emissions of dioxins/furans (focused on here because they are the pollutants the risk assessment demonstrated to cause the highest potential risk) could occur from the incinerator stack during upset conditions because of the presence of waste still burning in the incinerator for a certain period of time even after a waste feed cut-off. It is believed that the occurrence of such events during the operation of the incinerator would likely be indicated by large fluctuations in the total hydrocarbons (THC) emitted from

¹⁵The current understanding of the mechanism of formation of dioxins/furans in an enclosed incinerator is that these compounds are created after the gases leave the combustion chamber, generally in the heat exchanger or air pollution control devices where small organic molecules encounter conditions that are thought to encourage the formation of dioxins/furans. These conditions include being held at a temperature between 450 F and 750 F, in contact with a large surface area such as might be encountered on the collected dust within a heat exchanger or dry pollution control device. Combustion gases leaking from a combustion chamber would be expected to quickly cool when they encounter the ambient air, without exposure to a large amount of surface area, so that significant amounts of dioxins/furans would not be expected to form in such gases.

the stack of the incinerator. The risk assessment used this concept to evaluate potential increased risk due to upset, as described below.

Monitoring of stack emissions at the VRA/WTI facility has indicated that under normal operating conditions, the typical THC concentration is approximately 1 part per million (ppm). Incorporating the periods of operation when the THC fluctuates significantly (e.g., during upsets), the estimated annual average THC concentration was determined to increase by approximately 30 percent. Emissions of stack gas constituents, including dioxins, during these periods of fluctuation are unknown; however, if it is assumed that the cancer potency of the emissions during the periods of upset is the same as the potency of emissions during normal operation on a gram-per-gram comparison basis, the estimated cancer risk could increase by 30 percent. An increase of 30 percent in the estimated risks for the VRA/WTI incinerator would not result in significant cancer risks to the population in the vicinity of the incinerator.

16A.14) Dr. Harrison continues:

-It did not, in any timely way, consider the accident records or the statistics of "off-design" operations at comparable toxic waste incineration facilities, and especially from WTI's sister plant at Biebesheim, Germany.

Response to 16A.14:

See responses 16A.6 and 16A.13 regarding Biebesheim and off-design operation, respectively.

16A.15 Dr. Harrison continues:

-It did not quantify uncertainties in estimated risks. In my judgment, these uncertainties are so great as to vitiate the sensible use of 'a priori' risk estimates at WTI.

Response to 16A.15:

As described in the response to Comment 16A.7, the risk assessment did address uncertainties in estimated risks. To provide an indication of the potential impact of uncertainties in the estimated risks, an uncertainty analysis was conducted. The uncertainty analysis used a methodology referred to as variance propagation to ascertain the cumulative effect of the uncertainty associated with the many individual assumptions used in the assessment. Thus, a distribution of possible risks was developed, based on the uncertainty of the input parameters used in the assessment. Please also see the response to Comment 16A.7. For more information, please see Volume V ("Human Health Risk Assessment: Evaluation of Potential Risks from Multipathway Exposures to Emissions") of the Risk Assessment, Chapter IX ("Uncertainty Analysis").

We believe that the uncertainty analysis showed the 1997 Risk Assessment to be a useful tool.

16A.16) Dr. Harrison continues:

The Executive Summary of the 1995 Risk Assessment Forum states .. among other conclusions that:

"Non-cancer health effects associated with stack emissions would not be anticipated".

Research data available in 1995 indicate that an increase in acute events of childhood asthma is to be expected from the WTI facility.

Response to 16A.16 :

Dr. Harrison provided a reference to the specific research data to which he was referring, a study conducted by J.Q. Koenig et al. titled "Part I: Effects of Oxidants, Combined with Sulfuric or Nitric Acid, on the Pulmonary Function of Adolescents with Asthma." This study was published in the Health Effects Institute Research Report Number 70 (1994) titled: "Oxidant and Acid Aerosol Exposure in Healthy Subjects and Subjects with Asthma." We obtained and reviewed a copy of the report.

This study was funded by the non-profit Health Effects Institute to investigate the hypothesis that asthmatic subjects exposed to combined or sequential controlled concentrations of oxidant gases (ozone/NOx) and acid aerosols (sulfuric acid or nitric acid) would exhibit measurable deficits in pulmonary lung function or exacerbation of asthma symptoms. The experimentally controlled studies were designed to investigate the pulmonary responses of adolescents with asthma to a mixture of ozone and NO₂, and this mixture combined with sulfuric acid or nitric acid aerosol. The purpose of employing the controlled acid aerosol atmospheres was to mimic the acidic summer haze conditions that persist in urban areas during periods of air stagnation (e.g., "ozone alert days").

The stated specific objectives of the study were:

- *to determine if exposure for 2 consecutive days to a mixture of ozone and NO₂ would produce greater effects on the pulmonary function of subjects with asthma than a single day of exposure.*
- *to compare the effects of added sulfuric acid or nitric acid to the oxidant gas mixture in order to determine if the addition of an acid aerosol would produce greater toxicity than the oxidant gas mixture alone.*

Following completion of the study, the study design and results were reviewed by the Health Effects Institute's Health Review Committee. This review committee prepared a Commentary on the study and included the Commentary in the published Report listed above. The Commentary described the findings of the study and the significance of the results, as follows:

"Dr. Koenig found no significant effects of exposure to any combination of the test atmospheres on the pulmonary function of the adolescents with asthma. Interpretation of these negative results is limited, however, because 6 of the 28

subjects were not able to complete the study. These individuals had moderate to severe asthma, and may represent a particularly sensitive subgroup of subjects with asthma."

"Dr. Koenig and coworkers originally hypothesized that deficits in pulmonary function would be observed after two days of consecutive exposure to oxidants, or oxidants plus an acid aerosol. However, they found no significant effects after exposures to any of the test atmospheres. The data from the pulmonary function tests summarized in Figures 2 through 6 of the Investigators' Report indicate that the pollutant exposures produced changes of only a few hundred milliliters in lung volume, and these changes could be attributed to normal test variability."

"The negative results of this study are intriguing because these investigators previously had observed statistically significant changes in pulmonary function after a 45-minute exposure of subjects with asthma to a range of H_2SO_4 concentrations (51 to $176 \mu g/m^3$) (Koenig et al. 1983; Hanley et al. 1992). In their previous studies, exposure to H_2SO_4 was associated with a decrease in pulmonary function measurements when subjects were tested immediately after the 45-minute exposure. No effect was observed, however, when exposure to H_2SO_4 was extended to 90 minutes (Koenig et al. 1992). Thus, the investigators speculated that a pollutant-induced effect may have been present but was "lost" at the 90-minute time point. In support of this hypothesis are other findings of Koenig and associates indicating that the effects induced by H_2SO_4 were statistically significant only when measured immediately after the end of a 45-minute exposure, and that a substantial lessening of effects was observed within 20 minutes of exposure termination (Hanley et al. 1992; Koenig et al. 1992). However, these results also are difficult to interpret because of the inverse dose dependence that was reported. A statistically significant decrease in FEV1 was observed after exposure to H_2SO_4 at $35 \mu g/m^3$ but not after exposure to H_2SO_4 at $70 \mu g/m^3$. Moreover, neither low-dose nor high-dose exposures to H_2SO_4 produced significant changes in pulmonary function if the duration of the exposures was increased from 45 to 90 minutes. One possible explanation for the loss of H_2SO_4 effect over time is a buildup of oral ammonia levels, which would act to neutralize the acid aerosol. In the present study, oral ammonia levels were consistently 40% to 60% higher than baseline levels after air and pollutant exposures."

"As noted earlier, the fact that six subjects left this study before completing all of the exposures atmospheres seriously complicates the interpretation of the results. On the basis of the subjects' airway responsiveness, as assessed by methacholine challenge tests (see Table 3), five of these six subjects were categorized as having moderate or severe asthma, and the sixth subject was not categorized. A review of the reasons given by the subjects who left the study suggests that aggravation of asthma symptoms was not an apparent cause for withdrawal from the exposure regimen. However, the investigators noted that all six of the subjects who left did so after a pollutant exposure rather than after exposure to clean air. In any case, the net result is that the data from a group of subjects, representing approximately 20% of the original subjects, were not included in the final data analyses."

Accordingly, the conclusions of the study may have been based on a group of subjects more tolerant to oxidants, acid aerosols, or both, than those constituting the original study group. The issue of the subjects who left the study raises concerns about extrapolating the results of this study and using them to anticipate the responses of the general population of individuals with asthma to similar pollutant exposures."

"In summary, the lack of any effects after subjects with asthma were exposed to the combinations of oxidants and acid aerosols was unexpected in this population of adolescent subjects that has, in Dr. Koenig's laboratory, previously exhibited increased airway responsiveness to at least one component of these pollutant mixtures. Given the sample size, the results are meaningful for subjects with asthma as a group, but are not definitive for all people with asthma. These limitations must, however, be balanced with the fact that studies that involve sensitive populations are difficult to do. Because the exposures were designed to simulate ambient conditions of acidic summer haze, these findings provide some reassurance for public health concerns regarding exposures to these pollutants. Nonetheless, the impact of the loss of data from the subjects who left on the study results remains indeterminable and seriously limits extending these findings to subjects with moderate or severe asthma."

Based on the above, it does not appear that the study by Koenig et al. provides any definitive evidence that acid aerosol exposure in combination with ozone exposure to asthmatic subjects is associated with significant measurable deficits in pulmonary lung function, even at ozone/acid aerosol concentrations that might be encountered during air stagnation events.

In addition, the U.S. EPA's 1997 Risk Assessment considered emissions of hydrochloric acid ("HCl"), a known pollutant from the VRA/WTI facility. Based on a maximum HCl emission established during the trial burn (.032 g/sec) and a dispersion factor (0.91 $\mu\text{g}/\text{m}^3/\text{g}/\text{sec}$) reflecting the meteorology of the area, the risk assessment predicted and evaluated a maximum ground level HCl concentration of .029 $\mu\text{g}/\text{m}^3$ and an average of .0093 $\mu\text{g}/\text{m}^3$. From these values and from the Reference Air Concentration value of 0.00175 mg/m^3 , the following hazard quotients were calculated for Subarea E1 (the area of maximum exposure)

Adult: .016

Young Child: .06

School Age Child: .035

Since these predicted levels do not approach the hazard quotient value of 1.0 (a widely accepted safe exposure benchmark), the conclusion was that the ground-level impacts of HCl should not create a health threat.

16A.17) Dr. Harrison continues:

"Predicted off-site air concentrations of US EPA regulated "criteria pollutants" [SO₂, NOx, HCl, Pb, and particulate matter] "are determined to be less than National Ambient Air Quality Standards."

No information was presented on the pre-WTI levels of these pollutants and whether increments from WTI would produce exceedances above the National Ambient Air Quality Standards. If ambient levels at East Liverpool are typical of similar communities, then models suggest significant haze increments from sulfate aerosols and -O₃ production in the downwind plume from the WTI facility, and likely exceedances of the NAAQ standards. The 1995 Risk Assessment document did not address these issues.

Response to 16A.17 :

Please see the response to Comment 16A.9

16A.18) Dr. Harrison continues:

"For on-site accidents, only events with minor off-site consequences are considered likely to occur at the WTI facility, and only events with minor or potentially moderate off-site consequences are determined to be reasonably likely to occur."

Well before this summary was written at least one serious accident had already occurred, with a mercury metal release and detectably elevated mercury levels in children from the adjacent community. Evidence of this failure was NOT presented to the Risk Assessment Forum.

Response to 16A.18 :

The only non-routine mercury release of which we are aware occurred in connection with the March 1993 trial burn test.¹⁶ During that test, the incinerator achieved a mercury "control" or "removal efficiency" which was less than the facility personnel had anticipated. It was not a spill or similar event. This was a one-time event resulting from the "worst case" operating conditions created only for purposes of the test. The U.S. EPA's response to the event was to further restrict the amount of mercury that Von Roll could feed into the incinerator under the RCRA permit. The U.S. EPA is not aware of any other significant non-routine releases of mercury from the VRA/WTI facility.

The Ohio Department of Health (ODH) issued a report in August 1995 prepared by Drs. Thomas Halpin and Peter Somani that examined blood lead levels and urine mercury levels in children under 16 years of age residing in the East Liverpool area or attending East Liverpool area schools. ODH conducted the study to determine if emissions from VRA/WTI were associated with observable increases in these levels. The study period, August 1992 through December 1994, includes the date of the non-routine mercury emission in March 1993 described above. The study concluded that "[n]either the lead nor the mercury samples taken from the children showed that the operation of the WTI incinerator caused East Liverpool children to have higher levels of lead or mercury."

¹⁶As noted in the response to Comment 16A.5, the risk assessment did not predict that WTI's routine emissions of mercury would be close to the level necessary to produce a significant health impact.

16A.19) Dr Harrison continues:

Nor was the record from the Biebesheim facility made available to me or other reviewers before the EPA supplemental report of May, 1997, on the potential for accidents at WTI.

Response to 16A.19 :

Please see response to Comment 16A.6, above.

16A.20) Dr. Harrison continues:

None of these and other questionable assertions from the Executive Summary, were made available to the peer-review panelists before their publication. The summary does NOT correctly reflect my judgment, nor my memory of the peer consensus.

Response to 16A.20 :

It was not clear to us whether Dr. Harrison was referring to the Executive Summary of the 1996 Risk Assessment Forum, or the Executive Summary of the 1997 Risk Assessment report. We believe it to be the former, and have provided an answer based on that assumption.

The peer review process, including the publication of the 1996 Executive Summary of the peer comments, was conducted independently from the rest of the U.S. EPA by a contractor who worked for the Risk Assessment Forum. The contractor's 1996 summary report was largely based on individual summary reports from the Chairpersons of each "sub-panel" or "workgroup" of the peer panel (such as the Air Dispersion/Deposition Modeling and Accident Analysis workgroup on which Dr. Harrison sat). Each workgroup Chairperson conveyed what he thought to be the most significant comments and suggestions from his workgroup. In addition, the Chair of the overall peer panel further summarized the findings of each workgroup. Region 5 was not involved in the summarization of the peer review, and hence would not be able to address the issue of why the summary did not reflect his memory of the peer panel.

In completing the 1997 Risk Assessment, the U.S. EPA took special efforts to respond to the comments and suggestions contained in the 1996 Executive Summary of the Peer Review.

16A.21) Dr. Harrison continues:

In my judgment, structural inadequacies in the risk assessment process, and errors, omissions, and distortions in the Executive Summaries of the 1995 and 1997 risk-assessment documents, are sufficiently serious to discredit their use to assist wise decisions on the licensing of further operations of the WTI facility at East Liverpool.

Response to 16A.21 :

We respectfully disagree, for all the reasons given in our responses above. As far as perceived errors, omissions, and distortions in the VRA/WTI risk assessment, the U.S. EPA has attempted to respond in detail directly to each of Dr. Harrison's specific concerns in this response document. We do not believe that Dr. Harrison's characterization of the risk assessment process, executive summaries or documents was consistent with the

consensus of the peer reviewers as a whole.

For example, Thomas McKone wrote in the "Chairperson's Summary" of the May 2, 1996 "Report of the U.S. EPA Technical Workshop on WTI Incinerator Risk Assessment Issues" (1996 Report):

As noted by several peer reviewers, the draft WTI incinerator risk assessment is one of the most extensive and comprehensive risk assessments ever compiled for a stationary combustion source. The assessment goes to great lengths to address regulatory requirements and EPA guidance.¹⁷

1996 Report, at 2-4.

The Combustion Engineering Work Group's summary in the 1996 Report states:

The WTI risk assessment document represents a highly professional and dedicated effort by EPA and its contractors. In 1993, the combustion engineering panel offered detailed recommendations for improving the draft risk assessment. EPA made an exceptional effort to follow the spirit of the recommendations and, in some instances, the Agency's efforts can be termed heroic. The Combustion Engineering Work Group is confident that the WTI risk assessment document (at least the part we reviewed in detail) is fair and scientifically unbiased.

1996 Report, at 3-1.

The Exposure Assessment Work Group stated that "[t]he exposure assessment is a large and comprehensive document. EPA expended a great deal of effort to assemble data, construct models, run simulations, and evaluate data. The resulting draft risk assessment addresses most of the recommendations of the 1993 project plan peer reviewers." 1996 Report, at 3-22.¹⁸

Members of the Toxicology Work Group characterized the risk assessment as overall "thorough and comprehensive," 1996 Report at 3-28, and the Ecological Risk Assessment Work Group stated that "EPA conducted the SERA in a technically competent manner that conforms with the state-of-practice for SERAs." 1996 Report, at 3-36.

The general overview of the 1996 Report, which was prepared by an EPA contractor, states:

Overall, comments on the draft WTI incinerator risk assessment were favorable.

¹⁷Chairperson McKone noted that the question of how precisely we can estimate a source's "true" impact on public health and how well we can address and answer the concerns of affected communities were challenges for future risk assessments.

¹⁸Although the Work Group thought that information was "frequently buried and difficult to track," the Work Group nonetheless concluded that the "document contains information required for an informed debate on health issues . . ." *Id.*, at 3-22.

Indeed, throughout the workshop, as the expert peer reviewers discussed the assessment as a whole and specific parts of it, workshop participants repeatedly prefaced suggestions for improvement with praise for the overall thoroughness, quality and integrity of the assessment. Noting that they had been quite critical of the draft project plan for the assessment, the peer reviewers stated that by contrast they were very impressed with the thoroughness, organization, and clarity of the draft assessment - and with the seriousness and faithfulness with which EPA had followed the comments and recommendations of the project plan peer reviewers. Their most substantive comments pertained to three topics (accident scenarios, cumulative risk, ecological risk)¹⁹ that were not covered in the initial project plan for the assessment and thus had not benefitted from previous review. The peer reviewers described most of their other comments as questions of clarification or as other minor issues not likely to affect the overall results of the assessment.

1996 Report, at 1-1.

As noted above, while we believe that risk assessments can be conducted in a manner which provides a sound basis for risk management decisions that are protective, we recognize that no risk assessment can achieve a perfect assessment of risks and that risk assessments cannot guarantee safety. As also noted above, to compensate, U.S. EPA uses conservative risk assumptions to provide a margin of safety and ensure that risks are not underestimated. The resulting over-estimation of quantifiable risks tends to balance against the unquantifiable risks.

We've provided below a list of the major issues that the present science of risk assessment is not able to completely address. The U.S. EPA communicated these issues to the Ohio EPA when U.S. EPA transmitted the results of the VRA/WTI risk assessment to it (See Attachment H), to provide a framework in which to place the results of the risk assessment and to assist the Ohio EPA in making risk management decisions .

- 1) The potential endocrine disruptor effects of dioxins/furans have not been evaluated due to the lack of essential dose/response information. The risk assessment evaluates only the carcinogenic effects of PCDDs/PCDFs, and not potential endocrine disruption effects. The U.S. EPA is aware of the growing body of scientific research that indicates a number of synthetic chemicals may interfere with the normal functioning of human and wildlife endocrine systems. The U.S. EPA is very concerned about these findings and is investing significant resources into learning how and to what extent these chemicals may be adversely affecting human health and wildlife. However, no substantiated dose-response profiles have yet been established. Without this type of information, a quantitative risk assessment cannot be performed for these effects at this point in time.
- 2) There is currently no established method to evaluate potential synergistic or antagonistic effects of the many trace chemicals known or suspected in the

¹⁹Commenters for this Response to Comments have also submitted comments concerning the accident analysis, discussed in detail in the response to Comments 16C.7 et seq. , and concerning cumulative risk, discussed at length above.

emissions. Synergistic effects could potentially increase toxic responses above those predicted in a current risk assessment, and antagonistic effects could reduce the toxic responses. The VRA/WTI risk assessment did consider the potential additivity of chemical impacts.

- 3) *Current risk assessments do not completely address the possible existence and potential effects of "dioxin-like" compounds which, due to insufficient test methods or toxicological standards, cannot be evaluated further. Such compounds could possibly result in the risks being greater than predicted. The risk assessment did conservatively take into account the potential for brominated dioxins/furans, which we believe is a major category of such "dioxin-like" compounds.*
- 4) *In some cases, risk assessments use national statistics in lieu of site-specific demographic information. For example, the VRA/WTI risk assessment uses many of the same assumptions that other U.S. EPA assessments have used, including an assumption that people generally only live in an area for nine years. (However, please see the response to comment 16A.7 for a more detailed explanation of this matter.)*

16A.22) Dr. Harrison commented:

I append... ..an open letter addressed to Carol Browner, then Director of EPA, dated April 6, 1999.

Response to 16A.22:

Dr. Harrison submitted a copy of a letter he had written to former Administrator Browner, providing suggestions on how the risk assessment process in general could be improved. We are including it as Attachment A to this document. Because we believe the essential questions in the letter have already been responded to in our above responses, we are not further responding to it at this time.

16B) COMMENTS ON THE RISK ASSESSMENT FROM MS. TERRI SWEARINGEN

(Comment document dated May 9, 2003, submitted electronically May 11, 2003):

16B.1) Ms. Swearingen commented:

The 1997 Von Roll/WTI risk assessment does not prove that the facility is safe, that there is no health risk from its operation or that additional monitoring is not necessary to protect human health and the environment.

The 1997 Von Roll/WTI risk assessment cannot legitimately be used to say that the WTI is "safe" or that it poses no risk to the health and safety of citizens in the community or beyond. It is too terribly flawed to use it as a measure of risk to the community, to set standards and emission limits or to avoid additional monitoring of the facility. If the Von Roll/WTI toxic waste incinerator is allowed to continue operating, then a better risk assessment with some credibility must be performed. Even if the 1997 risk assessment was flawless, an up-dated risk assessment should be conducted considering the most current scientific information, methods and data.

Response to 16B.1:

As noted above, while we recognize that no risk assessment can achieve a perfect assessment of risks and that they can't guarantee safety (i.e., can't guarantee that there are no risks), we believe that they can be conducted in a manner which provides a sound basis for risk management decisions that are protective. As also noted above, U.S. EPA uses conservative risk assumptions to provide a margin of safety and ensure that risks are not underestimated. The resulting over-estimation of quantifiable risks tends to balance against the unquantifiable risks. Please see the response to Comment 16A.1.

16B.2) Ms. Swearingen continues:

1. The Impact of the WTI Incinerator to Human Health and the Environment

In the most recent EPA Response to Comments, dated April 24, 2003 --- which respond to comments made by citizens in November 2000 --- 2 ½ years ago --- it is clear that the EPA relies heavily on the risk assessment to say that the operation of the Von Roll/WTI toxic waste incinerator poses no unacceptable risk to human health and the environment. For nearly every suggestion made for additional monitoring or testing, changes in operation or health concerns, EPA's standard answer is: "WTI's emissions have been checked via an EPA-conducted peer-reviewed risk assessment, which failed to reveal unusual risk associated with the operation of the incinerator." EPA is accurate in that "it failed". It failed to reveal unusual risks associated with the operation of the incinerator because reliance on the 1997 risk assessment is irresponsible, unprofessional, unethical and unacceptable. The risk assessment is extremely flawed and without merit. The EPA cannot continue to use the risk assessment to ignore the health risks posed by Von Roll/WTI nor can it be used to argue against additional monitoring which may help to ensure the safety of the community. Outlined below are just a few of the serious flaws in the Von Roll/WTI risk assessment. For these reasons, the EPA can no longer use this risk assessment to justify the operation of the Von Roll/WTI facility.

a. Health Risks not addressed in EPA Risk Assessment

Due to lack of EPA-approved toxicity values. The WTI risk assessment simply omits the risks of compounds for which there are no EPA-approved toxicity values and the risks of health impacts for which there is no clear scientific consensus. The lack of EPA-approved toxicity values may mean, as in the case of dioxins, that the compound is controversial, not that adequate data doesn't exist to determine a value. Plausible alternative values may form the basis of a series of alternative risk calculations.

Response to 16B.2:

U.S. EPA respectfully disagrees with Ms. Swearingen's characterization of the 1997 risk assessment and her assertion that U.S. EPA ignored health risks posed by the VRA/WTI incinerator.

While the accuracy of our risk assessments could certainly be improved if there were approved toxicity factors and carcinogenicity factors for all possible effects from all

chemicals known or believed to be emitted from combustor stacks, there currently exist gaps in the available data. There is no objective basis for calculating potential risks attributable to chemical emissions for which there are no toxicity or carcinogenicity factors. Considerable toxicity information is available for most of the chemicals of concern, however, and the U.S. EPA uses conservative approaches in applying this information in a risk assessment. The resulting over-estimation of quantifiable risks tends to balance against the unquantifiable risks.

In the case of dioxin, for example, we believe that the combination of conservative methods used to address the high carcinogenic potency of dioxin would tend to minimize the potential for non-cancer effects of dioxin from VRA/WTI for the following reasons: a) For deriving a dose-response slope factor for the cancer potency of dioxin, U.S. EPA uses a linear low-dose extrapolation which assumes that there is no threshold dose for the induction of cancer; this means that we assume that any exposure level causes some amount of cancer risk; and b) U.S. EPA places a conservative limit on allowable cancer risks from VRA/WTI emissions - the cumulative cancer risks from multiple chemicals are not allowed to exceed 1 in 100,000.

Furthermore, the VRA/WTI risk assessment includes an evaluation of the uncertainty associated with poorly characterized constituents or compounds with little or no toxicity data. For example, to conservatively account for the potential toxicity of brominated and other halogenated dioxins and furans, the risks associated with chlorinated dioxins and furans were multiplied by a factor of 1.5 in the uncertainty analysis. The risks associated with other organic constituents in the stack emissions were multiplied by a factor of 2.5 to conservatively account for a potential uncharacterized fraction of incinerator stack emissions. Thus, the U.S. EPA has taken a number of steps in the VRA/WTI risk assessment to avoid underestimating the potential toxicity of facility emissions, in light of the uncertainties that exist for some chemicals.

Ms. Swearingen states that the risk assessment cannot continue to be used to argue against additional monitoring which may help to ensure the safety of the community. However, U.S. EPA's regulations under RCRA covering hazardous waste combustion do not require or address ambient air monitoring. U.S. EPA could impose additional terms in VRA/WTI's RCRA permit to conduct ambient air monitoring, even if it is not required by the regulations, if the Agency could demonstrate that monitoring would be necessary to protect human health or the environment. Neither the risk assessment nor the short-term ambient air monitoring event conducted in the Fall of 2000, however, demonstrated a threat to human health or the environment.

16B.3) Ms. Swearingen continues:

- (ii) Risks assessed in alternative metrics that prevent estimates of cumulative risk and prevent comparison to potentially-exceeded standards (e.g., Margin of Exposure analysis for non-cancer dioxin effects instead of probabilistic and hazard indices for other compounds; risks to breast-feeding infants)

Response to 16B.3:

Please see the discussion of cumulative risks in the response to Dr. Harrison's Comment 16A.4.

16B.4) Ms. Swearingen continues:

- (ii) Incremental risks not calculated -- ambient air not characterized for background contaminants and levels -- background population not evaluated for existing health problems likely to be aggravated by incremental emissions.

Response to 16B.4:

Regarding background levels of contaminants in ambient air: As we discussed more fully earlier in this document in the responses to 16A.4 and 16A.10, the model that we used to evaluate the potential impacts of environmental exposure to lead did take into account existing levels of air and soil lead, or alternatively used conservative default values for these. For other regulated toxic metals and organics that were evaluated in the risk assessment, resultant air concentrations did not specifically take into consideration the actual existing air concentrations. U.S. EPA's guidance on conducting risk assessments for hazardous waste combustors currently does not incorporate this technique. However, consistent with the U.S. EPA's Draft Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities, EPA 530-R-94-021, April 1994, the VRA/WTI risk assessment was conducted in a manner that assumed other sources of the same toxic metals and organics contribute up to three times the amount of the facility being evaluated. The U.S. EPA compared modeled air concentrations of toxic metals and organics not only to a hazard quotient ("HQ") value of 1.0 (i.e., a widely accepted safe exposure benchmark), but also to an HQ value of 0.25 -- to account for the fact that other facilities in the area might, for example, be emitting that same toxic metals and organic compounds in even greater quantities, and that those emissions will be additive. We believe this technique is just as protective, much simpler, and a much less resource intensive way of addressing the concern over additive emissions.

Regarding the study of the background population, the U.S. EPA recognizes that the East Liverpool community includes a wide variety of individuals, each with different behavioral patterns and each from different locations with respect to the facility. Therefore, the U.S. EPA evaluated the risks to a number of different types of individual lifestyle/activity types, including residents (children and adults), school children, farmers (children and adults), and subsistence farmers (children and adults). While not every individual is expected to fit precisely into one of these lifestyle/activity categories, these groups provide an indication of the typical risks faced by people in the area surrounding the VRA/WTI facility to the stakeholders and the decision makers evaluating the VRA/WTI permit renewal.

The exposure estimates presented in the VRA/WTI risk assessment are believed to be conservative (i.e., tend to overestimate potential risks) for most individuals in the vicinity of the VRA/WTI facility. Please see the response to Comment 16A.7 for further discussion.

16B.5) Ms. Swearingen continues:

- (iii) Risks not calculated under permitted emission rates. The WTI risk assessment did not evaluate risks based upon maximum permitted levels of emissions; it evaluated expected levels. (We requested that EPA make the emission limits used to calculate risk in the WTI risk assessment be incorporated into WTI's permit as maximum emission limits. They ignored

our request.)

Response to 16B.5:

At the time of the risk assessment, the only PCDD/F emission limit in the RCRA permit was the value of 30 ng/dscm total sum of the dioxin/furan congeners. Because there is no way to directly convert this "sum of the congeners" value into a "toxic equivalents" value, a risk assessment could not be based on this value. Instead, the PCDD/F portion of the risk assessment was based on the average of the PCDD/F emissions actually measured in 26 test runs conducted over a one-year period in 1993 - 1994. In order to ensure that the rate of PCDD/F emissions would stay in the same range as during these tests, the U.S. EPA established permit limits on minimum feed rates of activated carbon (i.e., the means of removing PCDD/Fs from the combustion gas stream and keeping emission low). The feed rate of carbon can be much more easily and frequently monitored than actual stack emission of PCDD/Fs. The U.S. EPA believes this to be an effective means of controlling PCDD/F emissions.

Including the average of those 26 emission values as a permit limit would not have been appropriate, since an average is only a central value. A permit emission limit or regulatory emission limit, on the other hand, would be a maximum allowed value.

As of September 30, 2003, VRA/WTI is now required under Clean Air Act regulations to comply with a specific PCDD/F stack emission limit of 0.2 ng/dscm TEQ, as well as a minimum activated carbon feed rate. This regulatory emission limit is implemented as the highest emission value occurring in a single test (generally three or four test runs). We expect VRA/WTI to normally operate at emission rates lower than the allowable maximum.

The RCRA permit also includes maximum metals emission/feed limits (maximum mass feed rate values) which were checked via the risk assessment and in some cases reduced in response to the results of either the human health or the ecological portion of the risk assessment.

16B.6) Ms. Swearingen continues:

(iv) Unreliable data

-- In a January 4, 1993 confidential memo, OEPA toxicologist David Nuber wrote about ambient air monitoring during WTI's trial burn:

--Mercury monitoring -- We have not overcome a major impediment of ambient air mercury monitoring. Mercury exists in 2 phases (solid particulate and vapor) which make it impossible to obtain an analysis for total ambient mercury. There is not US EPA or private contractor derived method for accurately assessing ambient mercury concentrations. This problem is further compounded by the length of time we will be collecting samples; an unknown amount of particulate mercury will volatilize prior to having the canisters analyzed. We might be able to estimate total ambient mercury if we had some reliable research guidance, but we do not have and I am not aware of a method for doing this.

-- Site selection - These particular sites appear to be chosen without concern for high human exposure receptor areas; Phil has suggested that the initial modeling is obsolete. The US EPA risk assessment did not identify high concentration impact points in relation to population. I am left to wonder why someone didn't run a new model...based on the most recent census data showing the high exposure areas. Wouldn't this have provided the basic information needed to assess possible monitoring sites? If this had been done, couldn't we have placed more confidence in the monitoring data... I realize that the monitoring sites were limited by public accessibility and security but the use of data from these sites in a risk assessment may lead to erroneous conclusions.

-- Chemical selection - It is my understanding that we will not be monitoring for any other chemical beyond lead, mercury and VOCs. From toxicity standpoint I am much more concerned with PAHs, dioxins, and benzene emissions than VOCs. ...Who decided this? Wouldn't it be better from a PR standpoint to be able to say "Emissions of PAHs, dioxins and benzene and other VOCs from WTI will not present a health concern to the residents of East Liverpool"... Dr. Nuber continues: Any risk assessment based on this data would be highly suspect, at best. If the agency cannot use the data to quell the health concerns of the residents of E. Liverpool, then what will we use the data for? Phil tells me we will not do anything with the data, which begs the question: Why are we conducting this monitoring?

Response to 16B.5:

Ambient air concentrations were not used as part of the input to the risk assessment, with the possible exception of lead. The risk assessment was based on stack emissions. Nor is ambient monitoring part of a RCRA trial burn. The uncertainties associated with ambient monitoring that Dr. Nuber describes are some of the very reasons why we believe risk assessments are more conservative and precise if based on stack emissions.

16B.7) Ms. Swearingen continues:

- News accounts of NOVAA corruption
- Undue influence by Von Roll
 - The possibility of inappropriate influence exerted by Von Roll/WTI on the East Liverpool Health Board (including the Health Boards relationship with Von Roll/WTI, the soil and vegetable studies, air monitoring, testing of children.), the North Ohio Valley Air Authority, and the on-site Ohio EPA inspectors.
- The possibility of tainted monitoring reports
 - In a 1997 investigation by the Beacon Journal, it was reported that Von Roll/WTI made payments on the side to employees of the North Ohio Valley Air Authority (NOVAA), the regulatory agency responsible for monitoring air emissions from the facility. The US EPA's risk assessments were in part based on WTI's 1993 "trial burns" and some of WTI's pollution monitoring irregularities date back to that time.

- According to the US EPA: In 1999, certain individuals connected with NOVAA, including NOVAA's former director, pleaded guilty to felony public corruption and tax offenses. In a related case, on March 1, 2000, another individual was indicted on 37 felony counts of conspiracy, unlawful payments to a public official, money laundering, and asbestos violations. NOVAA was involved in ambient air monitoring, facility inspection and performed other functions for the Ohio EPA. To the extent that trial burns and other stack testing, and the operation and certification of continuous emission monitors were overseen by the air regulatory program of the Ohio EPA, NOVAA was also involved in overseeing these activities. NOVAA was also involved in ambient air monitoring for lead in 1993, on-site meteorological data collection from April 1992 through March 1993 and dioxin sampling conducted around East Liverpool. U.S. EPA Region 5 provided funding directly to NOVAA for one or more years of monitoring ending in FY 1986. Beginning with FY 1987, NOVAA started receiving federal funds through the OEPA (as a pass through agency).

- A January 4, 1993 memo written by OEPA toxicologist David Nuber clearly shows that the North Ohio Valley Air Authority was involved with air monitoring during the 1993 test burn. In fact, Dr. Nuber states his alarm over the fact that NOVAA's Dan Zorbini had not had the air canisters that were previously collected in 1992 analyzed for a baseline and that the samples would be worthless. Dr. Nuber is concerned that the samples will not be reliable as a baseline and may not represent actual average ambient air concentrations.

- U.S. EPA Region V Administrator stated in a February 28, 1994 letter to East Liverpool Health Commissioner Gary Ryan that, "Region V EPA's role in environmental monitoring is to provide assistance to the lead agency for air monitoring, which is the Northern Ohio Valley Air Authority (NOVAA)."

- Robert Springer, on behalf of Region V Administrator Val Adamkus, wrote in a January 12, letter, "As part of EPA's effort to assess risk from the WTI incinerator, a multipathway Phase II risk assessment is currently underway. Food chain exposures and fugitive emissions and accidents will be addressed in the risk assessment as appropriate. This data includes soil and milk samples requested by the East Liverpool Department of Health, air-monitoring data collected by the Northern Ohio Valley Air Authority (NOVAA), and soil data collected by the Ohio Department of Health. The results of this risk assessment will be considered in setting final operating conditions for the WTI incinerator." "...U.S. EPA will continue to provide technical assistance to NOVAA as requested. Dan Zorbini of NOVAA remains the primary contact for air monitoring activities."

- Information considered in the risk assessment provided by the North Ohio Valley Air Authority (NOVAA) is suspect. Can we trust the data used in the risk assessment supplied by NOVAA when it has been revealed that NOVAA employees were on Von Roll's payroll, receiving "supplementary" shadow payments from Von Roll/WTI!

- North Ohio Valley Air Authority involvement taints the risk assessment. If the risk assessment is to be of any value, a new one must be conducted using current data and valid information. A more comprehensive study must be conducted which takes into consideration recent scientific findings.
- Can we trust the data used in the risk assessment supplied by NOVAA, considering that it has been reported that every NOVAA employee was on WTI's payroll?
- The possibility of inappropriate influence exerted by Von Roll/WTI on the East Liverpool Health Board (including the Health Board's relationship with Von Roll/WTI, the soil and vegetable studies, air monitoring, testing of children.), the North Ohio Valley Air Authority, and the on-site Ohio EPA inspectors.

Response to 16B.7:

The above comments deal almost exclusively with issues concerning the North Ohio Valley Air Authority (NOVAA), and the commenter's opinion that NOVAA's activities have tainted the risk assessment. While the issue of NOVAA's activities is important, it has virtually no impact on the risk assessment because NOVAA was not involved in the risk assessment. The risk assessment was not based on ambient air sampling conducted by NOVAA, and NOVAA did not conduct the trial burn or any risk burn testing. NOVAA was involved in certain side issues, such as collecting samples that could be used for comparison to the risk assessment. It was not involved in the risk assessment itself.

While the Springer memo referenced by Ms Swearingen indicates that early in the project, it had been contemplated that some NOVAA data might be directly used in the risk assessment, this did not come about, with the possible exception of background concentrations of lead. These lead data were later substituted with other information. For a more detailed explanation of this, please see Attachment C, which is a memo from Francis Lyons to Timothy Fields, Jr., dated December 5, 2000.

As to Ms. Swearingen's allegations of potential inappropriate influence over the ELBH and the OEPA site inspectors, we have no basis at this time to question their integrity.

16B.8) Ms. Swearingen continues:

(v) Conflict of interest and/or unethical practices/unreliability of contractors involved in conducting the risk assessment:

-- ENSR. ENSR collected the stack samples and provided the stack emission data that was used in the Von Roll/WTI risk assessment. At the time, ENSR was a subsidiary of ThermalChem, a company that builds and operates hazardous waste incinerators, one of them in Rock Hill, South Carolina. Wouldn't it be beneficial to ThermalChem for the results of the risk assessment for the world's most controversial toxic waste incinerator in the world to show little risk?

Response to 16B.8:

We know of no information indicating that ENSR engaged in unethical practices in conducting the testing.

16B.9) Ms. Swearingen continues:

-- **Environ.** U.S. EPA contracted with Environ to conduct the actual risk assessment. Environ is a hired gun of the industry. Environ was hired by the pulp and paper industry to "detoxify" dioxin — that is to say that dioxin poses little risk. Wouldn't it be beneficial to Environ for the results of the risk assessment for the world's most controversial toxic waste incinerator to show little risk from dioxin?

Response to 16B.9:

Because of the importance of this risk assessment, a U.S. EPA national workgroup was assembled for the purpose of conducting this assessment. That workgroup directed virtually every aspect of this risk assessment and made decisions on how it would be done. Environ and other contractors assisted the U.S. EPA by conducting research, performing calculations, proposing language and techniques, and performing word processing and document assembly. In addition, the Agency's staff in charge of contracting also performed a "conflict of interest" review on Environ. The Agency concluded that Environ's past activities did not compromise its ability and integrity to provide objective assistance on the VRA/WTI risk assessment.

16B.10) Ms. Swearingen continues:

(vi) No review of accident risks at other facilities as recommended by Peer Review scientists.

On September 09, 2002, at 11:00 p.m., there was a fire and explosion at the BDT (Safety Kleen) hazardous waste incinerator in Clarence, NY. The explosion and subsequent chemical fire, which involved 150,000 pounds of hazardous materials, severely damaged the incinerator. On March 28, 2003, the incinerator was permanently closed. What health effects were experienced within community residents?

Response to 16B.10:

The U.S. EPA did utilize a review of accidents at other similar facilities. This was part of the basis for expected frequencies of different types of accidents. The U.S. EPA compiled a review of reported emergency incidents at hazardous waste incinerators and commercial treatment, storage and disposal facilities (TSDFs) regulated under the Resource Conservation and Recovery Act (RCRA). Descriptions are provided for incidents reported to have occurred between 1977 and May 1995 at 11 commercial hazardous incinerators, 10 noncommercial incinerators and 23 other commercial TSDFs in U.S. EPA document EPA 530-R-99-014. This information is summarized in Tables 1 and 2 of Appendix VII-1 of Volume VII of the Risk Assessment. A total of 50 emergency incidents, as defined by U.S. EPA, were reported at the hazardous waste incinerators identified in the study. For commercial hazardous waste incinerators only, 24 emergency incidents at 11 facilities were reported, with 10 of these incidents involving a release of hazardous waste.

Accidents that have occurred since the time of completion of the VRA/WTI accident analysis obviously have not been considered. The Accident Analysis considered a certain

frequency for this type of event.

16B.11) Ms. Swearingen continues:

b. Risks first observed after EPA Risk Assessment

-- For the health of the residents in the community, EPA must act on the recommendations of the peer reviewers who said existing pollution levels and existing health conditions in the valley must be considered. The peer review panel recommended that existing air quality conditions in the valley be considered in the final risk assessment. Specifically, the peer reviewers recommended that the final risk assessment address the cumulative risk associated with background plus WTI incinerator exposures. Page 4-1 of the May 1996 *Report On The U.S. EPA Technical Workshop On The WTI Incinerator Risk Assessment Issues*, states,

"Peer reviewers of the project plan for the risk assessment noted that exposure to emissions from the WTI incineration facility occurs against a background of previous and ongoing exposures to a variety of other chemicals, including chemicals of concern for the WTI facility. Because the additional burden from the WTI facility might move total exposures to a steep part of the dose-response curve (or to levels greater than acceptable limits), estimating WTI-related exposures alone might underestimate the impact of the facility. ...They recommended that EPA address the cumulative exposure issue further to determine whether WTI-related exposures will increase total exposures to unacceptable levels." (See also pages 1-3, 3-18, 3-23, 2-3, 4-5, etc.) The EPA could not have considered existing background levels of pollution in the area, as recommended by the peer review panel, without using NOVAA information."

Response to 16B.11:

Please see earlier response to Dr. Harrison's comment 16A.4.

16B.12) Ms. Swearingen continues:

-- New information on the effects of Lead: A five-year study, published in the *New England Journal of Medicine*, has found that lead is harmful to children at concentrations in the blood that are typically considered safe. On April 17, 2003, Cornell University scientists reported that low lead levels, below those once thought safe, pose significant risk to children's cognitive functioning. Scientists say that children suffer intellectual impairment at a blood-lead concentration below the level of 10 micrograms per deciliter (mcg/dl) -- about 100 parts per billion -- currently considered acceptable by the Centers for Disease Control and Prevention (CDC). "We also found that the amount of impairment attributed to lead was most pronounced at lower levels," says Richard Canfield, lead author of the journal paper and a senior researcher in Cornell's Division of Nutritional Sciences. Most of the damage to intellectual functioning --- and the scientists found it to be substantial --- occurs at blood-lead concentrations that are below 10 mcg/dl. This is significant new information that is important to consider when setting lead emission limits for Von roll/WTI, given it's location next door to a 400-student elementary school and

in the middle of a neighborhood where these children live and play. The closest home is only 320 feet away. It is also important to consider that 1992 baseline testing of the children in East Liverpool showed that there was already a lead problem.

Response to 16B.12:

The U.S. EPA and other federal agencies (e.g., NIEHS, Centers for Disease Control) are aware of and are actively reviewing the study by Richard Canfield and co-workers that was published in the New England Journal of Medicine (April 2003). The study followed 172 children from the Rochester, NY area who had blood lead levels measured at 6, 12, 18, 24, 48, and 60 months of age, and who were tested for IQ (Intelligence Scale) at 3 and 5 years of age. Adjustments were made for certain factors such as birth weight, maternal intelligence, household income, maternal education, and household educational stimulation. The general findings indicated that IQ scores ranged from approximately 4 to 7 points lower as blood lead concentrations increased from 1 microgram/deciliter up to 10 microgram/deciliter. The study also reported that an increase in blood lead from 10 to 30 microgram/deciliter was associated with only a small additional decline in IQ. The results indicate that lead could be associated with adverse cognitive effects at blood lead levels lower than previously suspected. It should be noted that IQ score is not by itself an indicator of a clinical adverse health effect for an individual, and the study did not follow or predict any specific outcome for the individuals who participated in the study. In referring to the significance of the study results, one of the authors (Dr. D. Cory-Slechta, Univ. of Rochester) stated that "Our study also emphasizes the need to understand the behavioral deficits indicated by lower IQ scores." (NIEHS press release; April 16, 2003).

A discussion with Dr. Patricia Vanleeuwen (a member of U.S. EPA's Technical Workgroup for Lead) indicated that the approach used by U.S. EPA and other federal agencies for lead risk assessment and risk management will likely be a subject for review by the National Academy of Science (NAS) in the near future. This review may include Superfund methodology for lead risk assessment, the IEUBK model, and the blood lead level of concern employed by federal agencies. This would be a prime opportunity for the NAS to examine the blood lead level of concern and to present recommendations about the protectiveness of the 10 µg/dL value that federal agencies are currently using.

The VRA/WTI risk assessment presented the IEUBK Model results for the effect of lead in the environment on the blood lead level for children living in the vicinity of the VRA/WTI facility. The model includes a conservative "background" contribution for pre-existing lead in ambient air and soil based on default values from U.S. EPA's national guidance. The results of the IEUBK Model, considering this background lead contribution plus expected lead emissions from WTI, predicted that more than 98% of children might be expected to have blood lead levels below 10 µg/dL (the action level for health concerns used by the Centers for Disease Control (CDC)), with a mean value below 4 µg/dL. The model also predicted, however, that the potential for VRA/WTI lead emissions to increase blood lead levels in children was so low that the blood lead distribution attributable to VRA/WTI lead emissions added to pre-existing background lead was indistinguishable from the effect of background lead alone. See also the response to comment 16A.18, which describes a study conducted by the Ohio Department of Health during the period August 1992 through December 1994. The study concluded that "[n]either the lead nor the mercury samples taken from the children showed that the operation of the WTI incinerator caused East

Liverpool children to have higher levels of lead or mercury. . . . Neither soil nor air lead nor air mercury levels showed evidence of significant impacts by the WTI facility."

Since the mean blood lead value predicted by the model, based on lead from all sources (less than 4 $\mu\text{g}/\text{dL}$), falls in the range where recent published information (described above) suggests that young children could experience an adverse effect on intellectual development (i.e., IQ scores), it is instructive to compare this predicted value to published monitoring survey data on blood lead levels in young children. Actual blood lead measurement data will be influenced by lead exposure from all possible sources, including soil, air, water, food, and other additional "household" exposures such as lead paint and lead paint dust. While the mean blood lead values predicted by the IEUBK model might seem high, they are not atypical for the United States.

We consulted national and State of Ohio data on blood lead surveys in young children. The CDC obtains and publishes data on nationally representative blood lead surveys through its periodic National Health and Nutrition Examination Surveys (NHANES). For the latest reporting period (1999-2000), the survey data for children 1-5 years of age showed a nationwide mean blood lead level of 2.2 $\mu\text{g}/\text{dL}$ (with a 95% probability that the true mean would fall in the range of 2.0 -2.5 $\mu\text{g}/\text{dL}$). The 90th percentile value was 4.8 $\mu\text{g}/\text{dL}$. The prevalence of measured blood levels greater than 10 $\mu\text{g}/\text{dL}$ was 2.2%. The CDC data can be found in the following publications: "Children's Blood Lead Levels in the United States" (<http://www.cdc.gov/nceh/lead/research/kidsBLL.htm#National%20surveys>) and "Second National Report on Human Exposure to Environmental Chemicals" (<http://www.cdc.gov/exposurereport/2nd/pdf/nersummary.pdf>).

The Ohio Department of Health (ODH) collects and publishes survey data on blood lead levels in Ohio children (http://www.odh.ohio.gov/Data/Lead_Poison/lead1.htm). The data are reported at the county level. The data are reported on all survey results collected in a given year and are presented in concentration ranges rather than mean values. (ODH uses the concentration range results to determine geographic locations where special intervention activities may be needed.) For the latest reporting year (2003), Columbiana County reported blood lead measurement results for a total of 986 children up to 6 years of age. From this total, 966 (98%) had blood lead levels under 10 $\mu\text{g}/\text{dL}$. For the remaining 20 results, no value exceeded 19 $\mu\text{g}/\text{dL}$. The general survey trend in Columbiana County is that the proportion of children with blood lead levels exceeding 10 $\mu\text{g}/\text{dL}$ is decreasing. The reported data for Columbiana County the last 5 years are summarized below:

Year	Total # of Samples	Total # of Samples under 10 µg/dL	Total # of Samples over 19 µg/dL	Percent of Samples under 10 µg/dL
2003	986	966	0	98
2002	839	817	5	97.4
2001	841	806	3	95.8
2000	643	612	5	95.2
1999	893	844	9	94.5

These recent national and local Ohio survey results indicate that a very high majority of children show blood lead levels below 10 µg/dL. The typical child blood lead level was found to be in the range of 2.0 - 2.5 µg/dL, which is a value influenced by all sources of lead exposure.

Regarding 1992 testing that Ms. Swearingen mentioned, we would welcome the opportunity to review whatever data Ms. Swearingen has available on this matter.

16B.13) Ms. Swearingen continues:

-- New information about health risks of Dioxins - EPA has determined that the risk is 10 times greater than previously acknowledged. In July 2000, the government released the findings of their latest dioxin reassessment, showing that the risk from dioxin is 10 times greater than previously acknowledged. In fact, the risk to humans for developing cancer from existing background levels ranges from 1 per 1000 to 1 in 100, if your diet consists of meat and dairy products. And if you live near of source of dioxin, such as an incinerator, the risk increases 2 to 3 times. This is cause for revocation of WTI operating permit. In the least, it is cause for recalculation of the dioxin risk from WTI.

Response to 16B.13:

The U.S. EPA has been reviewing recent research regarding the health effects of dioxins in humans and has made draft findings available from time to time. (See also the response to Comment 16B.14.) The most recent Draft Dioxin Reassessment is a December 2003 document known as the "National Academy of Science (NAS) Review Draft." This Draft document can be viewed or downloaded at: <http://www.epa.gov/ncea/pdfs/dioxin/nas-review/>²⁰. This Draft was sent to the NAS because the Agency determined that specific topics in the Reassessment could benefit from additional external scientific peer review. The NAS began its review in June 2004 and the review will take approximately 18 months

²⁰The Draft Dioxin Reassessment has not been finalized as of this writing. Please keep in mind that it remains subject to correction and further revision, and that it doesn't represent approved Agency policy.

to complete. A summary of the scope and topics for the NAS review is located at: <http://www4.nas.edu/webcr.nsf/ProjectScopeDisplay/BEST-K-03-08-A?OpenDocument>.

Based on the NAS review, EPA will determine how to revise the Dioxin Reassessment, if necessary. While the U.S. EPA's 2003 Draft Dioxin Reassessment is subject to change, it does in part currently suggest that the carcinogenic potency of 2,3,7,8-TCDD could be approximately 8.7 times higher than the previously derived potency, based only on a re-analysis of the laboratory animal data. At the current time, this issue and the reassessment itself have not been finalized pending the NAS review, and no changes have been proposed in risk evaluation techniques. (For example, it is possible that the NAS could recommend that EPA should adopt the revised cancer potency based on the re-analysis of animal data, or the NAS could recommend a different approach, such as basing the cancer potency on human epidemiological studies.) It is currently unclear how the finalized dioxin reassessment might change the technique of risk assessment and/or the recommended risk management benchmarks. Since both the background level and the facility-specific contribution of dioxin would be increased by the same factor (i.e., 8.7X), the ratio of PCDD/F impact from any one individual facility to its background concentration would remain exactly the same. Clearly, background concentrations may become more important to the overall calculation of health impact. The increased importance of background concentrations on health impact could actually shift the U.S. EPA's risk reduction priorities to focus more on reducing emissions from the largest sources of PCDD/Fs, to more quickly achieve background reductions.

The NAS version of the Dioxin Reassessment does not place an explicit range on the estimated dioxin cancer risk from background exposures in the U.S. population (Part III, Chapter 5 "Dose-Response Characterization" Section 5.2.1 "Cancer"). It states that the calculated upper bound cancer slope factor based on human data is 1×10^3 per pg TCDD/kg-day. Since the current estimated average total intake of dioxins in the population is 1 pg/kg-day, the upper bound cancer risk for the average background exposure is 1×10^3 (i.e., 1 in 1000).

The VRA/WTI risk assessment calculated average daily doses expected from exposure to stack emissions for a number of scenarios and population groups examined in the risk assessment. For a subsistence farmer assumed to live in the highest impact zone in the vicinity of VRA/WTI, the average daily dose for combined exposure to all toxic dioxin and furan congeners was calculated to be $1.03E-02$ pg/kg-day. Consequently, the estimated daily dose of dioxins attributable to VRA/WTI emissions was estimated to be about 1% of the current average total daily intake dose of dioxins expected for a typical person living in the U.S. population.

After the dioxin reassessment is finalized, work will begin on how risk assessments will need to change in response to the new information.

16B.14) Ms. Swearingen continues:

- New information about health risks of endocrine disruptors and other persistent chemicals
- New information that shows there are male/female differences in disease following exposure to toxic substances. For example, women appear to be

8 to 9 times more susceptible to autoimmune attack, i.e., diseases of the immune system.

-- The EPA must take into account the differences between exposure to an adult and a baby or toddler in assessing cancer and other risks. In March 2002, the government proposed tougher guidelines for evaluating cancer risks to children on grounds the very young may be 10 times more vulnerable than adults to certain chemicals. The EPA viewed the question of exposure to children so significant that it decided to develop a separate guidance paper on risks of cancer to the very young, acknowledging for the first time that fetuses, infants and toddlers are substantially more vulnerable. The guidelines would dramatically alter current agency policy, which assumes cancer risks to a fetus or an infant are no greater than for a similarly exposed adult. Limiting its analysis, for the time being, to mutagenic chemicals, or those that cause gene damage to genes which causes them to mutate so that cancer may develop more easily later in life. The EPA said exposure to these chemicals is significantly more dangerous to young children. Among these are some pesticides as well as a number of chemicals released in combustion. They cause a 10 times greater risk of a future cancer in children under 2 years old and in fetuses when the mother is exposed, the EPA guidance concluded. It said children from 3 to 15 may face a risk at least three times greater than adults. The findings suggest, when more studies come in, the same disparity on risk between adults and the very young is likely to be observed, officials suggested. According to EPA's Bill Farland, the final guidelines are to be reviewed by the EPA science advisory board in May, with a final document to be issued by summer.

-- The EPA must also take into account other differences among the population, such as that women are more vulnerable than men to cancer risk from exposure to some toxic chemicals.

-- Recent research suggests that exposure to organochlorines, that possess estrogenic properties, may increase the risk of breast cancer by promoting growth of malignant cells. These findings suggest that past exposure to estrogenic organochlorines may not only affect the risk of developing breast cancer but also the survival. (Hoyer, A., Jorgensen, T., Brock, J., Grandjean, P., 2000. Organochlorine exposure and breast cancer survival. *Journal of Clinical Epidemiology* 53: 323-330)

-- Recent studies suggest that environmental estrogens polychlorinated biphenyls (PCBs) and phthalate esters (PEs) are potential environmental hazards in the deterioration of semen. PCBs were detected in the seminal plasma of infertile men but not in controls, and the concentration of PEs was significantly higher in infertile men compared with controls. Ejaculate volume, sperm count, progressive motility, normal morphology, and fertilizing capacity were significantly lower in infertile men compared with controls. PCBs and PEs may be instrumental in the deterioration of semen quality in infertile men without an obvious etiology. (Rozati, R., Reddy, R., Reddanna, P., Mujtaba, R., 2002. Role of environmental estrogens in the deterioration of male factor fertility. *Fertility & Sterility* 78: 1187-1194)

-- Recent studies of calamities have shown that dioxins negatively influence the respiratory system. It was hypothesized that perinatal exposure to

background dioxin levels leads to lung suboptimality, probably through developmental interference. A significant decrease in lung function in relation to both prenatal and postnatal dioxin exposure was seen in children. A clinical association between chest congestion and perinatal dioxin exposure was seen. (Ten Tusscher, G., de Weerd, J., Roos, C., Griffioen, R., De Jongh, Westra, M., van der Slikke, J., Oosting, J., Olie, K., Koppe, J., 2001. Decreased lung function associated with perinatal exposure to Dutch background levels of dioxins. *Acta Paediatr* 90: 1292-1298)

Response to 16B.14:

There are several issues raised in this comment, which we would like to address separately:

Regarding potential unknown health effects: *The use of conservative assumptions and methodologies in risk assessments can provide the basis for risk management decisions that are protective even where there are adverse impacts from pollutants that are unknown or imprecisely understood. For the chemical categories that Ms Swearingen lists, such as PCBs, phthalate esters, organochlorines and dioxins, the dose-response toxicity and carcinogenicity factors that we use are derived by employing a very conservative methodology. Because the methodology is so conservative, it is believed to also help address other suspected or potential adverse effects associated with these chemicals. For example, while little is known about potential endocrine disrupting effects of dioxins in humans, we believe that cancer risk can occur at extremely low concentrations. Restricting dioxin exposure in order to protect against cancer risk will result in very small exposures to the dioxins, and this should similarly help protect against potential endocrine disruption effects from the dioxin. Use of conservative assumptions can also help insure that risk management decisions are protective even where pollutants affect certain groups more adversely than other groups in ways that are unknown or imprecisely understood, e.g., differences in effects between males and females, or between children and adults. (See below for a summary of current research regarding non-cancer effects of PCDD/Fs and related chemicals.)*

Regarding differences in sensitivity between males and females: *When developing dose-response relationships for the risk assessment of chemicals, U.S. EPA will consider both qualitative and quantitative gender differences reported for the toxic effects of a given chemical. U.S. EPA will generally base the recommended dose-response factor (e.g., RfD, slope factor) on the results for the gender that displayed the more severe toxic effects as determined by: a) which gender exhibited the on-set of the critical toxic effect at the lowest dose; and b) which gender exhibited the higher magnitude of toxic response at the same dose.*

Regarding differences in sensitivity between children and adults: *While neither the VRA/WTI risk assessment nor final U.S. EPA guidance for risk assessments uses different dose/response toxicity or carcinogenicity factors for children and adults, the risk assessment did take into account the fact that doses of chemicals from exposure could be different in children and adults based on differences in intake rates versus body weights. The VRA/WTI risk assessment accounted for several of these differences by using specific exposure factors for children and adults.*

In addition, the issue of possible differences in sensitivity to pollutants between children and adults is currently under active review. The U.S. EPA recently completed and published a draft final document entitled, "Guidelines for Carcinogen Risk Assessment," along with an associated draft document entitled "Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens" (draft Supplemental Guidance). The U.S. EPA solicited comments from the public on these 2003 drafts during a 60-day comment period last year.

The draft document focuses on assessing the effects of early life stage exposure and includes a review of existing scientific literature on chemical effects in animals and humans, as well as human exposure to ionizing radiation. Because the areas of carcinogenicity, genesis of disease, and effects on susceptible life stages and populations are constantly and quickly evolving, the U.S. EPA expects that this will be the first of several supplemental guidance documents to the Guidelines for Carcinogen Risk Assessment. These companion documents will provide additional information on how to address specific aspects of cancer risk assessment. To enhance the Agency's understanding of age-related cancer susceptibility, U.S. EPA's Office of Research and Development is expanding its research through an initiative that focuses on exploring appropriate measures of dose-response characteristics, and exposure variables that may be affected by age. This research will be done through a combination of studies in U.S. EPA laboratories, the Agency's Science to Achieve Results (STAR) grants program, and collaborations with other federal agencies.

The U.S. EPA's Science Advisory Board ("SAB") reviewed the 2003 version of the draft guidance document and sent a Review Report to the Administrator on March 3, 2004. The U.S. EPA recently responded to the SAB in a letter dated September 1, 2004, agreeing to incorporate most of the SAB's recommendations.

The documents listed above are available via the Internet at <http://epa.gov/ncea/cancer2003.htm> and <http://epa.gov/ncea/raf/cancer2003.htm>.

Attachment D of this Response to Comments document is a Question and Answer document which provides general information and a summary of key points in U.S. EPA's Draft Final "Guidelines for Carcinogen Risk Assessment".

Also attached is an excerpted version of the executive summary of a document entitled A Review of the Reference Dose and Reference Concentration Processes, from November 2002, which explains steps which have been taken to re-evaluate, and preliminary recommendations regarding, the reference dose and reference concentration values upon which risk assessments are generally based. Although this is just the first step, we believe this document provides valuable information on how the U.S. EPA re-evaluates the science underlying such matters as risk assessment.

Regarding suspected or imprecisely understood noncancer effects of dioxin and related chemicals: *Ms. Swearingen's comments above refer to several types of suspected non-cancer effects on human reproductive, respiratory and immunologic systems that have been attributed to dioxin and dioxin-like chemicals, such as 2, 3, 7, 8-TCDD and polychlorinated biphenyls (PCBs). U.S. EPA has been reviewing recent research regarding the known or suspected health effects of dioxins in humans and has*

made draft findings available in the Draft Dioxin Reassessment (including, e.g., Part II: Health Assessment for 2, 3, 7, 8-Tetrachlorodibenzo-p-dioxin (2, 3, 7, 8-TCDD) and Related Compounds; Chapter 7 of Part II: Epidemiology/Human Data; and Part 7b: Effects other than Cancer).²¹ In the following paragraphs we've summarized some of the draft findings regarding suspected non-cancer effects on the human reproductive, respiratory and immunologic systems, but please keep in mind that the Draft Dioxin Reassessment has not been finalized as of this writing, that it remains subject to correction and further revision, and that it doesn't yet represent approved Agency policy. We've included a more detailed summary in Attachment I. (The following summary is based on the year 2000 draft of the Draft Dioxin Reassessment.)

The majority of effects on humans have been reported among occupationally exposed groups, such as chemical production workers, pesticide users, and individuals who handled or were exposed to materials treated with 2,3,7,8-TCDD-contaminated pesticides. Non-occupational exposures have been investigated among residents of communities contaminated with tainted waste oil (Times Beach, Missouri, USA) and the chemical fallout from an explosion at a chlorinated pesticide manufacturing plant (Seveso, Italy).

These effects represent a complex network of responses to dioxin exposure ranging from changes in hepatic enzyme levels which, based on current evidence, do not appear to be related to clinical disease, to observable alterations in the character and physiology of the sebaceous gland, as seen in the well characterized condition known as "chloracne." Part II, Chapter 7 of the Dioxin Reassessment describes, by human organ system, the noncancer effects associated with exposure to 2,3,7,8-TCDD. The characterization of the effects by system provides a context within which to compare the results of the various studies. However, it is important to recognize that the observed effects are not independent events but rather may be one outcome in a series of interrelated outcomes, some of which may be incapable of measurement with the present technology or which we currently do not recognize as an outcome of exposure to 2,3,7,8-TCDD.

The information describing human effects attributed to exposure to 2,3,7,8-TCDD-contaminated materials is derived from a wide variety of sources, including clinical assessments (case reports) of exposed individuals and analytic epidemiologic studies using case-control, cross-sectional, and cohort designs. The case reports describe the acute outcomes of exposure to 2,3,7,8-TCDD and provide the basis for hypothesis generation for controlled epidemiologic studies; however, they are not suitable for demonstrating actual causal relationships between exposure and related effects.

Cohort and case-control studies have been used to investigate hypothesized increases in cancer among the various 2,3,7,8-TCDD-exposed populations. Cross-sectional studies have been conducted to evaluate the prevalence or extent of diseases in living 2,3,7,8-TCDD-exposed groups. Many of the earliest studies were unable to define exposure-outcome relationships owing to a variety of shortcomings. These included small sample size, short latency periods, selection of inappropriate controls, and the inability to quantify exposure to 2,3,7,8-TCDD or to identify exposures to other toxic chemicals.

²¹This summary is based on the 2000 draft.

In more recent cross-sectional studies of U.S. chemical workers, U.S. Air Force personnel, and Missouri residents, serum or adipose tissue levels of 2,3,7,8-TCDD were measured to evaluate 2,3,7,8-TCDD associated effects in exposed populations. The ability to measure tissue or serum levels of 2,3,7,8-TCDD for all or a large sample of the subjects confirmed exposure to 2,3,7,8-TCDD and permitted the investigators to test the suspected dose-response relationships.

- **Regarding potential dioxin effects on reproductive hormones**, the human data offer some evidence of alterations in male reproductive hormone levels associated with substantial occupational exposure to 2,3,7,8-TCDD. These results were described as supporting the animal literature, in which dioxin-related effects have been observed on testosterone synthesis and on the control of testicular function (via hormone synthesis and uptake along the hypothalamic-pituitary-Leydig-cell pathway). However, because these data involved substantial occupational exposure as opposed to environmental-level exposures, it is not clear how useful they might be in evaluating risks from environmental exposure.
- **Regarding a potential connection between dioxin and endometriosis**, two studies of infertility patients did raise the potential for an association between endometriosis and TCDD exposure. However, these studies were characterized as being small and of limited statistical power. A third study compared women who were breast-fed as infants to women who were bottle-fed, but the study contained little documented data on dioxin exposure and, most likely, an incomplete and potentially biased selection of cases. As a group, these studies were characterized as being of limited use for examining the relationship of dioxin to endometriosis
- **Regarding potential effects on the respiratory system**, case reports indicated that intense acute exposure to 2,3,7,8-TCDD can produce respiratory irritation. However, the findings from controlled epidemiologic studies were described as not supporting an association between 2,3,7,8-TCDD exposure and chronic noncancer effects on the respiratory system.
- **Regarding potential impacts on the immunologic system**, at the present time there appears to be too little information to suggest definitively that 2,3,7,8-TCDD is an immunotoxin in humans. Additional studies of highly exposed adults are said to be needed to shed light on the effects of long-term chronic exposures.

The science of risk assessment will undoubtedly continue to evolve, providing us with more certainty and, if necessary, a basis to require reductions in emissions. However, it is important to understand that the approach the U.S. EPA used in the VRA/WTI Human Health Risk Assessment resulted in conservative estimates of overall risk, and the resulting over-estimation of quantifiable risks tends to balance against the unquantifiable risks.

16B.15) Ms. Swearingen continues:

-- Von Roll/WTI has had a number of fires, explosions, accidents, spills, fugitive emissions and other permit violations that may have negatively impacted the health the residents.

Response to 16B.15:

The U.S. EPA is always concerned about abnormal events, and emphasizes that they are not allowed and that the Permittee should take all reasonable measures to avoid them. Because of the nature of these events, it is very difficult to quantify or characterize the emissions that might result, and therefore difficult to estimate potential off-site impacts.

The U.S. EPA's detailed risk assessment did consider various types of fugitive emissions which were thought to be the most significant, and the results of the assessment reflect these. In addition, many of the fires which have been recorded at VRA/WTI have occurred within enclosed areas (such as the waste pit enclosure) where the majority of emissions would be collected and treated. This helps minimize off-site impacts.

16B.16) Ms. Swearingen continues:

-- "Purple plume" - Have constituents of the purple plume been analyzed more than once? What else is in the purple plume besides iodine? Are there exceedances of any other hazardous constituents during the purple plume? If the problem is iodine, why does the Enhanced Carbon Injection System (ECIS) not absorb the iodine before it has a chance to be released from the stack? If the carbon is not capturing the iodine, as it's supposed to, then perhaps it's not capturing the dioxins or mercury? Has an analysis been conducted to test this theory? I have tried for years, unsuccessfully, to obtain a copy of the 37 page Draft report/analysis NOVAA's Harold Strohmeyer was working on just before NOVAA was disbanded. In a December 1996 report, Mr. Strohmeyer noted an exceedance in mercury associated with the purple plume.

Response to 16B.16:

We believe the purple color of the plume is due to the presence of iodine in the particulate matter. Neither the U.S. EPA nor the OEPA haves analyzed the particulate matter emissions during a purple plume incident, because the purple plume events are unpredictable and our efforts have been focused on making sure the events are avoided. Improvements have been made to reduce the frequency of these purple plume events.

As to why the carbon does not remove the iodine: while the carbon system may remove some iodine, it is mainly designed to remove dioxin from combustion gases, rather than iodine. It is currently thought that the iodine is being liberated from the scrubber water at a point where the carbon absorption activity is low.

We have not been able to find any information in our files linking the purple plume to mercury exceedances, and would appreciate receiving a copy of the 1996 report referenced by Ms. Swearingen, or any other information on this issue.

16B.17) Ms. Swearingen continues:

-- actual observed health problems - Dr. Dorothy Canter could not tell the community that WTI was not the cause of immune and reproductive problems in the community.

Response to 16B.17:

No risk assessment can achieve a perfect assessment of risks, since there are inevitably gaps in the scientific understanding of the nature of risks (e.g., information gaps in chemistry or toxicology for certain substances) and limitations in risk methodologies. In response, the U.S. EPA uses conservative risk assumptions to provide a margin of safety and ensure that risks are not underestimated. While risk assessments cannot guarantee safety, they can be conducted in a manner which provides a sound basis for risk management decisions regarding the protectiveness of permits and permit terms. To the extent a risk assessment uncovers risks that might not be addressed adequately by the RCRA regulations and permit, action can be taken to reduce potential health impacts and help ensure that the RCRA permit is protective.

16B.18) Ms. Swearingen continues:

--- Cancers -

- According to the Ohio Department of Health, East Liverpool's cancer rate (based on death certificates), is 40.25% higher than the national average. The cancer rate in East Liverpool is 588.9 per 100,000. This is only the tip of the iceberg since these figures are based on mortality rates rather than incidence rates. A more recent study concluded that the incidence of cigarette smokers in East Liverpool is very low.
- _____²² was a local subsistence farmer who lived in the vicinity of the incinerator and ate homegrown meat, vegetables and dairy products from her 100-year old family farm. As such, she fit EPA's profile of the "MEI" --- or maximally exposed individual. _____ died of cancer in 1998 at the age of 55.
- Citizens have documented over 200 new cases of cancer near the incinerator since it began burning in 1992. _____ and _____, two life-long residents and long-time WTI opponents who live just yards from the incinerator, were both recently diagnosed with cancer. In the past few years, we've seen children suffering from rare forms of cancer. There've been two young boys, both under age 3 at the time of diagnosis, who've been forced to have an eyeball removed because of retinoblastoma, a rare form of eye cancer. The expected incidence rate of retinoblastoma is 1 in 250,000. East Liverpool, with a population of only 13,000, has **two** cases, both in the vicinity of the incinerator. One of the little boys lives just 800 feet from WTI. There's a young girl with another rare cancer, rhabdomyosarcoma, and four cases of male breast cancer. Last year, a 10-year old girl had a hysterectomy because of uterine cancer. Just this summer, an 11-year-old girl died from a cancer that's never been seen before. On the young girl's street, which is two blocks from WTI, there've been 5 other kids with cancer.

Response to 16B.18:

Unfortunately, cancer is a disease which typically can be expected to affect one-in-three to one-in-five people within their life times. The U.S. EPA's regulations and other methods

²²For privacy reasons, names have been omitted.

for protecting people from potential emissions from a facility such as VRA/WTI seek to ensure that this often overlooked cancer rate does not increase significantly for anyone due to the regulated facility, even a sensitive person who would have the highest calculated level of exposure.

We are referring Ms. Swearingen's comment to the Ohio Department of Health and the Agency for Toxic Substances and Disease Registry for review. However, we would also like to offer the following response regarding (1) the incidence of cancer and (2) retinoblastoma in the vicinity of incineration facilities.

The National Academy of Science (NAS) is an independent nonprofit organization of scientists and engineers that investigates important technical, health, and social issues and provides advice useful to the federal government and other interested parties. The NAS issued a report entitled "Waste Incineration and Public Health." As part of the Report, the NAS committee investigated the literature on studies of health effects in the vicinity of waste incinerators (this could include hazardous waste, municipal waste, and medical waste facilities). The general conclusion of the Report is that there is no convincing evidence available to document increases in adverse health effects in the populations living near such facilities. In addition, the Report concluded that the most modern and well operated facilities should not emit levels of pollutants which would pose a significant health risk to the nearby populace. The Report also: 1) provided recommendations for improving future studies to look for health effects; and 2) stated that on-site workers at such facilities would be likely to have the highest risk for exposures and health effects and should be studied in more detail. This Report is available for reading at the following Internet web site: <http://bob.nap.edu/books/030906371X/html>

Regarding the concern about the origin of retinoblastoma and possible environmental causes of retinoblastoma (environmental causes could include such factors as air pollution, industrial chemicals, tobacco smoke, viruses); it is difficult to pinpoint definite environmental causes for a disease as rare as retinoblastoma. In order to look into this possibility further, we contacted Dr. Youn Shim at the Agency for Toxic Substances and Disease Registry in Atlanta, Georgia. Dr. Shim is a specialist in identifying causes of childhood disease. She stated that because retinoblastoma accounts for only 2-4% of all childhood cancers, it is difficult to find confirmed risk factors. The major problem is that the population available for study is very small. There are apparently a few examples available of non-confirmed environmental risk factors. For example, a study in Great Britain suggested an increase in retinoblastoma rate around a nuclear facility. However, in similar studies around nuclear facilities in the U.S., no increases in rates were found. In another U.S. study, there was a report of increased risk for retinoblastoma in the children and grandchildren of persons who worked in the agricultural sector.

Dr. Shim emphasized her concern that these studies should not be taken as providing confirmed evidence that certain occupations or locations are associated with an increased rate of retinoblastoma. The information about these studies was derived from a publication titled: "Epidemiology of Childhood Cancer" (by Julian Little; published by International Agency for Research on Cancer; IARC Scientific Publication No. 149; Lyon, France; 1999).

It is our understanding that retinoblastoma has been found to have a genetic link and to be an inherited disease in 30 - 40% of patients. Scientists have found convincing evidence

for the existence of a retinoblastoma gene (the "Rb gene"). This genetic link explains the likely origin of retinoblastoma in many families.

16B.19) Ms. Swearingen continues:

--The Ohio Valley is ranked number 26 nationwide among counties with the dirtiest air. According to the American Lung Association, only 25 counties nationwide have air that is dirtier than in the Ohio Valley. Nearly half the American population—more than 137 million Americans—continues to breathe unhealthy amounts of the toxic air pollution, according to the American Lung Association State of the Air: 2003²³ report released in May 2003.

Response to 16B.19:

We agree this is a very important issue and that air quality needs to improve in many areas of the country. The web site appears to specifically focus on ozone levels. Please see the response to Comment 16A.5 and 16A.10 for information regarding air quality in the vicinity of VRA/WTI.

16B.20) Ms. Swearingen continues:

For the health of the residents in the community, EPA must act on the recommendations of the peer reviewers who said existing pollution levels and existing health conditions in the valley must be considered. The peer review panel recommended that existing air quality conditions in the valley be considered in the final risk assessment. Specifically, the peer reviewers recommended that the final risk assessment address the cumulative risk associated with background plus WTI incinerator exposures. Page 4-1 of the May 1996 *Report On The U.S. EPA Technical Workshop On The WTI Incinerator Risk Assessment Issues*, states,

"Peer reviewers of the project plan for the risk assessment noted that exposure to emissions from the WTI incineration facility occurs against a background of previous and ongoing exposures to a variety of other chemicals, including chemicals of concern for the WTI facility. Because the additional burden from the WTI facility might move total exposures to a steep part of the dose-response curve (or to levels greater than acceptable limits), estimating WTI-related exposures alone might underestimate the impact of the facility. ...They recommended that EPA address the cumulative exposure issue further to determine whether WTI-related exposures will increase total exposures to unacceptable levels." (See also pages 1-3, 3-18, 3-23, 2-3, 4-5, etc.) The EPA could not have considered existing background levels of pollution in the area, as recommended by the peer review panel, without using NOVAA information.

Response to 16B.20:

Please see response to Comments 16A.4 and 16B.19.

²³Found at <http://lungaction.org/reports/stateoftheair2003.html>.

16B.21) Ms. Swearingen continues:

-- Asthma and respiratory problems appear to be epidemic in the area.

While citizens have never collected information on incidence, we have seen more and more folks complaining of respiratory ailments since Von Roll/WTI began operating. _____, son of _____, who lives just 800 feet behind Von Roll/WTI, never had asthma or sinus problems while growing up until he moved back home after college. He is now so sensitive that he cannot function for a day without taking some kind of allergy/sinus medication. _____'s biology teacher just this week reported the same experience --- she never previously had any kind of respiratory problems, but now she has serious sinus and allergy symptoms.

-- Across the river, a young child has a serious case of scleroderma, only one of about 700 in the nation.

Response to 16B.21:

As the U.S. EPA and other public health non-profit agencies have reported, the incidence rate for asthma appears to be increasing across the U.S. There appear to be multiple factors involved in asthma induction and exacerbation, including exposure to both indoor factors (e.g., cockroach antigen, dust mites, pet dander, second-hand cigarette smoke, family smoking history) and outdoor triggers (ozone, pollen). Because these factors are wide spread, it would not be surprising to see an increase in asthma incidence in the East Liverpool area compared to a decade earlier. If asthma and respiratory allergy response problems are becoming an epidemic in East Liverpool, then the municipal health department should become involved. We are forwarding a copy of the Response to Comments Document to the ELBH.

16B.22) Ms. Swearingen continues:

c. Risk management vs risk assessment.

"Risk management" is the process of determining which risks to assess and the level of risks considered acceptable. "Risk assessment" is the process of calculating the chances that the risks selected in the Risk Management process will occur. This includes the processes of identifying hazards and emissions, determining toxicity values and calculating risk estimates. Risk assessments are supposed to answer the questions and satisfy the standards established in risk management standards. The processes are distinct. Both should be performed with public input, especially the process of risk management.

The EPA, however, has no formal risk management or risk assessment standards. The EPA can change the standards with each risk assessment and each permit decision at each plant. The EPA can change the scope of risks it evaluates, the methods of performing risk assessments and the standards of acceptable risk for each plant. The risk management and risk assessment standards used in the decision to approve WTI's commercial operation were ad hoc standards that were developed during and after the risk assessment, without public input and without the separation required between risk managers and risk assessors.

Response to 16B.21:

U.S. EPA risk assessments are currently guided by draft national guidance published in 1998. That guidance grew out of national conference calls, risk assessment work done in Region 6 and many other Regions, and the detailed "Phase 2" VRA/WTI risk assessment, which had served as a prototype for risk assessments that followed it. The 1998 draft guidance was the subject of its own independent peer review. Following this guidance helps achieve consistent treatment of the regulated facilities, and helps avoid the kind of problems described in Ms. Swearingen's comment.

Ms. Swearingen is correct that the risk management benchmarks have never been officially published or promulgated. To date, national public participation on risk management benchmarks has been limited, but does include public participation in the regulatory promulgation process for the "BIF" rule (40 CFR 266.100 et seq), which includes the benchmarks of 1×10^{-5} for carcinogens and $HI = 0.25$ for toxics. The U.S. EPA generally recommends the risk management benchmarks of Hazard Index = 0.25 or less, and potential increased cancer risk of 1×10^{-5} or less. These recommended values were published in the U.S. EPA's Draft Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities, EPA 530-R-94-021, April 1994. To the extent that these types of risk assessments are used to support draft RCRA permit decisions, the draft permit receives comment during an official public comment period. Comments and responses are available to the decision maker(s) at the time the final decision on the issuance or renewal is made. This public comment period is part of the public involvement process for the RCRA permit renewal decision and the risk evaluations that support it.

Please also see the response to comment 16A.4.

16B.23) Ms. Swearingen continues:

a. Ad hoc standards and manipulation.

The ad hoc process of risk management and risk assessment for WTI gave the EPA risk managers the opportunity to manipulate and target the scope of risks assessed and the permitting standard to conform with the expected risk assessment results. Conversely, the process also gave risk assessors the opportunity to manipulate the results to satisfy the risk management standards.

An example is the use of the Margin of Exposure analysis for non-cancer effects of dioxins. Instead of using a toxicity value for the non-cancer analysis which would have produced an unacceptable risk estimate, the EPA developed a MOE analysis (which included its own standard of acceptable risk) and, surprise, the results showed acceptable risks. A similar example includes the analysis of dioxin non-cancer effects on breast-feeding infants. Using the MOE approach, which the EPA had by then incorporated into risk assessment guidelines, the EPA ignored the standard for breast-feeding infants in the guidelines. A similar example included the analysis of the risks from accidents. The risk assessors developed both the risk assessment process for this risk and the standards to judge whether the calculated risks were acceptable.

Response to 16B.23:

The MOE approach was used when evaluating non-cancer effects of dioxin because published non-cancer toxicity factors were not available. Because VRA/WTI was shown to be a very small source of overall pollution in the area, we do not agree that a detailed analysis would have shown unacceptable results, even if it could have been done. See also the response to the following comment, regarding the non-cancer effects of dioxin on breast-feeding infants.

As to the accident analysis, the U.S. EPA had no regulations, guidelines, or clear regulatory authority which could be used in potential risk management decisions regarding possible risks from accidents, nor any real guidance on how the U.S. EPA might assess the potential risks. Normally in such a situation, the U.S. EPA would not conduct an accident analysis. However, since the peer panel involved in the human health risk assessment recommended that some form of accident analysis should be done, we did our best to meet the peer panel's expectations. We attempted to develop a method which would allow us to consider issues such as whether certain operations or categories of operations might warrant additional restrictions, and provide us with enough certainty to make a finding under 40 CFR 270.32(b) that such restrictions were necessary. That method, which is fully described in Volume VII of the risk assessment (See page I-7 et seq of that Volume), was based on techniques contained in relevant guidance documents from the Federal Emergency Management Agency and from the U.S. EPA. The results of the accident analysis were presented to the appropriate U.S. EPA risk managers.

16B.24) Ms. Swearingen continues:

Another example involves the EPA's December 1994 risk assessment guidelines. The December 1994 guidelines established a process and risk management standard for the non-cancer effects of dioxins on breast-feeding infants. The December 1994 guidelines were silently ignored in the WTI risk assessment.

Response to 16B.24:

The December 14, 1994 draft document to which Ms. Swearingen refers is entitled Revised Draft Guidance for Performing Screening Level Risk Analyses at Combustion Facilities Burning Hazardous Waste. Attachment C, Draft Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities According to information received from the Office of Solid Waste, this draft document was reportedly released for internal review, but never formally or officially released as a program-supported document. In addition, the described technique for evaluating potential non-cancer effects on breast-feeding infants was not incorporated into subsequent U.S. EPA guidance.

16B.25) Ms. Swearingen continues:

b. Risk management and risk assessment standards determined without public input in violation of EPA policy.

The EPA's Combustion Strategies recognized the importance of public participation in the permitting process and recommended improved public participation opportunities and methods in the process, including risk assessments.

The EPA did not solicit public input on the risk assessment process or in the risk management decision to start commercial operations after the completion of the risk assessment.

Response to 16B.25:

We believe that all the stakeholders were given considerable opportunity to participate in the VRA/WTI risk assessment process beginning as early as 1993. In addition, the draft risk assessment was available from November 1995, so the draft document had been available for review for well over a year before the assessment was completed.

The U.S. EPA made an early decision to rely heavily on an independent peer review process, and that process included the opportunity for the community to nominate their choice of experts, and to provide comments to the independent reviewers for their consideration. Community representatives were indeed part of the peer review process, and spoke at the peer review workshop.

At this time, any risk management decision based on the risk assessment is being made by the Ohio EPA concerning renewal of the RCRA permit. That decision will be based on regulatory criteria, technical information, public comments, and other appropriate information.

16B.26) Ms. Swearingen continues:

Public input should be allowed on the following:

- to help develop the risk management standards that determine which risks will be assessed, the metrics in which the risks will be calculated and whether any calculated risks are acceptable;

Response to 16B.26:

To the extent that risk assessments support risk management decisions that supplement the RCRA regulations, we believe that both the assessment techniques and the risk management benchmarks must be developed and implemented in a nationally consistent fashion. We have incorporated public comment in the draft national guidance on risk assessments. To date, national public participation on risk management benchmarks has been limited, but does include public participation in the regulatory promulgation process for the "BIF" rule (40 CFR 266.100 et seq), which includes the benchmarks of 10^{-5} for carcinogens and $HI = 1$ for toxics. In addition, appropriate risk management benchmarks can be part of the public debate associated with each specific permit action which considers the results of a risk assessment.

16B.27) Ms. Swearingen continues:

- to help develop the risk assessment standards which determine how to

conduct a risk assessment.

-- to help develop the site-specific assumptions used in the risk assessment process

-- to develop an alternative set of plausible assumptions to provide a reality check on the accuracy of the agency's results.

Response to 16B.27:

The current 1998 draft of the combustor risk assessment guidance was the subject of a peer review and national public comment period.

16B.28) Ms. Swearingen continues:

c. The National Research Council's recommendations on risk assessments state that policy-laden risk management issues should be determined in a process distinct from risk assessment issues. Decisions on risk management and risk assessment issues for WTI appear to have been made by the same people. Separation between risk management (policy decisions on reasonableness of risks) and risk assessment (policy and technical decisions on how to assess identified risks) was not practiced in violation of accepted practice.

Response to 16B.28:

We agree that risk management issues should be determined in a process distinct from risk assessment issues, and believe they were at the U.S. EPA in the case of the VRA/WTI Risk Assessment. The staff involved with developing the assessment provided the appropriate managers with the results of the assessment. Managers were also informed of the typical risk management benchmarks for the HHRA and SERA frequently used within U.S. EPA, but ultimate decisions on the appropriate risk management benchmarks were made by the appropriate managers. In the case of the accident analysis, where there were no specific benchmarks, upper management was briefed on the calculated results alone.

For practical reasons, the technical staff involved in the assessment felt that the risk assessment, when it was released in 1997, would have been unsatisfactory to many interested readers if it did not give any indications as to whether or not risks were within the generally acceptable range for U.S. EPA decisions. We understood that preliminary risk management decisions needed to be made and incorporated into the document, lest it be considered a "document without conclusions". This was done, using the customary risk management benchmarks as a preliminary indication. We understand how this could be construed as mixing risk assessment with risk management, but we believe it was an appropriate method of releasing the document and communicating the results.

16B.29) Ms. Swearingen continues:

Remedies as they relate to the risk assessment

● If the EPA is going to continue to use the risk assessment to say that the Von Roll/WTI facility is "safe", that it does not pose an unacceptable risk, or that additional monitoring is unnecessary, then a better --- more legitimate and more credible --- risk assessment must be conducted. We don't want another risk assessment; however if a more credible risk assessment is done, we want the

opportunity to do alternative estimates based upon a set of assumptions determined by independent scientists with input from the victimized residents.

Response to 16B.29:

At this time, the U.S. EPA has no plans to conduct a new risk assessment. The new, and more protective "MACT" regulations went into effect September 30, 2003, and we believe that the existing risk assessment and the national risk assessment conducted as part of that rulemaking provide a sufficient check on the protectiveness of the new regulations. Please also see the response to comment 16A.1 for more information on this matter.

16B.30) Ms. Swearingen continues:

- We would prefer to have an "alternatives assessment" and a "needs analysis". If it is determined that the facility is necessary, then we look at the safest option.
- The most prudent action considering the precautionary principle is complete closure of the facility! There are no conditions that could be implemented to make WTI safe in its present location.
 - The number one priority should be always to use the precautionary principal.
 - A "needs assessment" should always be the given the highest consideration.
 - If need is determined, the second step should be an "alternatives analysis" to determine if there is a safer option to the proposed action.

Response to 16B.30:

We are not aware of any provision in the RCRA regulations that authorizes the Agency to perform any kind of needs assessment or alternatives analysis for hazardous waste facilities.

16B.31) Ms. Swearingen continues:

- EPA should determine risk management standards before doing another risk assessment. The public should be involved from the first step, early and often. First determine the scope of risks to be assessed, levels of acceptable risk and metrics of assessment before doing risk assessment.
- Risk management and risk assessment standards should be developed with public input, as should the performance of each risk assessment.
- Calculate alternative risk estimates based upon public assumptions.

Response to 16B.31:

The U.S. EPA generally uses the risk management benchmarks of Hazard Index = 0.25 or less, and potential increased cancer risk of 1×10^{-5} or less for hazardous waste incinerators. These recommended values were published in the U.S. EPA's Draft Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities, EPA 530-R-94-021, April 1994. To the extent that these types of risk assessments are used to support draft RCRA permit decisions, the draft permit receives comment during an official public comment period. Comments and responses are available to the decision maker(s) at the time the final decision on the renewal is made. This public comment period is part of the public involvement process for the RCRA permit renewal decision and the risk

evaluations that support it.

16B.32) Ms. Swearingen continues:

-Risk management decisions should be distinct from risk assessment decisions.

Response to 16B.32:

We agree. Please see the response to comment 16B.28.

16B.33) Ms. Swearingen continues:

-If the EPA continues in its attempt to use the risk assessment to say that WTI is "safe" and/or poses no threat, and that additional monitoring is not warranted, then a credible risk assessment needs to be performed. Citizens need to be involved from the very first step.

"THE 1997 RISK ASSESSMENT FOR VON ROLL/WTI WAS FLAWED AND INADEQUATE. THERE ARE TOO MANY UNANSWERED QUESTIONS AND UNRESOLVED ISSUES RELATING TO THE RISK ASSESSMENT AND THE THREAT TO HUMAN HEALTH AND THE ENVIRONMENT. IT IS NOT CREDIBLE, SCIENTIFIC OR PROFESSIONAL TO USE THE 1997 RISK ASSESSMENT TO SAY THAT THE VON ROLL/WTI TOXIC WASTE INCINERATOR IS SAFE, THAT IT POSES NO RISK TO NEIGHBORING RESIDENTS OR THAT IT SHOWS THAT NO ADDITIONAL MONITORING IS WARRANTED." [Emphasis in the original.]

Response to 16B.33:

We disagree with the comment. As explained in 16A.1, the emission standards and other requirements of the regulations are the primary means of ensuring that permits are protective. We believe that the VRA/WTI risk assessment provides a sound and scientifically objective tool for risk management decision-making when evaluating whether additional permit terms may be necessary to help ensure that the permit is protective. Please see the responses to comments 16B.29 and 16A.1.

16B.34) Ms. Swearingen continues:

- On May 8, 1997, during a public meeting in East Liverpool, Ohio, Dr. David Cleverly told the audience that he would not allow his children to attend the elementary school 1,100 feet from WTI.

Response to 16B.34:

There are many individual factors that go into a person's personal choice on such matters. However, the U.S. EPA is required to regulate based on promulgated regulations and statutory direction, not on the personal choices of individual agency personnel. Please also see the response to Comment 16A.1, regarding individual perception of risk.

16B.35) Ms. Swearingen continues:

- At the same May 8 meeting, Sandy Estell questioned Dr. Dorothy Canter for an answer to her 15 year old daughter's question about whether or not she would be safe in her home 800 feet from WTI. Dr. Canter said she could not tell Sandy's daughter not to be afraid.

Response to 16B.35:

We do not have a transcript, and therefore don't know the context of the statement, which could be important to understanding its meaning. As stated in the previous response, the U.S. EPA regulates based on promulgated regulations and statutory direction.

16B.36) Ms. Swearingen continues:

- It is very sad to note that EPA never suggested that the results of the risk assessment could or would be used to halt the facility's operations; only that it will be used to set operating conditions.

Response to 16B.36:

Our risk assessment did not show that it was necessary to prohibit operation in this case. In general, risk assessments can provide a basis for imposing more restrictive permit terms and conditions if unaddressed risks are revealed, and in appropriate cases, might form the basis for denial of permits.

16B.37) Ms. Swearingen continues:

- In 1995, two years before completion of the Von Roll/WTI risk assessment, the EPA itself became a Von Roll/WTI customer when they began sending Superfund waste to the facility. Therefore, citizens were not surprised that EPA's 1997 risk assessment did not reveal unacceptable risk. Who would have been responsible for the detrimental health impact if the risk assessment concluded that the operation of the incinerator posed a risk?

Response to 16B.37:

There are many available facilities to which Superfund cleanup waste could be sent, and the U.S. EPA's contractors and on-scene coordinators who determine to which facility each load of such waste will go are constrained by the "off-site" policy (which tracks regulatory compliance status of potential receiving facilities) and by the typical governmental requirements to use the lowest bidder.

On the question of responsibility for detrimental health impact if the risk assessment had concluded that the operation of the incinerator posed a risk, this is not relevant because this is not what the risk assessment concluded.

16B.38) Ms. Swearingen continues:

- There was no consideration of background pollution/emissions or existing health conditions. Why did the EPA not take the recommendations of the peer review panelists to look at the existing pollution burden and health status of the community?

Response to 16B.38:

Please see our response to Dr. Harrison's comments 16A.4 and 16A.5.

16C) COMMENTS ON THE 1997 RISK ASSESSMENT BY DR. PAUL CONNETT

(The following comments from Dr. Paul Connett were included as part of Ms. Swearingen's submittal.)

16C.1) Dr. Connett comments:

- Serious omissions in data. There are glaring omissions and use of poor data in the general health risk assessment:
- Poor analysis of the fly ash. Accentuating the poor science involved in this risk assessment and the poor review of it by EPA scientists was the failure to look for dioxins and furans in the fly ash. When considering the risks posed by fugitive fly ash, EPA used ash analysis performed by WTI, who did not examine the ash for dioxins or furans, even though they knew, or should have known, that if the air pollution control equipment was doing its job, the dioxins and furans had to be in the fly ash! The carbon injection system, added after the first trial burn in order to reduce dioxin and furan emissions, must have resulted in the dioxins and furans being deposited on the carbon. The carbon powder is subsequently captured with the fly ash in the electrostatic precipitator. Why did they not look for dioxins and furans? Why did none of EPA's scientists spot the absence of these key (as far as risk is concerned) pollutants before an extensive dispersion and exposure analysis was performed on the fugitive fly ash? With all the attention to dioxin, it is such an obvious point and yet it was not picked up under review. These flawed calculations were then used in a more extensive dispersion and exposure analysis to determine the risk of exposure to the fly ash.

Response to 16C.1:

After receiving this fly ash comment from Dr. Connett in 1997, Region 5 made arrangements for samples of VRA/WTI's fly ash to be analyzed by one of its contractor laboratories to search for traces of dioxins/furans. Five separate fly ash samples were taken between January 6, 1998, and February 5, 1998. Based on the results of the analyses of these samples, the dioxins/furans from fugitive emissions of fly ash were determined to be less than 1 percent of the stack emissions of these same compounds. Therefore, the potential risks from fly ash handling are negligible compared to the potential risks from stack emissions at VRA/WTI.

Regarding Dr. Connett's statement about omissions of data and use of poor data, we have responded below to each of his specific concerns.

16C.2) Dr. Connett continues:

- Key assumptions are not conservative. When EPA considered the exposure to dioxin and other toxic emissions, they considered only nine years for an adult! They assume that on average, an adult will only spend 9 years in the area before moving. According to EPA, this assumption is based on lifetime occupancy rates for the U.S. (According to the 1996 statistics from the Department of Commerce's Bureau of Census, 83% of the U.S. population are non-movers! See chart number 33: Mobility Status of the Population, page

32.) No local data are used to back this up. No allowance is made for the fact that people might move, but to another location in the impacted area. EPA ignored the peer reviewers comments on this issue. Just this one poor "assumption" will lead to a significant underestimation of the projected incremental cancer risk for an adult.

Response to 16C.2:

Please see the response to Comment 16A.7

As also explained above, the U.S. EPA believes that the VRA/WTI multipathway risk assessment is based on conservative assumptions and is, therefore, a sound basis for risk management decisions that are protective of human health and the environment. The VRA/WTI risk assessment was designed to estimate risks to many different types of individuals that may be exposed at different locations with respect to the facility. Specific groups within the population that may be exposed to emissions from the VRA/WTI facility were identified, including residents (children and adults), school children, farmers (children and adults), and subsistence farmers (children and adults). Furthermore, risks to individuals within these groups were estimated for 12 "subareas" located around the VRA/WTI facility, which were identified to account for location with respect to the facility. The highest risks were estimated for individuals who are exposed in the subarea referred to as E1, which is a pie-shaped area that starts at the facility and extends eastward for 3 kilometers (less than 2 miles). Subarea E1 covers a total area of 2.7 square miles, much of which includes the Ohio River upstream of VRA/WTI.

In estimating exposure and risk within each of the 12 subareas surrounding the facility, a series of conservative assumptions were applied. Many of the assumptions used in the risk assessment are associated with the modeling of the fate and transport of chemicals in the environment and the estimating of human exposures to chemicals in the environment. The fate and transport models used in the risk assessment are based on fundamental scientific principles, but represent a simplification of the processes that will determine actual chemical concentration in environmental media. In the VRA/WTI risk assessment, models were selected that are more likely to overestimate, rather than underestimate, chemical concentrations in the environment given the conservative nature of the input parameters to these models.

Exposure assumptions also were selected to be conservative. As an indication of the conservative nature of the exposure assumptions used in the risk assessment, the following are examples of the assumptions that were used in estimating the risks to subsistence farmers in subarea E1, the group within the local population for which the highest risks were estimated:

- The subsistence farmer in subarea E1 was assumed to be exposed 24 hours per day, 350 days per year, for 40 years, entirely within subarea E1. In other words, all exposure to this individual was assumed to occur in a 2.7 square mile area in which the highest concentrations were estimated.*
- All of the beef, pork, poultry, eggs, and milk products consumed by this individual were assumed to be from livestock raised within subarea E1.*
- All of the fruits and vegetables consumed by this individual were assumed to have*

been grown within subarea E1.

Even with the assumptions listed above, risks to the hypothetical subsistence farmer in this subgroup did not exceed 7×10^{-6} (for all high end assumptions) for the average exposure predicted in area E1 (See Table VIII-14 on page VIII-49 of Volume V of the Risk Assessment). Estimated cancer risks for a breast-feeding infant of the hypothetical high-end subsistence farmer ranged from 2×10^{-6} to 5×10^{-6} (See Table VIII-20 on page VIII-55 of Volume V of the Risk Assessment).

In estimating exposure, these are clearly conservative assumptions about typical behavior patterns in the area surrounding the VRA/WTI facility. Similarly conservative assumptions were applied to other population groups, as well. When combined with the conservative assumptions in other portions of the assessment, the U.S. EPA believes that the estimates of exposure for the populations evaluated and the resulting estimates of risk are conservative.

16C.3) Dr. Connett continues:

- Failure to consider the most obviously potent carcinogens after dioxins and furans. When considering stack emissions, other than dioxins and furans (which are known to drive the incremental cancer risks), EPA examined several hundred compounds, but failed to consider compounds which are closely related to the chlorinated dioxins and furans, and which are just as toxic. Knowing that dioxin drove the incremental cancer risk the logical approach would be to start with the compounds that act like dioxins and/or furans. These are basic chemical oversights which smack of malfeasance. The most charitable statement about these oversights is that they were the result of incompetence; a less charitable statement is that the risk assessment was rigged from the beginning -- that EPA had set out to prove that WTI was safe instead of trying to find out if there was risk.

Response to 16C.3:

The list of chemicals of potential concern in the VRA/WTI risk assessment was compiled from a variety of sources. An initial list was developed from the analytical results of the trial burns and performance tests and a list of substances fed to the incinerator. This initial list was supplemented by chemicals recommended for inclusion in the risk assessment by the peer review panel and constituents included in U.S. EPA guidance on conducting risk assessments of hazardous waste combustors. It is possible that various halogenated dioxins and furans (other than chlorinated dioxins and furans) and other unidentified chemicals that were not included in the list of substances may also be present in stack gases. No information was available, however, on the potential emissions of these types of compounds from VRA/WTI.

Considerable toxicity information is available for most of the chemicals of concern, and the U.S. EPA uses conservative approaches in applying this information in a risk assessment. The VRA/WTI risk assessment includes an evaluation of the uncertainty associated with poorly characterized constituents or compounds with little or no toxicity data. In the uncertainty analysis, the emission rate for PCDD/PCDF was multiplied by a factor of 1.5 to conservatively account for brominated and other halogenated dioxin-like compounds. This factor is believed to be conservative because brominated waste is much less prevalent than chlorinated waste at VRA/WTI. While the factor of 1.5 is based primarily

on professional judgment, rather than any specific data, it is believed to be conservative based on available information regarding the amount of chlorine, bromine, and other halogens in waste received at VRA/WTI and the relative toxicities of halogenated dioxin-like compounds. The risks associated with other organic constituents in the stack emissions were multiplied by a factor of 2.5 to conservatively account for a potential uncharacterized fraction of incinerator stack emissions. Thus, the U.S. EPA has taken a number of steps in the VRA/WTI risk assessment to avoid underestimating the potential toxicity of facility emissions, in light of the uncertainties that exist for some chemicals.

U.S. EPA disagrees with Dr. Connett's views regarding the competence and motivations of individuals performing the risk assessment. These views are not representative of the views of other scientific authorities who have reviewed the risk assessment. Please see the response to Comment 16A.21.

16C.4) Dr. Connett continues:

- Risks are segmented, not summed. When calculating risks, EPA segments off different parts of the population. For example, they separate the risks to breast fed infants from the risk to children, adults, farmers, subsistence farmers, hunters and fishermen. They do not appear to present the total lifetime risks for anyone! Thus, what the lay reader might assume to be the incremental cancer risk the WTI facility poses to an adult is actually the risk to an adult living in the area (as an adult) for only nine years --- they were conceived elsewhere, breast-fed elsewhere, went to school elsewhere, is not a fisherman nor a hunter, and is going to move out of the area after nine years of exposure!!! Moreover, this risk is calculated assuming that he or she is a healthy person, with no other exposure to cancer causing chemicals!!!

Response to 16C.4:

The risk assessment followed the general guidelines contained in the U.S. EPA's July 1998 Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities²⁴ for estimating the risks to specific population subgroups which may, in fact, have significantly different intake and behavior patterns. Also, reporting the risks for different population subgroups was consistent with the peer reviewers' recommendations and the public's concerns that risks to specific population subgroups should be addressed. The fact that the risk assessment examined the incremental risks from VRA/WTI emissions is consistent with the purpose for which U.S. EPA conducts risk assessments as explained in more detail in other responses.

Please see the response to Comment 16A.7 on the issue of nine-year exposure.

16C.5) Dr. Connett continues:

- EPA ignored the current health status of the population being impacted by WTI's toxic emissions, even though the peer reviewers recommended that EPA consider this important information. EPA failed to investigate the current health status of the community. It is well

²⁴Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities; Peer Review Draft; EPA530-D-98-001A July 1998, available at <http://www.epa.gov/epaoswer/hazwaste/combust/risk.htm>.

known from classic pollution studies that many people who died in pollution incidents were those who were already ill and were pushed over the edge by added insult. EPA did not bother to acknowledge that any projected risks from both accidents and toxic emissions would be impacting highly sensitive populations and subsets of those populations who already have a high rate of respiratory problems, heart disease and cancer, especially in East Liverpool, due to the very high background levels of pollution in the Ohio Valley. No analysis of this site-specific sensitivity was attempted even though the peer review panel specifically emphasized the importance of considering the facility's emissions against existing exposures. Is it not reasonable to assume that being exposed to even small levels of carcinogens could accelerate the promotion of cancer in individuals who have already been initiated by other chemicals? Dioxin, for example, is known to be a very potent promoter of cancer. It is indefensible to do a risk assessment (especially in East Liverpool) without considering the baseline health of the community which will be impacted by the facility in question. This is very unprofessional and very unscientific. Both the peer reviewers and the citizens repeatedly recommended this important step to the EPA.

Response to 16C.5:

Risk assessment methods applied by regulatory agencies, and applied in the VRA/WTI risk assessment, do not, in fact, assume that the toxicity of a chemical is the same for all population groups. Risk assessments account for the potential sensitivity of children, elderly, and those with health problems. A brief discussion of the methodology by which regulatory agencies evaluate chemical toxicity and the procedure used to account for differences in sensitivity to chemical exposure follows.

Regulatory risk assessment methods are based on the well-established principle that exposure to chemical agents must exceed some threshold before effects are produced. [In evaluating the likelihood of developing cancer, the threshold principle is not generally applied; instead, an alternative "no threshold" approach that incorporates a series of health-protective assumptions is used.] In evaluating the non-cancer effects of chemicals, an objective of risk assessors is to identify the threshold of toxic exposure that can be said to apply to a large and diverse human population. This threshold is initially approximated as the highest exposure level producing no adverse effects in the most sensitive population studied (referred to as the no-observed-adverse-effect level, or NOAEL). In some instances, this NOAEL is estimated from the results of an epidemiological investigation. In such a study, the possible correlation between exposure and adverse health effects is studied in a group selected because of known past (i.e., historical) exposure events (usually an occupational exposure). More often, however, a NOAEL is measured in experimental animals.

The applicability of the NOAEL from a study population to the general population will vary from chemical to chemical. NOAELs derived from well-conducted epidemiological studies are generally considered to be more reliable estimates of the threshold dose for humans than are NOAELs from animal studies; however, some uncertainty is always present in extrapolating a NOAEL from the study population to a NOAEL for the general population. Regulatory agencies and other public health organizations generally account for this uncertainty by applying one or more uncertainty (or safety) factors to the NOAEL, with the number and magnitude of the uncertainty factors a reflection of the quality and completeness of the toxicity data base from which the NOAEL was derived. The U.S. EPA refers to the value developed by applying the safety factors to the NOAEL as the

Reference Dose (RfD).

Regulatory agencies traditionally use an uncertainty factor of 10 to account for the fact that the general population, which includes children, the elderly, and individuals with compromised health, is highly diverse, and that the population from which the NOAEL is derived may not fully reflect that diversity. Additional 10-fold uncertainty factors are typically added where the NOAEL is derived from animal data and where limitations in the data base exist. For example, if the NOAEL comes from a well-conducted study of animals exposed throughout their lifetime, and the toxicity data base for the chemical as a whole is extensive, a 100-fold uncertainty factor (10 x 10) is typically applied to account for both the presence of potentially sensitive individuals in the general population and extrapolation from animals to humans. Using this technique, conservative values are developed in a way that addresses the kind of sensitive individuals that Dr. Connett mentions in his comment.

This uncertainty factor approach has been adopted by all major regulatory agencies and public health bodies in the U.S., as well as by international public health bodies. It is a cornerstone of public health risk assessment not only for environmental contaminants, but for chemicals in foods, consumer products, and the workplace.

In evaluating potential cancer risk in a risk assessment, the U.S. EPA generally relies on a measure of carcinogenic potency known as the slope factor (SF). Chemicals believed to have greater carcinogenic potency have higher SF values. In developing SF values, it is conservatively assumed that any level of exposure to a chemical carcinogen has some potential to result in cancer, i.e., there is no finite threshold exposure below which the cancer risk is zero. As a conservative measure, the SF value is calculated as the upper 95-percent confidence limit on the slope of the dose-response curve in the low-dose, low-risk region. The U.S. EPA in its 1989 Risk Assessment Guidance for Superfund states that by using potency estimates derived in this manner, "EPA is reasonably confident that the "true risk" will not exceed the risk estimate derived through use of this model and is likely to be less than that predicted." Therefore, although the U.S. EPA does not specifically incorporate a factor for individuals with an increased "tendency to cancer," risk assessment methods generate estimates of risk for the general population that are almost certainly overestimates of actual risk. This conservative (health-protective) approach is intended, in part, to account for the diversity of chemical sensitivity in the general population.

16C.6) Dr. Connett continues:

Considering just a few of these underestimated factors, the incremental cancer risk for a resident in East Liverpool could be several hundred times greater than estimated in this report! There are many unknowns about computing the health risks posed by incinerator emissions. Risk assessors attempt to partially address these unknowns by being very conservative about their assumptions so that they have a margin of safety in what they have predicted. In this assessment the authors frequently chose non-conservative assumptions. If we consider just a few of the non-conservative assumptions used by EPA, we estimate, in a ball-park fashion, that the actual lifetime incremental cancer risk could be two order of magnitude (or several hundred times higher) than they report for an adult resident and for a subsistence farmer!

- All of these points were clearly underscored when not one of EPA's experts were able to present any satisfactory arguments on these fronts.
- Possible synergistic effects between chemicals are ignored. The authors of the risk assessment tell us on page VIII-2, Volume V; that "A quantitative evaluation of synergistic and antagonistic effects is not performed due to limitations in available data and methodologies for characterizing or quantifying these effects at exposure levels estimated in the vicinity of WTI." Thus, EPA simply ignores the possible synergistic effects of chemicals reacting in combination.
- The endocrine disrupting effects of chemicals are given a zero risk because EPA does not know how to handle this "hot potato." On page III-17, Volume V, the risk assessors tell us "given the current limited state-of-the-art science, it is premature to attempt to evaluate the potential risks from human exposure to chemicals from the standpoint of endocrine disruption."

Response to 16C.6:

We disagree with Dr. Connett's assertion that the VRA/WTI risk assessment is not conservative. Please see the responses to Comments 16C.2 through 16C.5 above, plus the discussion below, for an explanation of some of the methods the U.S. EPA used in the VRA/WTI risk assessment to ensure it was conservative.

Dr. Connett raises in this comment the possibility of synergistic effects of chemical emissions. The U.S. EPA typically assumes there is no significant interaction between chemicals (i.e., either synergistic or antagonistic) when the chemical exposures are extremely small. However, the U.S. EPA does add the toxic effects of emissions as a surrogate for potential chemical interactions, even though it is understood that toxic effects are, in reality, only additive if and when the chemicals affect the same target organ or act through the same mechanism. In the case of the VRA/WTI risk assessment, the chemical exposures were predicted to be extremely small, so adding the toxic effects as a surrogate for potential chemical interactions was deemed appropriate.

The U.S. EPA's acceptance of the concept of additivity for risk characterization of chemical mixtures at low dose exposure levels is consistent with other scientific conclusions, and we refer the reader to reports published by the Commission on Life Sciences of The National Academy of Science/National Research Council (NRC); and the Presidential/Congressional Commission on Risk Assessment and Risk Management.

The NRC is Report is titled: "Complex Mixtures: Methods for In Vivo Toxicity Testing" (1988). The Executive Summary includes the following statement:

On the basis of theoretical considerations and its examination of some epidemiologic studies, the committee noted that effects of exposures to [chemical] agents with low response rates usually appear to be additive. The only examples of interaction that were considered greater than additive occurred in humans exposed to agents, such as cigarette smoke, that alone produced a high incidence of effects. Current quantitative models used to assess cancer risks support these results.

The Presidential/Congressional Commission Report is titled: "Risk Assessment and Risk Management in Regulatory Decision-Making" (1997). In the Section on Evaluating Chemical Mixtures, the Report makes the following statement:

Most of the information that is available on interactions among chemicals comes from human occupational studies and from rodent bioassays. Those studies generally evaluate doses that are much higher than the low, environmental doses commonly encountered. Interactive effects (either synergistic or antagonistic) depend heavily on dose; therefore, characterizing interactions that occur at one set of doses (such as those used in a rodent bioassay) is likely to provide very little information about interactions at very different doses (such as those generally encountered in the environment). "High" doses for combined effects are defined as those at which statistically significant increases in detrimental outcomes are observed in either laboratory or occupational studies. For the most part, exposure to chemical mixtures in the environment occurs at "low" doses - typically, one thousandth (or less) of the doses at which toxicity is observable in rodent bioassays or in epidemiologic studies of highly exposed workers. The ratio of exposures observed to cause adverse effects and actual human exposures is called the margin of exposure (EPA 1996b) (see Need for a Common Metric on page 43).

The combined effects of exposure to chemicals in a mixture are determined by how individual components of the mixture affect the biological processes involved in toxicity. Components of a mixture can affect biological processes in many ways. For example, anything that affects the absorption, distribution, metabolism, or elimination of a chemical will affect the amount of that chemical that is available to react with DNA or other cellular targets. Because interactions leading to synergism or antagonism are the result of reactions of many molecules at many cellular sites, a mathematical dose-response model of a synergistic or antagonistic response that depends on such mechanisms is most likely nonlinear at low doses. Such logic strongly suggests that any disease process that depends on such interactions is only marginally important at low exposure levels. Only at high doses of one or more mixture components - such as cigarette smoke, alcohol, and some substances in occupational exposures - is the combined effect likely to be detectably greater than the sum of the individual effects. For example, occupational exposure to asbestos is associated with a mortality ratio for lung cancer of up to 5 (that is, in comparison to persons not occupationally exposed to asbestos) and smoking with a mortality ratio for lung cancer of about 10; but asbestos workers who smoke have a mortality ratio for lung cancer of 50, not 15. Similarly, the risk of liver cancer associated with aflatoxin is increased markedly by hepatitis B virus infection.

The National Academy of Sciences report Complex Mixtures (NRC 1988) also concluded that effects of exposures to agents with low response rates usually appear to be additive. The experimental evidence that can be used to infer effects at low doses appears to support the assumption that low dose additivity does not underestimate, and in most cases probably overestimates, risk (see, for example, Acadia 1988).

When the individual components of a chemical mixture exhibit different kinds of

toxicity or have different biological mechanisms of toxicity, they do not interact - they act independently at low doses. In that case, the dose-response relationships for each chemical should be considered independently. For example, if the chemicals of concern at a Superfund site are copper, a gastrointestinal toxicant; lead, a developmental toxicant; and heptachlor, a neurologic toxicant, their toxicity should be evaluated independently and not combined into a single "noncancer" risk estimate. Experiments have shown that when groups of unrelated chemicals with unrelated targets of toxicity were administered to rodents simultaneously at doses equal to their separate NOAELs, no cumulative effects were observed; each chemical acted independently (Joker et al. 1990, Groton et al. 1994). The same is true of groups of chemicals with the same target but different mechanisms of action (Joker et al. 1993); studies in which similar chemicals with similar mechanisms and targets were administered simultaneously indicate that antagonism, is the usual outcome (Falk and Captain 1964, Schmähl et al. 1977).

On the issue Dr. Connett raises about potential endocrine disruption effects, please see our discussion in the responses to comments 16B.14.

16C.7) Dr. Connett continues:

- The accident analysis -- the most critical part of the risk assessment -- confirms that the Von Roll/WTI incinerator is too close to homes and the 400 student elementary school. In their screening level evaluation of accident risk, EPA determined that at least 27 accident scenarios produced health- and/or life-threatening results for the children at the elementary school. Five of these scenarios would produce toxic chemical concentrations ten times above levels which would be health- or life-threatening to healthy workers, and 100 times health- or life-threatening to children! Because EPA's accident analysis showed the risk of serious harm or even death in various accident scenarios, the rest of the risk assessment is moot.

Even though the accident analysis --- the most critical part of the risk assessment --- is fundamentally flawed, it confirms that the Von Roll/WTI incinerator is too close to homes and the elementary school. In their screening level evaluation of risk from accidents at the facility, EPA examined 84 accident scenarios for impact on the school children 400 yards away. These were comprised of on-sites spills, fires, and mixing accidents and off-site fires and spills. These five basic types of accidents were increased to 84 scenarios by considering other variables, i.e., large volume versus typical volume incidents; worst case chemicals versus typical chemicals; accidents occurring under three different meteorological conditions; and finally, comparing unmitigated accidents versus those mitigated after 10 minutes. After determining the concentration of chemical in question at the distance of the school, the level of danger for each accident scenario was quantified. EPA calculated the danger level for only 64 out of the 84 scenarios. Of the 64 that were calculated, 29 accident scenarios projected chemical concentrations at the school above levels which could be health- or even life-threatening to the children. Of these, 12 scenarios could produce chemical levels which would be life threatening to healthy workers and over 10 times the level of concern for children, and 5 scenarios would produce levels ten times more life threatening for healthy workers and 100 times health- or life-threatening to children!

Instead of acknowledging that the Von Roll/WTI incinerator should not be allowed to operate in such a sensitive location, the EPA used a very superficial analysis to discount the seriousness of their own calculations. These justifications are the least well defended in the whole risk assessment. A mere three pages out of 3,800 were devoted to arguments used to establish that these events were unlikely to cause a serious threat to the children at the school 400 yards away. Considering the very serious nature of the results of these accident scenarios, it is unprofessional to the point of recklessness not to consider in painstaking detail every piece of data and every calculation concerning accidents which could damage, maim or kill some of the children at East Elementary School. The level of detail in the risk analysis is least comprehensive when it will uncover information threatening to Von Roll/WTI's future.

Response to 16C.7:

In assessing the results of the Accident Analysis, it was just as important to consider the likelihood that an accident scenario would occur, as it was to consider its potential consequences. However, the techniques used in estimating likelihood of the accidents are much more qualitative, generalized and judgement-based than the highly precise techniques available for calculating downwind impacts. Because of this, the report might appear as though the impacts were calculated in excruciating detail while the likelihoods were not fully explored. More detailed techniques for estimating likelihoods were considered, but the U.S. EPA workgroup didn't believe that the information such models might generate would be any more representative or useful for regulation than the approach we used.

The Accident Analysis concluded that the scenarios with the most significant potential consequences (such as those for which Level of Concern ("LOC") values might be exceeded by 10 or even 100 times) are unlikely or very unlikely to occur. In making risk management decisions based on the Accident Analysis, the risk managers must consider both consequence and probability of occurrence in determining overall risk.

In addition, as stated on page IV-8 of Volume VIII of the risk assessment:

"We urge caution in the use of such maximum concentrations because the original analysis was conducted in a very conservative way, designed to err on the high side. Because the intent of the original analysis was only to define vulnerability zones off site, erring on the high side (that is, erring on the side of safety) was deemed to be entirely appropriate when defining a vulnerability zone. But it must be remembered that such overestimated values are high-end predictions, and not accurate estimates. An example of the conservative nature of the original estimates is the plume modeling generally used in this portion of the accident analysis. The modeling assumes dense gases moving in flat terrain. Because the ground level of the school is approximately 50 feet above the ground level of the plant, it is quite likely that in reality the terrain would severely reduce the ability of dense gases from actually getting to the school."

Dr. Connëtt states in his comment that the U.S. EPA only calculated the relative hazard

ratio ("RHR") results for 64 of the 84 hypothetical scenarios impacting the school, creating the impression that 20 scenarios were not addressed. This is not correct, as discussed below:

Page IV-28 of Volume VII of the risk Assessment states:

"Of the 84 individual emission scenarios evaluated, RHR values are below 1 for 44 scenarios, between 1 and 10 for sixteen scenarios, between 10 and 100 for seven scenarios, and are equal to or greater than 100 for five scenarios. RHR values were not estimated for 12 scenarios because the accidental fire events could not be modeled under calm/inversion conditions using ISC-COMPDEP (see Chapter V, Section A). Fire events modeled under calm/inversion conditions using an alternative model (CALPUFF) are discussed in Chapter VIII."

Therefore, 12 scenarios were modeled using an alternative model, addressed elsewhere in the report. In addition, the remaining eight scenarios that Dr. Connett mentions as not being calculated are addressed in footnote 4 of Table VI-24 of Volume VII of the risk assessment, which states that these scenarios were not calculated because the upper bound concentration was determined to be negligible at the distance of the school. Therefore, all 84 scenarios were addressed.

Finally, it is not unexpected that certain hypothetical accident scenarios at the VRA/WTI facility result in predicted air concentrations exceeding LOC values. Several of the accident scenarios evaluated in the VRA/WTI Accident Analysis are clearly "worst case"; for example, assuming very large spills of particularly hazardous liquids during times when atmospheric dispersion is reduced by calm winds and thermal inversions. For each of the scenarios, the U.S. EPA has described potential consequences alongside estimated probabilities of occurrence, so that decision makers can consider both in evaluating the safety of the facility.

Under the current regulatory framework, accident analyses are not generally used to make decisions about whether an industrial plant should operate, but rather, are used to consider issues such as whether certain operations or categories of operations might warrant additional restrictions. If, for example, it were apparent that truck spills at a plant demonstrate a significant potential for unacceptable consequences, the decision makers could then consider whether those truck operations need to be prohibited, restricted, or redesigned in some way to reduce the combined probability and consequence of the event to reasonable levels. The U.S. EPA has no national guidelines or recommendations about acceptable severity/likelihood risk management targets for accident analyses.

16C.8) Dr. Connett continues:

- The authors have told us, but in such a way that the average reader might not have realized it, that a life threatening accident is likely to occur within the lifetime of this plant's operation.
- A "moderate" accident becomes one which, within 656 feet of the accident, certain sensitive citizens and children could be confronted with a life-threatening situation. This could happen, according to the authors, on average between once every ten years and once every 100 years, i.e., within the operating life of the WTI facility.

Response to 16C.8:

While it is not clear whether or not such an event would be "life-threatening", there indeed were two postulated categories of events which had potentially moderate impacts and that had a likelihood of between one in ten years and one in 100 years. These were (1) a spill of approximately 100 gallons of a waste represented by formaldehyde (i.e., both very volatile and very toxic), and (2) mixing of 200 gallons of incompatible wastes which causes the liberation of a gas such as hydrogen chloride.

For the U.S. EPA's accident analysis, predicted off-site concentrations associated with selected accident scenarios relevant to the VRA/WTI facility were compared to acute toxicity criteria known as "Immediately Dangerous to Life or Health" (IDLH) values. IDLH values are developed by the National Institute for Occupational Safety and Health (NIOSH), and represent the maximum concentration of a chemical in air from which an individual could escape within 30 minutes without experiencing any escape-impairing or irreversible health effects. However, the IDLH values published by NIOSH were originally developed to be protective for healthy adult male workers, but have not been adjusted to account for the heterogeneous population (e.g., children, elderly) who might be exposed to chemicals in an event with off-site consequences. Because some individuals in the general population might require a longer escape time and/or be more sensitive to the chemical exposure compared to healthy adult male workers, the U.S. EPA also compared predicted off-site concentrations to "Level of Concern" (LOC) values, which are generally more conservative than the IDLH values. As referenced in Volume VII of the U.S. EPA risk assessment (see page I-5), LOC values have been peer reviewed by the U.S. EPA's Science Advisory Board, and they are intended to be protective of the general public for exposure periods of up to an hour. The LOC value for a given chemical is usually, but not always, equal to the IDLH divided by a factor of ten.

In addition to IDLH and LOC values, the American Industrial Hygiene Association (AIHA) has developed Emergency Response Planning Guideline (ERPG) values for examining the potential consequences of acute exposures. According to AIHA, the ERPG values are intended to provide estimates of concentration ranges above which one could reasonably anticipate observing certain adverse effects. Three tiers of ERPG values are listed by AIHA, based on the consequence of exposure to a specific substance (AIHA 1994).

-The ERPG-1 value is the maximum airborne concentration below which it is believed nearly all individuals could be exposed for up to 1 hour without experiencing other than mild transient adverse health effects or perceiving a clearly defined objectionable odor.

-The ERPG-2 value is the maximum airborne concentration below which it is believed nearly all individuals could be exposed for up to 1 hour without experiencing or developing irreversible or other serious health effects or symptoms that could impair their abilities to take protective action.

-The ERPG-3 value is the maximum airborne concentration below which it is believed nearly all individuals could be exposed for up to 1 hour without experiencing or developing life-threatening health effects.

For substances with both an ERPG-2 value and an LOC value, the LOC value is similar to and in some cases identical to the ERPG-2 value. A comparison of IDLH, LOC, and ERPG values for the specific constituents evaluated in the Accident Analysis are presented in Section D of Chapter III of Volume VII of the risk assessment.

In interpreting the potential impacts of such concentration levels, we believe it is unlikely that most people potentially in the path of a plume of contamination would remain outdoors or be left outdoors in the plume for anywhere near one hour, thus reducing the overall impact. For this reason, the U.S. EPA does not agree with Dr. Connett that these hypothetical impacts should be considered life-threatening. These events/frequencies were not judged to be atypical of many industries. No additional permit restrictions were deemed necessary at this time. However, even though the U.S. EPA does not currently believe that these findings rise to the level of requiring additional permit restrictions, this conclusion could be re-evaluated at any time depending on actual recorded releases, violations, or other events observed or recorded at VRA/WTI.

16C.9) Dr. Connett continues:

● The statement in the Executive Summary of the risk assessment that "for most accident event scenarios, estimated worst-case concentrations at the school are below LOC [Level of Concern] values" is very misleading. The use of the word "most" is technically correct, but the accident screening analysis actually showed that of the 84 accident scenarios, a total of 29 would exceed the level of concern; 7 scenarios would exceed it by ten times, and 5 scenarios would exceed it by 100 times! The seriousness of this analysis is not conveyed in the executive summary.

Response to 16C.9:

The sentence in Volume I (page VII-11, first full paragraph) following the one Dr. Connett repeats is: "Those accident scenarios for which LOC values might be exceeded at the distance to the school are expected to be very unlikely to occur during the life of the plant." We believe this puts the risk of these 29 accident scenarios into the appropriate perspective for the purpose of risk management decisions.

16C.10) Dr. Connett continues:

● The risk assessment did not consider what impacts these accidents (modeled for the school) would have on people and children who live even closer to the incinerator than the 1100 foot distance to the school, e.g., 320 feet away.

Response to 16C.10:

The descriptors in the risk assessment such as minor and moderate were intended to provide a way to address the accident risks within the community. The distance terms in this chart are non-directional, allowing dwellings to be considered simply by their distance from the plant.

TABLE VI-2 in Volume VII provides the criteria used in ranking the severity of consequence based on "Level of Concern" values, as follows:

- *Minor: No exceedance of an LOC value in inhabited off-site areas; and negligible potential for off-site fatalities or serious injuries due to heat effects from a fire.*
- *Moderate: Exceedance of LOC values in inhabited off-site areas over distances of 200 m or less; injuries due to heat effects limited to a distance of 200 m into inhabited areas.*
- *Major: Exceedance of LOC values in inhabited off-site areas over distances between 200 m to 2000 m; injuries due to heat effects limited to a distance of 2000 m into inhabited areas.*

The U.S. EPA developed these categories to approximate the guidelines published by the Federal Emergency Management Agency, as described on page I-10 of Volume VII of the risk assessment. Please see the discussion in response to 16C.8.

16C.11) Dr. Connett continues:

● We are informed that based upon a review of the history of accidents reported at U.S. incineration facilities, none of the reported incidents "resulted in a fatality or serious injury in off-site communities, although on-site worker injuries and fatalities have occurred." While this is repeated 10 times in the report, there is never any comparison between the location of the facilities listed and the unique location of WTI. To the best of our knowledge, none of the facilities listed are 320 feet from homes and 1100 feet from an elementary school. The absence of a serious comparison of facility locations with that of the sensitive location of WTI, using maps, aerial photos, etc., indicates either incompetence or malfeasance.

Response to 16C.11:

Dr. Connett is correct that few hazardous waste combustion facilities have been built in locations like that of VRA/WTI. The specific wording he cites from the accident analysis was included to suggest that large-scale releases have not been observed at the other facilities. We now see Dr. Connett's point that the actual wording could have been more precise.

16C.12) Dr. Connett continues:

● As far as a comparison with the Von Roll incinerator in Germany, EPA claims that the information on accidents at Biebesheim arrived too late for more than a cursory review. This poor effort to investigate the accident history of WTI's sister plant reflects a lack of seriousness in their overall handling of the accident analysis. Citizens have been asking EPA to look at the accident history of Biebesheim since 1991, with their latest request in

January 1996, when the peer reviewers made the same request. EPA did not try to obtain information on accidents at Biebesheim until November 1996 --- 10 months later --- then in May 1997, they say that they didn't have enough time!

Response to 16C.12:

Please see previous Response to 16C.1 to comment 16A.6.

16C.13) Dr. Connett continues:

- Despite the public relations twist which was put on the accident analysis in the executive summary, and despite the limitations of the study, enough has been revealed to demonstrate that the WTI incinerator poses serious dangers to the local community and the children of East Elementary school. The U.S. EPA failed to prove that the incinerator is safe to operate at this extremely sensitive location. The rest of the risk assessment is moot.

Response to 16C.13:

The accident analysis was designed to study the likelihood and potential magnitude of off-site consequences of general categories of accidents, to help identify where additional preventive measures and protective measures might be warranted, and to help put potential risks from routine emissions into perspective with potential risks from accidents. In addition, in reviewing the results of the accident analysis, the U.S. EPA did not conclude that the risks were unusual for industrial facilities in the United States.

16C.14) Dr. Connett continues:

- Questions for EPA scientists who worked on the WTI risk assessment:
 - Can you tell _____, who lives with her three children 800 feet from the incinerator, that the operation of WTI did not cause the endocrine, immune and reproductive health problems her daughters have experienced since 1996?

Response to 16C.14:

Nothing in the Risk Assessment suggests that VRA/WTI's emissions caused these problems. Nevertheless, we are referring this report to the ATSDR for evaluation.

16C.15) Dr. Connett continues:

- If there is a catastrophic accident at the facility, can the EPA be held accountable? If there should be a catastrophic accident, will the EPA accept responsibility for not enforcing their own rules and regulations?

Response to 16C.15:

Dr. Connett's comment failed to specify the regulation or statutory provision he believes the U.S. EPA has not enforced. We believe the U.S. EPA's RCRA permit satisfied the requirements of RCRA and the RCRA regulations. It is Von Roll's responsibility to operate in compliance with the currently applicable RCRA permit.

16C.16) Dr. Connett continues:

- The risk assessment did not take into consideration "transient puffs". Why not?

Response to 16C.16:

Transient puffs were addressed in Volume III of the Risk Assessment document, Appendix III-1, pages V-7 through V-13 (pages 184 through 190 in the Adobe version).

16C.17) Dr. Connett continues:

- Even though Von Roll/WTI had requested approval to handle lab packs on at least three earlier occasions, approval was not granted by the EPA until just AFTER the risk assessment was released. Why did the EPA wait until AFTER the risk assessment was complete to approve the handling of lab packs? (So that the handling of lab packs --- which have caused problems at other incinerators, including an explosion that closed the Chicago incinerator --- would not have to be considered in the risk assessment? The risk assessment did not take into consideration the handling of lab packs at WTI. Why not? If a credible risk assessment is performed, the handling of lab packs must be considered.

Response to 16C.17:

The U.S. EPA did not approve Von Roll to receive labpacks until April 8, 1999, roughly two years after the risk assessment was finalized. The Permittee had been pursuing authorization for labpacks since 1993, but it was not until 1999 that the U.S. EPA and Ohio EPA were both satisfied that they had jointly developed conditions which could restrict labpack operations in such a way that the lab packs would not present an unusual hazard. Attachment XIV to the U.S. EPA RCRA permit, added April 8, 1999, contains eight pages of restrictions which apply specifically to labpack operations at VRA/WTI. These conditions have been incorporated into Ohio EPA's renewal RCRA permit.

16C.18) Dr. Connett continues:

● In 1994, EPA built a scale model of WTI to conduct modeling in a wind tunnel. From 1994 through 1996, citizens repeatedly asked EPA to use the wind-tunnel model of WTI to analyze for a ground level release of a poisonous gas such as hydrogen cyanide, phosgene, methyl isocyanate or a combination of substances to determine the impact on the children at the school or in their homes. Why did EPA ignore our requests and dismantled the wind-tunnel model? Why would they go to the trouble and expense to build a wind tunnel model and then not conduct such an important study. All they would have needed to do was rotate the model to conduct the simulation. (We believe no analysis was done because EPA already knew the outcome. During site preparation in 1990, workers struck a gas main. Gas vapors engulfed and filled the elementary school 400 yards away causing hundreds of frightened school children -- many vomiting and complaining of headache and nausea -- to be evacuated from the school.)

Response to 16C.18:

Wind tunnel analysis is generally called for only in situations where existing computer modeling is thought to incompletely address certain important aspects of a site. This was not the case for modeling the accidental releases. The U.S. EPA has a number of recommended computer models available for assessing ground level impacts of accidental releases.

In certain limited cases, computer models may not accurately assess the way pollutants move over certain terrain, and it was this particular situation at the VRA/WTI site where the experts of the scientific peer panel recommended further study via a wind tunnel. In response to the concerns of the independent experts, the U.S. EPA evaluated two specific wind directions, over a range of wind speeds, using the wind tunnel.²⁵

Although the scientific Peer Review Panel recommended wind tunnel analysis to supplement the computer modeling of routine emissions, they did not suggest that any wind tunnel analysis was necessary with respect to the accident analysis.

16C.19) Dr. Connett continues:

● Why was Richard Guimond's January 22, 1993, memo, outlining a strategy to avoid acknowledging the risk from dioxin at WTI, "confidential"? Why did the EPA attempt to suppress the memo during the federal court challenge against WTI? Who wanted the memo to be kept a secret?

Response to 16C.19:

The January 22, 1993, memo does not outline such a strategy. The memo (1) calls attention to the need for a rigorous examination of the risks associated with indirect routes of exposure, (2) raises concern over the greater degree of uncertainty in conducting these indirect risk assessments and (3) raises concern that because the indirect exposure calculations are sensitive to conservative exposure-related assumptions "...risk estimates can be unrealistically high". However, the memo also states that "...the risks to the public during the [VRA/WTI] trial burn period would be within what has been considered acceptable."

The U.S. EPA's risk assessment responded to this memo by incorporating a rigorous examination of the risks associated with indirect routes of exposure in the Phase II risk assessment. In evaluating these exposures, the risk assessment did not uncover risks that exceeded the risk management benchmarks.

²⁵The wind tunnel study was designed to quantify potential impacts due to windflow perpendicular to the valley. Such windflow, although rare, should result in the maximum impact of "terrain-induced downwash" in the East Liverpool surroundings. In our study, we looked at a range of wind speeds which represented the windflow perpendicular to the maximum terrain heights in our study. Many different flow patterns can occur when air flows over topographic obstacles. It was found that, at various wind speeds, "decoupling" of winds can occur, resulting in the development of a pronounced down-valley flow. This phenomenon, called channeling, has been well documented as occurring in valley situations, and was observed in the wind tunnel study.

Please note that at the end of the Swearingen/Connett comments on risk assessment in Ms. Swearingen's May 9, 2003, submittal, Ms. Swearingen has appended what appears to be an outline of her entire submittal, including not only her comments about risk assessment, but also containing comments not specifically related to risk assessment. In some cases, the elements of that outline were raised elsewhere in the body of her submittal, and the Agencies have responded to those comments in the appropriate section of this response document. We have not in this section responded to comments that do not specifically relate to risk assessment.

16D) COMMENTS FROM GREENPEACE

(Document dated and submitted electronically May 11, 2003)

16D.1) Greenpeace Comment:

EPA's response to this comment ["The EPA should employ the "AMESA" method of continuous slip-stream sampling"], while interesting, does not fully or accurately reflect the state of knowledge, applicability and availability of the AMESA system. Indeed, it seems in some instances to be disingenuous in its assessment of the AMESA system.

One of the more important earlier studies of the AMESA system that apparently was not discovered by EPA is that by De Fre and Wevers (1998), in which these scientists found that, in comparison to the AMESA system, the standard 6-8 hour sampling time "underestimated the average [dioxin] emission by a factor 30 to 50.

Response to 16D.1:

Region 5 obtained assistance and input from the U.S. EPA's Office of Air Quality Planning and Standards on the AMESA® questions. As reported in a U.S. EPA memorandum titled the "International Trip Report Memorandum" dated December 03, 2002, the U.S. EPA also found that manual stack sampling tended to underestimate average dioxin emissions when compared to continuous methods like the AMESA® system, but to a much smaller degree than stated by Greenpeace. The U.S. EPA memo reported that during a fact-finding visit to the Brussels, Belgium "SIOMAB" Municipal Incinerator, the AMESA® monthly data, as compared with manual dioxin measurements were fifteen to twenty percent higher. The memo states that the difference in average values is believed to be the result of either (1) furnace upsets, which could be expected to preferentially increase measured emissions using continuous methods and/or (2) the fact that some isomer non detect (ND) values are often encountered with the manual train sampling and analysis used in the United States. The ND values are usually counted as zero. However, because the AMESA® system collects a much larger sample (approximately 280 cubic meters of sample during a two-week period, while the manual testing only collects approximately 3.5 cubic meters), congeners which are not detectable in the manual method can become detectable with the AMESA® sample and add to the overall analytical result.

U.S. EPA Region 5 believes it is important to emphasize that while analytical non-detects for the various congeners of dioxin/furan can be considered as zero for regulatory compliance purposes, the VRA/WTI risk assessment did not use this same assumption.

In order to ensure that the assumed dioxin/furan emissions used in the risk assessment were not biased low, the U.S. EPA evaluated the impact of several different assumptions regarding "non-detect" congeners, including the assumption that non-detects were equal to ½ the detection limit and the assumption that non-detects were equal to the detection limit. The VRA/WTI risk assessment used the "½ detection limit" assumption to represent average emissions and the "full detection limit" assumption to represent the high-end emissions²⁶. In making such assumptions, the dioxin/furan emissions were either less likely to be biased low or were likely to be biased high. Therefore, if the 15 to 20 % underestimation observed by OAQPS were caused by assumptions about non-detects in the manual method, the assumptions used in the risk assessment would have compensated for this.

We obtained a copy of the De Fre and Wevers article from Organohalogen Compounds which Greenpeace cites above, to determine what might be responsible for the author's observation that emissions measured by the AMESA® system were 30 to 50 times the emissions measured by manual stack sampling. We have the following comments on the article:

- 1) The section in which this data appears in the article (Page 19: Representativity of point sampling of dioxin), indicates that the testing was done on municipal waste incinerators, not hazardous waste incinerators. Municipal waste incinerators are much larger, and are generally regarded as prone to emitting higher concentrations of dioxin.
- 2) The same section of the article begins as follows:

The following illustrates that even with the recent technological improvements for dioxin abatement the standard measurement technique underestimates the long-term emissions.

Representativity of point sampling of dioxin emissions

It is known that the start-up and shut-down periods in the operation of a MWI give particular risks for high dioxin emissions. This is especially the case for plants where by-passing of filters is possible. Bypassing of fabric filters is often related to abnormal gas temperatures.....

The U.S. EPA agrees that higher dioxin emissions can be expected during start-up and shut-down of an incinerator that is burning waste, and the language cited above from DeFre and Wevers may imply that the MWI they investigated did burn waste during start-up and shut-down. This therefore could account for the large difference between the average emissions concentration measured by the AMESA® system over two weeks and the short-term emissions concentration measured by manual stack sampling over six hours. But because regulated hazardous waste incinerators in the U.S. are prohibited from (or severely restricted in) burning hazardous waste during periods of start-up, shut-down, or malfunction, it might not be valid to

²⁶See Volume III, Table III-2 on page III-17.

conclude that hazardous waste incinerators in the U.S., would demonstrate the same higher emissions when monitored with an AMESA® device.

- 3) *There are only two data points which allow comparison of the AMESA® continuous sample results to the results of the 6-hour sample. The first (sampling from January 12, 1998 to January 26, 1998) did indeed show a factor 30 to 50 difference. However, the second (sampling from March 9, 1998 to March 23, 1998) showed a difference of a factor 2.75. As discussed above, the U.S. EPA observed much lower values (in the range of 15% higher for the AMESA®) in its evaluation of a different facility.*

16D.2) Greenpeace Comment:

Subsequently, the AMESA® system has not only been validated by the German EPA (as noted by US EPA in its comments) but is now in widespread use in Europe. For example, all municipal waste incinerators in the Flanders portion of Belgium are now required to use the AMESA® method and, through such use, have demonstrated substantial reductions in dioxin releases to air. Reinmann et al. (2001) summarize as follows:

"In the last three years the continuous dioxin and furan monitoring system AMESA® came to a standard for the continuous control of the dioxin emissions in waste incinerators in Belgium. Due to these results and the operators feedback, some new features were developed and results showed that the continuous emission control of dioxins and furans is necessary. ... Actual results of the Walloon region of Belgium, where the continuous control of the dioxin emission is obliged since the 1st January of 2001 shows once again, that plants which were still controlled by short time dioxin measurements can have too high dioxin emission when they were controlled continuously."

In a still more recent report, Reinmann (2002) concluded as follows:

"The actual results of the Walloon region of Belgium show the different advantages for all, the public, the environmental and the operator. If defects in the plant happen, which lead to higher dioxin emissions, these defects are recognized earlier and help to reduce the dioxin emissions. On the other side, if the values are constantly low, the public acceptance is higher and help to increase or to keep high the capacity of the plant. More and more countries start to think about a continuous control of the dioxin emissions of the waste incinerators. Therefore in different countries verification projects were started. If such regulations will be introduced global the dioxin emissions can be reduced world-wide in a strong way."

Response to 16D.2:

At this time, the U.S. EPA generally does not interpret its regulations to explicitly authorize it to require VRA/WTI or similar facilities to install such a monitor. Once these devices become certified for use as an alternative to the established U.S. EPA test protocols and testing frequencies specified in the regulations, owners and operators of these facilities will have greater incentive to consider installing such equipment. See the response to comment 16D.3.

16D.3) Greenpeace Comment:

The AMESA system has also been used for hazardous waste incinerators. For example, four years ago, Mayer et al. (1999) described in detail the use of the AMESA system, as required by German authorities, in a study of high- and low-temperature operation of a hazardous waste incinerator. A detailed technical description of the AMESA system can be found on the website of its developer, Becker-Messtechnik. (See <http://www.becker-messtechnik.de/amesa/eng/vergleich2.htm>)

In summary, the AMESA system for the quasi-continuous monitoring of dioxin releases in incinerator stack gases is well proven and has accumulated a substantial record of successful application with solid documentation of the benefits of such quasi-continuous monitoring in comparison to the standard occasional 6-8 hour sampling period. While the development of other methods of continuous or quasi-continuous stack gas sampling and analysis is to be encouraged, there is no sound rationale for waiting for their development rather than using the AMESA system, which is already well-developed, widely used and well-proven.

Response to 16D.3:

We agree that AMESA® systems do appear promising. In addition, there is also another dioxin semi-continuous monitor available called the Dioxin Monitoring System currently being marketed in Austria. The U.S. EPA has reviewed the operations for both systems. While the U.S. EPA has some reservations regarding each, both systems incorporate good, sound sampling protocols. They both have state-of-the-art computerized electronic circuitry that can be easily maintained, adjusted, and analyzed. They both sell for ~ \$120,000 US. The U.S. EPA has extended an invitation to each vendor to conduct U.S. EPA Method 301 evaluation testing to demonstrate that they produce similar dioxin emissions agreement as compared to EPA Method 23. If and when either system demonstrates they have met the Method 301 evaluation criteria, the U.S. EPA could then approve the semi-continuous system as an alternative compliance test method for the specific industry category on a facility-by-facility basis.

16D.4) Greenpeace comment:

EPA's above response [" The results of the EPA ambient air monitoring program around WTI in the fall of 2000 did not indicate a health concern from ambient emissions. EPA does not believe that additional ambient testing is warranted at this time"] is not supported by the data thus far released by the Agency and subsequently provided by Terri Swearingen. Specifically, according to "Table 14 SUMMARY TABLE FOR DIOXINS

DETECTED IN AIR – ROUND #4, Dates Sampled November 13-17, 2000”, the ambient air at two sampling stations -- the roof of the administration building (WTI-1) and the Water Treatment Plant (WTI-2 – were found to contain dioxin concentrations as shown below:

WTI – Dioxin Concentrations in Ambient Air, femtograms TEQ/cubic meter (fg TEQ/m ³)				
Date	Nov. 14	Nov. 15	Nov. 16	Nov. 17
Sample Location				
WTI-1	40.3	19.7	97.3	45.4
WTI-2	29.3	19.4	2370.2	18

Some of these dioxin levels are markedly higher than those reported in the scientific literature, in particular those reported for Nov. 16 and especially that for sampling station WTI-2 on this date. For example, Lohmann et al. (2003) reported 8.5 fg TEQ/m³ as representative of a U.S. urban/industrial area, while Fiedler et al. (1997) found levels of 12-67 fg TEQ/m³ for urban industrial areas in Germany.

These elevated ambient air levels of dioxins apparently occurred within the same time period that releases of dioxins in stack gases were reported as low according to the standard 6-8 hour, 'snapshot' stack sampling and analysis method. This circumstance attests to the need to require use of the AMESA quasi-continuous method in order to identify elevated dioxin releases and take action to avoid or reduce such occurrences.

Response to 16D.4:

The U.S. EPA's Environmental Response Team (ERT) released the report on results of ambient air sampling on May 19, 2003. The ERT report is available at <http://www.epaos.org/WTI>.

The ERT Report provided the results of 13 air samples taken for PCDD/PCDF taken over the time period 13 November 2000 through 17 November 2000. The results were as follows:

Summary of PCDD/F Sample Results in Ambient Air (in fg/m³ TEQ)²⁷

WTI-1	WTI-1	WTI-1	WTI-1	WTI-2	WTI-2	WTI-2	WTI-2	WTI-3	WTI-3	WTI-3	WTI-3	WTI-5
14Nov	15Nov	16Nov	17Nov	14Nov	15Nov	16Nov	17Nov	14Nov	15Nov	16Nov	17Nov	15Nov
41	20	97	45	29	19	2,370	18	13	8	52	21	2,201

Sampling site WTI-1 was located at the East Elementary School, WTI-2 was located at the East Liverpool water treatment plant, WTI-3 was roughly one kilometer South of VRA/WTI in Lawrenceville, WV, and WTI-5 was on the North bank of the Ohio at the end of Walter

²⁷ Note that "pg" is the abbreviation for picogram, and "fg" is the abbreviation for femtogram. The relationship between the two is 1 pg = 1000 fg, so that for example .09 pg/m³ = 90 fg/m³.

Street.

Two of the 13 samples demonstrated higher-than-expected values, and the potential cause(s) of these are still being analyzed. While the ERT report listed other potential sources of dioxins in the area²⁸ which might have caused the two outliers, it did not provide any suggestions or evidence as to the most likely source(s).

It is generally accepted that different emission sources of PCDD/PCDF have different signatures or "fingerprints" to their emissions which do not change appreciably with time, and that these can be used to establish a connection between those emissions and concentrations of PCDD/F found in the ambient air. Region 5 has evaluated the signatures of both the elevated air concentrations and VRA/WTI's emissions (both in mid-November 2000). Both of the high ambient air samples demonstrated a congener signature²⁹ which had a very high percentage of total heptachloro-dibenzodioxins (HpCDD) and total octachloro-dibenzodioxins (OCDD), but virtually none of the tetra-through-octa chlorinated dibenzofuran congener groups (See Attachment F). In marked contrast to this, the congener signature of VRA/WTI's emissions demonstrate a high percentage of furans, especially hexachloro-dibenzofurans, but extremely low values of tetra-through-octa chlorinated dioxins (also shown in Attachment F). Because the signatures observed in both VRA/WTI's November 2000 emissions and its historical emissions were so different from the signatures of the two high ambient air samples, we cannot conclude that the high ambient values were caused by emissions from VRA/WTI.

As to the low ambient PCDD/F values Greenpeace references in the literature, R. Lohmann also states³⁰ in the same article:

"These values are low for an urban center, and actually more typical of rural/remote areas (Lohmann and Jones, 1998). For example, $\Sigma\text{Cl}_{4-8}\text{DD/F}$ (ΣTEQ) concentrations of $\sim 500 \text{ fg/m}^3$ ($3\text{-}4 \text{ fg } \Sigma\text{TEQ/m}^3$) were measured at the remote western Irish coast and were $\sim 1000 \text{ fg/m}^3$ ($\geq 10 \text{ fg } \Sigma\text{TEQ/m}^3$) near Lancaster, a city of 100,000 inhabitants on the north-west coast of England in May 1997 (Lohmann, et al., 1996). Ambient PCDD/Fs in the NY/NJ complex were therefore only 2-3 times higher than at the remote Irish site. It is obvious of interest to consider why these low levels were measured in this study."

²⁸ The Report lists as potential sources of PCDD/Fs in the area as "...incinerators and other industrial combustion sources, home fireplaces, wood burning stoves, burn barrels, and diesel fuel combustion..."

²⁹ Following techniques frequently seen in the literature, the U.S. EPA used congener signatures which considered the ten congener groups (also known as homologues) of tetra-through-octa-chlorinated dibenzodioxins and tetra-through-octa chlorinated dibenzofurans, and report these as a percentage of the sum of the tetra-through-octa-chlorinated polychlorinated dibenzodioxins and furans (abbreviated $\Sigma\text{Cl}_{4-8}\text{DD/F}$). The emission signature was based on five test runs from 1993, when the carbon control system was first installed and evaluated, and recent test results from performance tests in 2000, 2001, and 2002.

³⁰ Lohmann, R., et al., Processes controlling diurnal variations of PCDD/Fs in the New Jersey coastal atmosphere. Atmospheric Environment 37 (2003); p 963

In contrast to this, the U.S. EPA's Draft Dioxin Reassessment³¹ (See Part I, Chapter 3, Volume 3 of the Draft Dioxin Reassessment) reports the following levels for ambient TEQ concentrations of PCDD/F:

"Assuming that nondetects are equal to one-half the detection limit, the mean TEQ -WHO concentration was 0.017 pg/m³ for rural background sites... .. and 0.12 pg/m³ for urban background sites.... ..Samples collected from urban locations not expected to be impacted by industrial point sources were assumed to represent "background" conditions for the majority of the U.S. population.

Therefore, the U.S. EPA's most recent analysis, as reported in the Draft Dioxin Reassessment, concluded that the observed average values in the United States were .017 pg/m³ (17 fg/m³) TEQ for rural background sites, and 0.12 pg/m³ (120 fg/m³) TEQ for "urban locations not expected to be directly impacted by industrial sources of PCDD/F".

17) TRANSCRIPT FROM THE PUBLIC HEARING:

COMMENTS FROM RICHARD WOLF:

17A) "My name is Richard Keith Wolf, R-i-l-c-h-a-r-d K-e-i-l-t-h W-o-l-f. I live at 934 Main Street in East Liverpool. I have no desire to be at this meeting tonight, but my conscience compels me to be here. I have attended far too many of these meetings and recognize what they are. At best, they are a perfunctory process. At worst, they are a conspiratorial sham. I am going to relate some history and it is going to bring about two questions. The first question is: The primary monitor for air monitoring at WTI was the Northern Ohio Valley Air Authority. It was an entity that came into existence in Jefferson County and ultimately encompassed six counties. And they were found to be a corrupt organization, in fact, the organization was disbanded. Most of the principals were convicted and either jailed, fined or both, and the Ohio EPA, which contracted with them summarily dismissed them. Now, three of us met and the Sheriff, Pat Della, down at Jefferson County jail. Talked to him and he went to the Jefferson County Prosecutor, Jeffrey Stern and gave us Zampanos' testimony. It's about this thick. (Indicating) Very interesting reading. NOVAA and its people were on the payroll of WTI. Now, we can either believe that WTI is a benevolent organization that just hands out money to people out of the goodness of their heart, or they were getting something for that service. My concern is this: All the primary air monitoring data came about as a result of NOVAA's monitoring of this. And if you read Zampanos' testimony you will read that Paul Voinovich of the V Group, George Voinovich, then the Governor, brother; Jeff Zeilich, Mike Parkes and other figures with NOVAA Canestraro, Zorbini, met at the Marriott in Greentree in Pittsburgh at a dinner meeting. Now, the mere fact of the composition of that meeting should certainly raise questions to any person with a reasonable knowledge of the situation. Now, my question is this: If the EPA

³¹Draft Dioxin Reassessment available at <http://cfpub.epa.gov/ncea/cfm/part1and2.cfm>

summarily dismissed NOVAA why in the world did they not call upon the Attorney General to convene a grand jury and conduct an investigation because today, as of this date, you are relying on the air monitoring information provided by NOVAA which is bogus. That was my first question."

Response to 17A:

Ohio EPA is not relying on air monitoring or any other data provided by Northern Ohio Valley Air Authority (NOVAA) in making a permit decision. While the issue of NOVAA corruption is important, it had virtually no impact on the risk assessment because NOVAA was not involved in the risk assessment. The risk assessment was not based on ambient air sampling conducted by NOVAA, and NOVAA did not conduct the trial burn or any risk burn testing. NOVAA was involved in certain side issues, such as collecting samples that could be used for comparison to the risk assessment. For a more detailed explanation of this, please see the attached memo from Francis Lyons to Timothy Fields, Jr., dated December 5, 2000. This is included as Attachment C. Please also see Ohio EPA response to comment 5B regarding reported payments by VRA to employees of NOVAA.

17B) "My second question goes to Heritage Environmental Services, LLC, now 51 percent owner of WTI, Von Roll, whatever you want to call it. Over the years it's had so many names no one can identify it. We've talked to U.S. EPA and Ohio EPA and best answer we could get was three different Von Rolls when we tried to pin them down. Now, we know that in 1986, Waste Technologies Industries ceased to exist. The Attorney General told us that much. From '86 until '95 there was no known permit holder for that facility yet, both of you, U.S. EPA and the Ohio EPA, allowed it to operate. We asked you who's the owner? You said, we know, but you never told us. You never told anybody, and that's regrettable. However, we know that the amount of liability insurance that WTI has is less than the liability insurance carried by the East Liverpool City School District. That's a laugher. And I submit to you that the reason that Heritage is not on that permit is because of a political decision; the deep pockets. In the event of a catastrophic event, there is going to be pointing of fingers in all directions and the court will never be able to make a determination like you weren't able to make when we asked you who owns this facility. The deep pockets will not be available. No one in their right mind can tell me that a 51 percent owner of Von Roll America, Inc. is not the owner of that waste facility. And Mr. Popotnik, you sat there and said the owner/operator is Von Roll America. That can not be right. I challenge it and I defy you to prove it to me. That's the end of my comments. Thank you."

Response to 17B:

Issues relating to: 1) the original transfer of ownership to Von Roll America (VRA); 2) the concerns raised in the Ohio Attorney General's 1993 investigative report, and; 3) Ohio EPA's actions concerning the WTI partnership's transfer were resolved via Ohio EPA's transmittal of WTI partnership's modification request to the Ohio Hazardous Waste Facility Board (HWFB) and the Board's subsequent 1998 decision (see response to comments 5A and 5B and 6H through 6R). On February 13, 1998, the HWFB authorized the transfer of the hazardous waste permit (originally issued to WTI in 1984) to VRA. Since that time, there have been no permit related changes in the ownership of the facility. Therefore, VRA is the owner of the facility as was indicated on the draft renewal permit and maintained on

the final renewal permit.

It is Ohio EPA's understanding that Heritage Environmental Services /WTI, LLC currently owns 51% of the Von Roll America, Inc. (VRA) stock. Heritage Environmental Services, LLC owned 51% of VRA stock prior to transferring it to Heritage Environmental Services/WTI, LLC.

In response to the comment on liability insurance, Ohio EPA has reviewed the financial requirements information provided by Von Roll America and has determined the liability coverage meets the requirements of Ohio state law.

COMMENTS FROM ALONZO SPENCER:

17C) "My name is Alonzo Spencer. I am here on behalf of the Save Our County group of which I am President. I would like to just follow up on what Dick said about this ownership; something that we had been pursuing for a number of years. I posed that question to the Ohio EPA and I got a answer that indicated - - I assume this is their definition owner: An owner means a person who owns a facility or a part of a facility. Does that cover that aspect of who is an owner? When you sent me that, was that the answer to that question? Okay. Well, the reason it's confusing - - well, that was sent to me by the EPA. So, I'm assuming when I asked that question that was the answer they were sending me and I'll read it again: owner means a person who owns a facility or part of a facility. However, when you go to the Administrative Code, their definition says: The owner means a person who owns a majority of a controlling interest in the facility. The operator means a person who is responsible for the overall operation of the facility. Now, I perhaps should have asked this before because I'm confused as to which one of those is the true answer to who owns the facility. And 202 and that was sent to the Ohio and U.S. EPA by the attorneys for Von Roll stating that they was a contemplating the purchasing of 51 percent of Von Roll America. Heritage Environmental Services, LLC was purchasing 51 percent of Von Roll America. Yet, the Disclosure and Background Unit of the Attorney General's office, doing a background check on that ownership that was mentioned in the letter that was sent to the Ohio and U.S. EPA. However, in a deposition regarding a case that involved a whistle blower, under oath, that question was asked of Mr. Sigg. I'm going to read from that deposition."

Question: "Who owns 51 percent of Von Roll America?"

Answer: "Heritage Environmental Services/WTI, LLC."

Question: "What is the difference between Heritage Environmental Services, LLC and Heritage Environmental Services/WTI, LLC? And then there was an objection by the attorney."

Answer: "They are two separate companies."

Question: "Which one is Rudolph Zaengerle the President of?"

Answer: "Heritage Environmental Services, LLC."

Question: "Do you know who the President of Heritage Environmental Services/WTI, LLC is?"

Answer: "No, I do not."

Question: "But that's the company that owns 51 percent of your employer"

Answer: "That's correct."

"Now, the Disclosure Background Unit of the Attorney General's office, evidently, - if we are to assume that this statement made by Mr. Sigg is correct - - did a background check on the wrong company. They did a background check on Heritage Environmental Services, LLC. In addition to that, the attorney for Heritage Environmental Services, in submitting his deposition, outlined the corporate structure of the facility. Heritage Environmental Services' attorney at the same hearing, court hearing, he indicates on his drawing that Heritage Environmental Services, - - I mean /WTI, LLC did purchase 51 percent of Von Roll America. Now, of that, Heritage Environmental Services, LLC, the company that the Background Unit of the Attorney General's office investigated, then bought the 99 percent of Heritage Environmental Services /WTI, LLC. Now, there was a time when we were so naive that we thought if a comma was inserted into an ownership and the next you saw it it said, Inc., and the next time you saw it, it said, Incorporated, we thought those were all typos, errors. We believed it's as indicated. It's simply a way of diverting liability, but until this day, you would think after some 20 years, if you asked that question you could get a straight answer. And I submit to you along that same line, you were good enough to send me, last week, an answer to that same question that I posed to the Attorney General's office. Question, my question: have you been able to talk to Gary Taylor and anyone else at the Attorney General's Background Unit to find out if you are looking at Heritage Environmental Services/WTI, LLC? Answer: Yes, I talked to Taylor last week. The Attorney General's office there is currently looking at Heritage Environmental Services/WTI, LLC as part of Von Roll America's next investigative report, next investigative annual report. So, the Attorney General has not had the opportunity to accept the final report from the Background and Disclosure Unit because it hasn't been brought to his attention. So, at this date, as we sit here tonight, that question is still up in the air. Now, if you think that "Slash" WTI and that "comma" LLC doesn't mean anything; of course it does. But the fact that we can not, as we sit here, get an answer to that question and the Attorney General hasn't gotten an answer because the Background Unit hasn't submitted to him for his acceptance or rejection. So, in essence, we're holding a meeting here tonight talking about the renewal of the original permit, the reissuance of Title V permit and the answer to who the true owner is is still in question. And I defy anyone to contradict me on what I just said. As I said, I'm here representing Save Our County which is an environmental group here in Ohio, I mean in East Liverpool and I am also here to share with you that the Ohio protection agency and the U.S. Environmental Protection Agency they are mandated to deny this permit to Von Roll for the following reasons - - I'm going to be shorter than I

normally would, I'll put them in my written comments. The Director determined that WTI has filed an appropriate disclosure information with the Director of the Ohio EPA and the Attorney General's office. This conclusion by the Director is absolutely wrong, and I cited the reason for that before I read that paragraph. The Attorney General's office and Environmental Background Investigation Unit, as I said before, are currently looking at Heritage Environmental Services/WTI, LLC as part of Von Roll's next investigative report annual update. The next one, annual. We don't even know when that will occur. Until that report has been reviewed and the Director has signed off on it, the appropriate disclosure is incomplete which is contrary to what the Director said about them filing a complete disclosure."

Response to 17C:

For purposes of ownership as it relates to the Hazardous Waste Permit, Von Roll America, Inc. is the owner. According to OAC 3745-50-10, an owner is defined as a "person who owns the facility or part of a facility." A facility or hazardous waste facility, according to this same rule, is "all contiguous land, and structures, other appurtenances, and improvements on the land, used for treating, storing or disposing of hazardous waste." Therefore, VRA owns the facility. Ownership of stock in a company was not contemplated in the regulations. It is Ohio EPA's understanding that Heritage Environmental Services /WTI, LLC currently owns 51% of the Von Roll America, Inc. (VRA) stock.

Heritage Environmental Services/WTI, LLC, however, was investigated by the AGO's Environmental Background Investigation Unit (EBIU), since VRA's facility is an offsite hazardous waste facility. The AGO's EBIU investigation primarily looked at the key employees of Heritage Environmental Services/WTI, LLC to see if they had any potentially disqualifying crimes as listed in Ohio Revised Code (ORC) 3734.44(B).

Since changes to key employees, e.g. employee retirement, new hires, etc., occur regularly, the Environmental Background Investigation law (ORC 3734.44) requires applicants to submit annual disclosure statements and thus the AGO's EBIU is required to provide the Director of Ohio EPA with annual updates to its original investigative report.

The most recent EBIU report which the Agency received looked at Heritage Environmental Services, LLC, which owned 51% of VRA stock prior to transferring it to Heritage Environmental Services/WTI, LLC. The AGO's EBIU was notified of this stock transfer and reviewed it as part of VRA's annual update investigation. Upon completion of this annual update investigation in June of 2004, the AGO transmitted an annual investigative report to the Director of Ohio EPA on July 8, 2004.

The renewal permit is premised, in part, on the acceptance of a May 2002 EBIU report and a July 2004 EBIU update report to Ohio EPA that determined there were no disqualifying crimes to warrant denying the renewal permit under the ORC 3734.44(B) standard. To the extent that new disclosures are brought to light in the future, the EBIU will incorporate them into their next update report and provide the Ohio EPA with their findings and recommendations. The Agency will have all its regulatory options available and will take the appropriate action at that time.

17D) "The Ohio EPA stated the draft air permit covers all emissions from the facility and

includes the conditions under which the facility must operate if it receives a final permit. The Ohio EPA makes no mention of fugitive emissions. I tried to get that out of them earlier. Nor how they monitor and how they are reported."

Response to 17D:

Fugitive emissions are regulated by both RCRA and the Clean Air Act ("CAA"). Under RCRA, fugitive emissions from the incinerator must be controlled by keeping the combustion zone totally sealed, maintaining a combustion zone pressure lower than atmospheric, or by using an alternate means. At VRA the combustion chamber is maintained at a pressure below atmospheric to prevent fugitive emissions. Shrouds are installed at both ends of the kiln, and a slight positive pressure is applied to the seals. This pressure further reduces fugitive emissions from the kiln. In addition, the seals located at each end of the kiln are designed to minimize leakage. The U.S. EPA has self-implementing regulations in place, 40 CFR 264.1050 to 264.1091, to monitor and control fugitive emissions from process units such as tanks as well as flanges, valves, pumps, and pipes. Since Ohio EPA is not yet authorized for these regulations, U.S. EPA will be drafting a federal RCRA permit portion to address fugitive emissions from these sources in the near future. VRA uses a vapor recovery system to collect fugitive emissions and vapors from process and storage areas throughout the facility. The Title V permit requires terms and conditions on all non-significant emission units. The Title V permit and the CAA address fugitive emissions, not as an emission unit, but on a facility wide basis. A separate responsiveness summary, associated with Title V permit issuance, addressed comments pertaining to the draft Title V permit.

- 17E) "Also, the letter from the East Liverpool Board of Health to Attorney General Betty Montgomery, dated September the 20th, 2002, requesting that the Attorney General's office initiate the appropriate legal necessary actions concerning WTI's change of ownership. That's an issue that's been up in the air for many a years. The fact that the Ohio Board of Health, and I won't go into all the details surrounding that, but they concluded in a request to the Attorney General, to take such actions."

Response to 17E:

Ohio EPA contacted Gary Ryan, the Health Commissioner at the East Liverpool Health Department ("ELHD"), in an attempt to obtain a copy of the above described letter. Gary Ryan could not recall a letter being sent to the Attorney General's Office from the ELHD in 2002. The ELHD was not able to locate a copy of the letter in their files. As discussed in Ohio EPA's response to comment 17B, issues relating to the transfer of ownership to VRA and concerns raised in the Ohio Attorney General's 1993 investigative report have been dealt with by Ohio EPA's transmittal of WTI partnership's modification request to the Ohio Hazardous Waste Facility Board and the Board's 1998 decision (as explained in Ohio EPA's Response to comments 5A through 5D and as detailed in Response to comments 6C through 6S). On February 13, 1998, the Ohio Hazardous Waste Facility Board (Board) authorized the transfer of the hazardous waste permit (originally issued to WTI in 1984) to Von Roll America (VRA).

- 17F) "I'm curious to find out -- and I'll put this in the form of a statement -- what will the Director do if there is evidence that WTI has lied regarding the rules and regulations that they are governed by under these two permits?"

Response to 17F:

At Von Roll America, Ohio EPA regularly inspects the facility and its records and checks for compliance with their permit and Ohio's laws and regulations. If Ohio EPA determines that non-compliance has occurred, we will evaluate whether escalated enforcement action (either civil or criminal) is warranted.

17G) "The director has made no determination regarding the cumulative synergistic effects and impacts on ongoing emissions related to the community. No air permit should be issued until that determination has been made and evaluated."

Response to 17G:

Please see the discussion of cumulative risks in the response to Dr. Harrison's Comment 16A.4.

17H) "The Director also determined that the WTI meets the Director's performance standard reliability, expertise and culpability under the rules and permit. The Director's final findings and orders related to their repeated violations contradict that statement. There's not enough time tonight to go into contradicting the Director's statements when he said, the Director determined WTI meets the Director's performance standards reliability, expertise and competency. They will be sent in my written statement. Lastly, the Director has stated that the facility has a history of compliance. I want to say that again. The Director has stated that the facility has a history of compliance. The truth is that WTI continues to have serious non-compliance problems. I'll give you two in the essence of time. Recently, on September the 17th, 2002, WTI experienced a hydrochloric acid that went into East Liverpool POTW, and then directly into the Ohio River. That's not non-compliance. On October the 23rd, 2002, WTI accepted waste not matching the profile. It was battery acid residue. Waste was received with no manifest. This is a small example of WTI's trustworthiness or lack of regarding laws and regulations. And finally, based on WTI's chronic and ongoing violations and history of non-compliance, it is impossible for WTI and the Ohio EPA to insure compliance with Title V Permit as required and the permits must be denied."

Response to 17H:

In the renewal process, Ohio EPA considers the application, inspection reports, and the facility's history of compliance with the present permit, and Ohio's hazardous waste laws. Ohio EPA has found that the facility has a history of compliance that demonstrates sufficient reliability, expertise, and competency to operate the facility. VRA/WTI has a history of working with Ohio EPA in day to day operations with planned modifications to the facility and permit, and when necessary, in developing corrective actions in response to incidents. At Von Roll America each incident is investigated to determine its significance relative to the facility's permit and Ohio laws and regulations. If appropriate, a violation is cited which may or may not lead to escalated enforcement. Our record of incidents at the Von Roll America facility has been evaluated and the Ohio EPA has determined that state renewal standards for compliance have been met. Ohio EPA has determined that VRA qualifies to receive a hazardous waste permit renewal.

Regarding the two incidents brought up by the commentator. The first incident, a spill of

hydrochloric acid to the East Liverpool publicly owned treatment works ("POTW") and to the Ohio River occurred on September 17, 2002. Reportedly, 5,000 gallons of the acidic solution were released to the East Liverpool POTW and approximately 300 gallons were released to the Ohio River. The spill resulted from operator error during cleaning of a boiler. Von Roll reported the releases to Ohio EPA's Emergency Response Hotline and notified the East Liverpool POTW. Ohio EPA investigated the incident. Impacts on the POTW and the Ohio River were minimal. Ohio EPA issued a notice of violation on October 17, 2002. In a letter dated November 26, 2002, VRA responded to Ohio EPA's notice of violation and agreed to implement several corrective actions to ensure a recurrence of the incident would be prevented. In response to the violations, the city of East Liverpool fined VRA approximately \$3,500. VRA also paid for damages incurred at the East Liverpool POTW as a result of the accidental discharge.

With regard to the second incident, Ohio EPA was not able to find an incident occurring on October 23, 2002, where WTI accepted waste not matching the profile. We believe the incident that you are referring to may be one that occurred on August 23, 2002. In this incident, VRA/WTI received a waste from an Ohio generator that did not carry a D002 code. The generator characterized the waste as having a normal pH range. The fingerprint analysis completed by VRA indicated a pH of 0.8 which is very acidic (normal would be a pH of 7.0 on a scale of 0 to 14). VRA contacted the generator and isolated the waste in a tank in the tank farm until the issue could be resolved. VRA/WTI did not violate any regulations or permit conditions. The checks and balances resulted in the waste being properly characterized after it arrived on site. Once VRA/WTI customer service called the generator, they reclassified their waste as being corrosive and added D002.

171) "In light of the above, it is clear that the issuance of a permit, of history of violations will have a discriminatory and disproportionate impact on low income citizens who live closest to the incinerator, which is in violation of Title VI of United States Civil Rights act of 1964. A thorough review of WTI's history can only lead to a speedy denial of this permit. Thank you."

Response to 171:

VRA/WTI remains one of the most stringently monitored facilities in Ohio, both out of regulatory interests and out of respect for citizen's concerns regarding this facility. The RCRA permit is designed to be protective and the facility should not emit levels of pollutants which could pose a significant health risk to the nearby populace, therefore there should not be a disproportionate impact on citizens living near the facility. Duly promulgated regulations which allow emissions, also ensure that the emissions have minimal impact on the surrounding community and environment. This is accomplished through trial burn testing of the incinerator and the establishment of operational parameters such as combustion temperature, residence time for the flue gas in the system and turbulence within the combustion system. These operating parameters ensure complete combustion of hazardous and non-hazardous waste in the incinerator. System removal efficiency (SRE) of the incineration system is determined for metals so as to establish feed limits of metal bearing waste. The SRE is tested routinely via stack testing of metals emissions. The formation of dioxin, a by-product of incineration, is controlled through rapid temperature reduction of the flue gas in the air pollution control units and via the facility's Enhanced Carbon Injection System (ECIS). The site specific risk assessment examined

risk to the community using the information obtained through trial burn testing. The emission limits or feed rates were adjusted when necessary to best protect human health and the environment.

The National Academy of Science (NAS) is an independent nonprofit organization of scientists and engineers that investigates important technical, health, and social issues and provides advice useful to the federal government and other interested parties. The NAS issued a report entitled "Waste Incineration and Public Health." As part of the Report, the NAS committee investigated the literature on studies of health effects in the vicinity of waste incinerators (this could include hazardous waste, municipal waste, and medical waste facilities). The general conclusion of the Report is that there is no convincing evidence available to document increases in adverse health effects in the populations living near such facilities. In addition, the Report concluded that the most modern designed and well operated facilities should not emit levels of pollutants which would pose a significant health risk to the nearby populace. The Report also: 1) provided recommendations for improving future studies to look for health effects; and 2) stated that on-site workers at such facilities would be likely to have the highest risk for exposures and health effects and should be studied in more detail. This Report is available for reading at the following Internet web site: <http://bob.nap.edu/books/030906371X/html>.

Ohio EPA and U.S. EPA are deeply committed to ensuring the health and safety of the citizens surrounding the facility as well as the citizens in other locals. That is why it is critical to the EPA to ensure that treatment, storage, and/or disposal facilities comply with the regulations, to ensure that everyone's health and the environment in all locations is protected.

COMMENTS FROM VIRGIL REYNOLDS:

17J) "Virgil Reynolds. I live in the east end of East Liverpool. My comment tonight will be on what I believe is the reason you shouldn't issue this Title V permit because this facility is not trustworthy enough to have that permit. I'll be referring to past incidents of the facility that will support my story. This facility engulfs the entire Ohio Valley with paradichlorobenzene. Twenty miles down the river, I got a call about the smell. My wife and I happened to be in East end at a pottery outlet. When we came outside, the gas smell was so bad that I went back into the outlet and asked them that they better check their gas line 'cause I think they got a horrible leak. Bless Ben Christian, because he set the record straight. We had city officials tell us it came from a gas station, about a gas station over here. It came from a truck out of Pennsylvania with a lid open on the tank. Ben Christian came up to to -- above the facility there, Sandy's home -- he said, you don't need to look any further. It came from that facility right down over the hill. That's where it came from. This facility did everything in their power to try to get out of that situation, that it wasn't them. It was someone else. At the whistleblower's trial that was mentioned a few minutes ago, it was brought out that there was a valve going into the river, stuck open and a 60 percent area letting acid into the river. In fact, I think the comment of the day was that people who owned boats on the river wouldn't have to clean them because the acid would take care it. This facility has hid their ownership, as Alonzo said, from day one. It has just been revealed that the ownership -- the

transaction with Heritage was done in December of 2001. I have information at home that said it was done in 1994. It came out of this trial. So, it's sworn evidence. It also came out of the trial that they had filed false reports. If they tested a tank that didn't meet what their - - what they expected it to be, they went to the next tank and tested that and that's the report that was sent in, late getting them in, months late getting them in. Some of them, I don't think was ever put in but I don't know if there was anything ever done about it. And another thing that takes me back, to March 10th and 11th of 1993, when this facility emitted 29 pounds of mercury in this Ohio Valley. And to the best of my knowledge - - I've been in this fight for almost 23 years - - I don't know of a thing that was done to that company for doing that. Do you Gary? Oh, I'm not allowed to ask you questions. But I don't know of any enforcement that was ever taken for spilling 29 pounds of mercury in this Ohio Valley, 1100 feet from 400 children at East Elementary school; less than half mile from 600 students at Allison Elementary in Chester, West Virginia. Now, that's just a few of the things I come to my mind and I'm sure that the good people of the tri-state area know a lot more that can be added to this list. So, I'm begging you to deny this Title V permit for this facility because I don't think they're trustworthy enough to do it and do it right. Thank you."

Response to 17J:

In response to the commenter's concern regarding noxious fumes and the strong cat urine smell, the facility did have odor problems associated with the various mercaptan wastes received on site. As discussed in Ohio EPA response to comment 15B, these sulfur-containing organic compounds have very low odor thresholds, on the order of parts per billion (ppb). The facility instituted a number of changes to mitigate or eliminate this problem. The changes included enclosing the tanker unloading bays where waste was off-loaded and adding vapor recovery. Also, to avoid problems with handling this and other problem waste streams, the facility installed direct tanker unload stations. These units are in an enclosed building with vapor recovery and the waste is pumped directly to the kiln rather than to a tank. The last odor incident associated with the mercaptan odors that Ohio EPA is aware of occurred several years ago. This was related to a problem with the tanker transporting the waste and not the result of waste management at the facility. There have been other odor complaints from the citizens since then, but these were traced to another company nearby.

With respect to the comment on "letting acid into the river", we believe that you may be referring to a spill of hydrochloric acid to the Ohio River that occurred on September 17, 2002. This incident is discussed in Ohio EPA's response to comment 17H.

Regarding the emission of 29 pounds of mercury, this occurred during trial burn testing in 1993 being conducted on the incinerator. It was not a spill or similar event. As part of the testing, VRA/WTI spiked mercury into the scrubber system recirculation loop. During the testing, the incinerator achieved less mercury "control" or "removal efficiency" than expected. The mercury was released via the stack during a couple of days of testing. As a result of spiking mercury into the scrubber system recirculation loop, mercury emission limits were exceeded. The U.S. EPA's response to the event was to restrict VRA/WTI by requiring in the RCRA permit that it assume all mercury fed to the incinerator would be emitted. Under their RCRA permit, an hourly mercury emission rate of up to 0.65 lb/hr is

permitted. That emission rate of 0.65 lb/hr translates into a feed rate of 0.65 lb/hr. Since for metals the long term exposure is most critical, the exceedence that occurred over a short time period is expected to have had very minimal impact. For more detailed information on this incident, please refer to comment 16A.18.

Issues related to ownership are addressed in Ohio EPA's response to comments 6A through 6S.

COMMENTS FROM TERRI SWEARINGEN:

17K) "Terri Swearingen. I'm from Chester, West Virginia and I'm totally unprepared for this evening. I just found out about this hearing about a week-and-a-half ago, but I do have a few comments. First, I'd like to read something from a local newspaper on Enron. They were just before the House-Senate joint committee on taxation and one of the -- the Chair of that panel, Senator Charles Grassley from Iowa had this to say, "Money above honesty in financial accounting." They just issued a three volume report that reads like a quote "conspiracy novel." So, can it happen? Can things like this happened? I'm not a conspiracy theorist, but sometimes I wonder about this case. Show me the money as it plays upon a recently released Enron Document. The report says, quote "Enron's behavior illustrates that motivated corporations can manipulate highly technical provisions of the law. By using advice from sophisticated lawyers, investment bankers and accountants, corporations like Enron have a distinct advantage." I'll start with that. I just want to say, I've been told for years, but I've tried to believe otherwise. I tried to believe in integrity and honesty of our government and the system but now I believe this is a done deal. Early in the permitting process Congressman Doug Applegate wrote to U.S. EPA about serious problems with the facility. One of them he was very concerned because he said he worked out -- he said he had somebody work out all the numbers and he said that this is a major source and we were told, no. And they were issued a permit because you couldn't get a permit for major source in this area. So, now, today, we learned it is a major source. He said, he felt that the government wanted the facility as much as WTI. That's what he said in his letter. A few years ago, when WTI was before the Hazardous Waste Facility Board, a former Ohio EPA chemical engineer by the name of Theresa Spezio wrote to the board outlining her concerns about WTI and basically what she said was that she had been told that no matter what -- no matter the problems whatever happened, that WTI would go forward. And for years, a high level, senior EPA employee has told me to move onto something winnable because with WTI, the fix is in."

Response to 17K:

The commentor is claiming that the permit should never have been issued since the facility was a major source. VRA/WTI was not a major source at the time the facility was initially permitted, consequently the information provided to Congressman Applegate was accurate. VRA/WTI did not become a major source until the Title V program was started in the mid 1990's. (See Ohio EPA DAPC Comment Response #16 in the Title V Permit Responsive Summary for WTI dated September 25, 2003)

17L) "Well, let's go back to Enron. The name Enron is now synonymous with corporate

corruption, accounting tricks, influence peddling and environmental negligence. Fictional investment partners were part of an elaborate shell game used to get around laws and regulations. The Powers Report, an in-house investigation, concluded that there about 4000 partnerships that were part of this corrupt shell game. A top Enron executive tried to fire one of their attorneys who tried to question all the partnerships. According to the San Francisco Examiner, "Our way or the highway" was the theme of Enron's corporate culture. According to a recent AP news account failed Enron Corporation used schemes of dizzying complexity to shrink its tax payment, inflate its income and basically overwhelm the regulatory agencies. Reading through the many stories about how Enron used a complex corporate shell game to stay in business, increase its profits and generally skirt the law. You know, it just sounded all too familiar. Remember the 44 different companies involved with Von Roll when they were investigated by the Ohio Attorney General Lee Fisher? And we're just now learning about more recent changes to the corporate structure of Von Roll/WTI with the involvement of Heritage. It's my understanding that Heritage Environmental Services/WTI, LLC purchased 51 percent of WTI. In 2000 news accounts only then made it known to the public that Heritage Environmental Services purchased a majority interest in WTI. I'm now told that this transaction may have taken place as early as '94, '95. Now, new information reveals that Heritage Environmental Services/WTI, LLC sold one percent of their 51 percent ownership to Heritage Environmental Services, LLC. Who are these people? Does anybody know, really? I mean, we are asking the same questions that we've been asking throughout the years with this facility. In the late '80s and early '90s corporations obviously got away with this kind of stuff as exemplified by Enron and so many other that we read about in the news all the time now. Even financial regulators were duped. So, it's no wonder that other regulators might not get it. Today, with all the news of Enron and other companies that have used similar schemes there's no excuse for not taking a closer look at the companies who are playing fast and loose with corporate rules and engaging in an elaborate corporate shell games. It should be a red flag. Is Von Roll/WTI above this kind of corporate behavior. Why don't you ask Rene Luthy, the recently retired chief executive of Von Roll's hazardous waste division. At the time, he was still with Von Roll, they bailed him out of jail where he was being held on bribery allegations. Not even Enron bailed out their jailed executives. We will see what happens in that case. Years ago, we brought up the fact that Von Roll had sold war material to Iraq for the construction of Saddam Hussein's "super-gun." That was after back during our first go around with Saddam in the early '90s and Von Roll continued to deny that. Well, a few years ago, several of their chief executives of Von Roll were convicted of that crime. So, are they above that? One Enron article regarding was titled, "When greed is fact and control is fiction." You, as regulators cannot believe in the fiction of control and ignore the facts. We need to know the truth. We need to know who owns WTI. No permit, not a Title V permit, and not the renewal of the hazardous waste permit should be granted until a full investigation is conducted into who really owns this facility. And certainly no permit should be issued until the AG completes his investigation. There's too much at stake here. Thank you."

Response to 17L:

Ohio EPA acknowledges the public's frustration with regard to understanding the

relationships of various corporate entities as they relate to facility ownership issues. This is especially true in today's dynamic business climate when corporate partnerships, parent companies and stock ownership may be involved. This permit renewal is being issued to a legally viable owner which ensures proper assignment of environmental obligations and liabilities.

Issues relating to: 1) the original transfer of ownership to Von Roll America (VRA); 2) the concerns raised in the Ohio Attorney General's 1993 investigative report, and; 3) Ohio EPA's actions concerning the WTI partnership's transfer were resolved via Ohio EPA's transmittal of WTI partnership's modification request to the Ohio Hazardous Waste Facility Board (HWFB) and the Board's subsequent 1998 decision (see response to comments 5A through 5D and 6C through 6S).

On February 13, 1998, the HWFB authorized the transfer of the hazardous waste permit (originally issued to WTI in 1984) to Von Roll America (VRA). In so doing, it deliberated upon various aspects of VRA's history of compliance with environmental and other laws.

During this process, the Board considered information presented regarding alleged or proven illegal dealings between Von Roll and its sister companies with Iraq and with NOVAA. The Board concluded that VRA/WTI or a sister or parent company had not been convicted of a disqualifying crime listed in ORC Section 3734.44(B) and no basis existed to revoke VRA/WTI's permit or to deny a modification to VRA. The Board's decision on this matter was appealed to both the Franklin County Court of Appeals and the Ohio Supreme Court. The Court of Appeals (case # 98AP-220) affirmed the Board's decision on December 28, 1998. The Ohio Supreme Court declined to hear the case (1999). Since that time, there have been no permit related changes in the ownership of the facility. Therefore, VRA is the owner of the facility as was indicated on the draft renewal permit and maintained on the final renewal permit.

As a result of the Board's decision and subsequent affirmation by the Franklin County Court of Appeals, the 1996 Iraq issue and the 1997 NOVAA issue have been adequately addressed. These issues are not considerations of Ohio EPA action on VRA/WTI's renewal permit.

It is Ohio EPA's understanding that Heritage Environmental Services /WTI, LLC currently owns 51% of the Von Roll America, Inc. (VRA) stock. As discussed in Response to comment 17C, the most recent EBIU report which the Agency received looked at Heritage Environmental Services, LLC, which owned 51% of VRA stock prior to transferring it to Heritage Environmental Services/WTI, LLC. The AGO's EBIU was notified of this stock transfer and reviewed it as part of VRA's annual update investigation. Upon completion of the annual update investigation in 2004, the AGO transmitted an annual investigative report to the Director of Ohio EPA.

The renewal permit was premised, in part, on the acceptance of a May 2002 EBIU report and a June 2004 EBIU update report to Ohio EPA that there were no disqualifying crimes to warrant denying the renewal permit under the ORC 3734.44(B) standard. To the extent that new disclosures are brought to light, the EBIU will incorporate them into their next update report and provide the Ohio EPA with their findings and recommendations. The

Agency will have all its regulatory options available and will take the appropriate action at that time.

COMMENTS FROM SANDY ESTELL:

17M) "Sandy Estell, E-s-t-e-l-l. I live at 1410 Etruria Street, that's E-t-r-u-r-i-l-a Street in East Liverpool. I hadn't intended on making any comments here tonight, but what I want to go on the record is - - with the question that I asked earlier in the question and answer portion. In Pat Natali's presentation, and in the paper that she passed out, it says when the Ohio permit is renewed, not if it is renewed. It says, when it is renewed, leading me and everybody else in this room to believe that this is a done deal no matter what your objections and no matter what your explanations are. We are used to the fix being in and it does not side on the citizens of East Liverpool. It always sides on the company's part and that is shameful. As usual, the comment back to me when I questioned, was this a typing error or was it deliberate? You said that it would be renewed unless compelling evidence was presented to the EPA by the citizens. So once again, the burden of proof is on us. We are your testers. We are your guinea pigs and we are your scientists. I am tired of doing your homework for you."

Response to Comment 17M:

The draft permit action is the director's tentative decision to issue the permit. The draft renewal Permit contains the conditions under which the facility must operate if the Permit receives final approval. To issue this draft renewal Permit, Ohio EPA determined that the Permit application is complete and meets appropriate standards and that the applicant has a history of compliance with relevant environmental laws, given the potential for harm to the public health and safety and the environment that could result from the irresponsible operation of the facility. The permitting process for a hazardous waste treatment facility is described in Ohio Administrative Code (OAC) Chapter 3745-50.

After the close of the public comment period, Ohio EPA can either issue a renewal permit or deny the request in accordance with Chapter 3734 of the Ohio Revised Code (ORC). As noted by the commenter, it is not correct to say "when the Ohio permit is renewed". Ohio EPA did consider public comments before the final decision was made. After carefully considering public comments, Ohio EPA reconsidered the draft renewal permit, making any necessary changes, and issued the final permit. Ohio EPA also issued this Responsiveness Summary, specifying changes made to the draft permit. The Responsiveness Summary and final permit have been sent to all individuals and organizations that provided comments on the draft permit. Ohio EPA and U.S. EPA invested a considerable amount of time in carefully considering and responding to comments submitted during the public comment process. The Agencies have prepared the detailed responses in this Responsiveness Summary (Ohio EPA's Division of Air Pollution Control has prepared a Responsiveness Summary for the Title V permit) to address the concerns of all those who participated in this process.

In the renewal process, Ohio EPA considers the application, inspection reports, and the facility's history of compliance with the present permit, and Ohio's hazardous waste laws. Ohio EPA has found that the facility has a history of compliance that demonstrates

sufficient reliability, expertise, and competency to operate the facility. Additionally, for facilities accepting waste from off-site, the owner/operator must have a history of compliance with environmental laws and must not have been convicted of disqualifying crimes (ORC 3734.44) listed in the statute. Ohio EPA has determined that VRA qualifies to receive a hazardous waste permit renewal. The Ohio EPA must have just cause to not renew a facility's permit to operate. VRA/WTI's history of compliance has been evaluated, their permit has been reviewed and revised to conform with the State of Ohio laws and regulations. Ohio EPA has found no cause to deny renewal of the VRA/WTI RCRA permit.

17N) "The other point I wanted to raise was, when I asked who the EPA would issue this permit to Frank Popotnik said, Von Roll America. He said they are the owner/operator. I questioned Heritage's involvement and somebody - - maybe Gary, I'm not sure who - - said they are merely a stockholder. So my question is: if Von Roll America is the owner/operator of this facility why then is Heritage, and whatever form their name takes, why did they sign and issue the paychecks to WTI employees?"

Response to Comment 17N:

It is our understanding that Heritage doesn't sign any pay checks for VRA employees. It is our understanding that VRA employees are paid by VRA. There are employees that previously worked for VRA, that now work for Heritage, who would have pay checks issued by Heritage. For issues related to ownership, please refer to Ohio EPA response to comments 17B and 17C.

17O) "And my final question or comment, rather, is I want to raise my objections to this hearing tonight. There was - - I understand there was a news release about this in very fine print in the Morning Journal. I do not subscribe to that paper. On February 14th, it was put in the Evening Review, which I do receive and that allowed us two weeks notice of this hearing. You have sat on this permit for eight years now and then had the nerve to tell us, tonight, because of money constraints you could no longer postpone this hearing to allow us time to review the permit, which only recently, was placed into the Carnegie Library for our review. It's a very, very large document I've been told and one that we are not permitted to remove from the library. That means that it will take countless hours on our part to sit down there and look at it. But yet, we had only two weeks time in which to do that to come here tonight to address you with intelligent questions. And then you so generously extended the time of our comment period to May 9th, like you were doing us a favor. Thank you."

Response to 17O:

In response to comments on the public participation process and requirements, please refer to Ohio EPA response to comments 10A through 10G. Ohio EPA followed the proper procedures for public participation as required by Ohio's hazardous waste laws. On January 25, 2003, the Agency issued a public notice of the issuance of the Draft Renewal Permit in a newspaper having general circulation in the county in which the facility is located and over a local radio station. These public notices were given at least thirty days prior to the public meeting held on February 25, 2003. Additionally, the public notice was sent to over 100 persons or organizations on the mailing list.

Even though the requirements imposed by Ohio law were met by issuing the public notice in the Lisbon "The Morning Journal", Ohio EPA will, in response to your comments, issue future public notices in both the East Liverpool "The Review" and the Lisbon "The Morning Journal".

COMMENTS FROM MIKE WALTON:

17P) "My name is Mike Walton. I live at 926 Orchard Grove Avenue here in East Liverpool. I apologize for -- Walton, W-a-l-t-o-n. I apologize for not filling out the card, observing the format of the meeting, but as it happens so often in these meetings, we come just to listen and to observe and then we sit here and we hear statements and we get material and handouts that inspires you to comment on something. So, we are forced to come up here late like this and that's the situation I find myself in tonight. Gary, I think you said I should do this so that I can get my dioxin concerns on the record and I am going to do that now. I was the recipient of the original permitted chemical list for WTI and on that list were codes -- and I don't have them with me -- specifically 24D and 245T which are herbicides, which in a 50-50 mix, made Agent Orange which was used extensively in Vietnam, which led to countless problems and still affecting second and third generation of Vietnam Vet's families. The statement in the overview concerning WTI not being permitted to accept dioxin bearing waste, seems to me to be misleading, disingenuous, wrong in some way. If, indeed, these wastes are inherently contaminated with dioxin -- and I have been led to believe through my research that that is a true fact -- then I believe that if this permit goes forward any waste that is on that list should be stricken from it and we should be told this. I'm not saying that just because of chemical is on the list that they are receiving it, had received it or intend to receive it, but the possibility that they will receive it is there and if it does contain any dioxin -- and I here again you may through at me a threshold of let's say 20 parts per billion or something like that, if that's What the thing is, if there is indeed a threshold under which waste can be contaminated with dioxin, that allows it to come onto that site, fine, but let's be public with it. Let's clarify in the permit. Let's tell the media. Let's tell the people around in this area that yes, they can bring dioxin into the facility. So, that's on the record now, I hope. I would like to have clarification of dioxin bearing waste."

Response to 17P:

We agree that some clarification is appropriate, and have also modified the language of the permit, as described in the response to 14G.

Our use of the term "dioxin bearing wastes" was intended to refer to the U.S. EPA waste codes designations F020, F021, F022, F023, F026 and F027, wastes which are known to bear concentrations of dioxins/furans so high as to warrant special regulation. The special standards required of these wastes include the requirement that, if incinerated, they be incinerated in a device that demonstrates 99.9999% destruction and removal efficiency (DRE) for wastes of that type. Because the WTI facility has not attempted to demonstrate 99.9999% DRE and it does not meet the 99.9999% criteria, VRA/WTI is not permitted to incinerate waste codes F020, F021, F022, F023, F026 and/or F027.

It is true that there are other hazardous wastes which may contain dioxins/furans, but the U.S. EPA's national regulations do not require 99.9999% DRE, evidently reflecting the lower concentrations of dioxins/furans in these materials. The regulations do not prohibit these wastes from being burned at VRA/WTI. However, if the waste carries any of the federal hazardous waste codes which are required to meet land disposal restriction "LDR" treatment standards for dioxins/furans, such as F032, K043, and K099, the waste must meet those standards prior to incineration. Other wastes are considered by U.S. EPA to typically contain insignificant levels of dioxins/furans and may be incinerated without pretreatment to meet LDR. The very restrictive U.S. EPA "land disposal restriction" standards (adopted by Ohio in OAC 3745-270-40)--generally provide concentrations at which a waste could be land disposed, or in some cases requirements for pre-treatment by specified technology. Wastes meeting the LDR treatment standards generally contain dioxin and/or furan in concentrations of less than 1 or 2 ppb TEQ.

The case of Agent Orange, as mentioned in the comment, provides a good example of how this would work. Agent Orange was reportedly an approximate 50/50 mixture of 2,4,5-trichlorophenoxyacetic acid ("2,4,5-T") and 2,4-dichlorophenoxyacetic acid ("2,4-D"). It is our understanding that in the manufacture of these compounds, the synthesis of the 2,4,5-T commonly resulted in a product that was highly contaminated with dioxins (primarily 2,3,7,8). The synthesis of 2,4-D, on the other hand, was much less prone to significant dioxin/furan contamination. When the U.S. EPA listed 2,4,5-T and 2,4-D as hazardous wastes, it gave 2,4,5-T the waste code F020 (which, as discussed above, requires 99.9999% DRE). A waste carrying the waste code F020 is prohibited from incineration at VRA. However, the U.S. EPA did not require 99.9999% DRE for 2,4-D. The waste code for 2,4-D is U240. A waste containing the waste code U240 may be incinerated at VRA/WTI without restriction, since it is considered by U.S. EPA to contain insignificant levels of dioxin.

17Q) "The second thing that really bothers me -- here is why I want you to deny the permit -- I can't argue technically, that monitoring that you folks do up there with the equipment that's on the stack, the equipment -- well, it's not on the fence line -- the equipment that's up there, I can't say that that isn't state-of-the-art. Although I believe there are other monitoring systems. I read once about a laser that shoots across a fence line, this, that and the other. But we had a meeting, Pat and, Frank, you were there up at the old port authority where your offices is and during that meeting, we talked about your monitoring. And in the permit thing that you go to great lengths to talk about tighter monitoring, we discussed this and, I think kind of grudgingly, you admitted to us in the meeting that your monitoring, for the most part, is reactive, you react to something. You may have monitoring equipment that is grabbing samples out of that stack, frequently, but you don't know that until several hours later when you sit down at a computer and you ask to see what came out of that stack. You can't unring a bell. Once it's out there, you can detect it. It may show up on monitoring. I'll give you that, but it's too late. I used to get the quarterly emissions reports for -- it was opacity, carbon monoxide, sulfur dioxide -- I don't know -- eight or nine chemicals. I can honestly say to you that I don't think I ever once got that quarterly emissions report that there weren't repeated, repeated violations in at least one, and usually more than one, of those listed monitored substances. And quarter after quarter after quarter this would go on. You were

monitoring but it was all already done. And tonight, Alonzo sat there and talked to you and tried to get you to explain to us fugitive emissions and fires and you admit that you relied on what the company provided you. And how did they provide that? You said that someone went out into the neighborhood with a meter, some type of a monitoring device. And you said that on occasions, you and the other young lady from that office had gone ridden around the neighborhood. Were you and the other young lady riding around in your EPA vehicle while the incident was occurring? Or did you do it after you reported down to your office at 9:00, had a cup of coffee, got the information then said, oh, let's go out and ride around in the neighborhood, six to eight hours after the event? We've had fires down there occurring in the a.m. hours, one, two o'clock in the morning, repeated fires. Two o'clock in the morning fire, you come down here and ride around East elementary at 10 o'clock in the morning, you don't pick anything up? Duh. Winds been blowing. For eight hours the winds been blowing. Of course it's not in the neighborhood. God knows where it is. In summation, your monitoring equipment and the parameters that you have set up for this facility may be the best that money can buy. It may be the best that you are willing or able to put on this thing, but I submit to you that most, if not all, of your monitoring is reactive. It is not proactive. It is not preventative. It is just after the fact. The bell has been rung. So, I say to you, you are not protecting public health. You are merely a witness to the possible decline in the public health and safety of this area. And I urgently request you - - although, it says when permit is renewed. Who is the figure in mythology? Is it Sisyphus? The one that keeps pushing the great big boulder up the hill. Our shoulders are starting to slope like this (demonstrating) and we've got callouses from leaning up against that boulder. I wish you folks would be on our side. Thank you."

Response to 17Q:

You are correct that Ohio EPA cannot always be aware of incidents and emission exceedences as they are occurring. It is the responsibility of the facility to operate in accordance with their permit. Ohio EPA and U.S. EPA believe that the RCRA permit is protective and should not have any adverse health consequences for residents living near the incinerator. Trial burns test the operation of the incineration system under worse case scenarios to establish operational parameter limits and conditions to achieve complete combustion of the waste fed and to comply with regulatory standards. The risk assessment examines risk to the community using the information obtained through trial burn testing. The emission limits or feed rates are adjusted when necessary to best protect human health and the environment. At Von Roll America each incident is investigated to determine its significance relative to the facility's permit and Ohio laws and regulations. If appropriate, a violation is cited which may or may not lead to escalated enforcement. Our record of incidents at the Von Roll America facility has been evaluated and the Ohio EPA has determined that state renewal standards for compliance have been met.

VRA/WTI remains one of the most stringently monitored facilities in Ohio, both out of regulatory interests and out of respect for citizens' concerns regarding this facility.

PERMIT CHANGES RESULTING FROM APPROVED PERMIT MODIFICATIONS:

Several changes to the Permit as a result of permit modifications approved since the draft permit issuance on January 24, 2003 are detailed below.

- A) On June 3, 2003, Ohio EPA received VRA/WTI's request to modify Section C (Waste Characteristics and Waste Analysis Plan) of the approved Part B permit application to add information to fully describe the facility's Loose Pack Program. This permit modification request was approved on October 28, 2003. As a result, permit condition A.27.(c) was marked "RESERVED".
- B) On May 20, 2004, Ohio EPA received VRA/WTI's request to add a Quality Assurance and Quality Control Plan to Section C (Waste Characteristics and Waste Analysis Plan) of the approved Part B permit application. This permit modification request was approved on October 8, 2004. As a result, permit condition A.27.(c) was marked "RESERVED".
- C) On January 6, 2004, Ohio EPA received VRA/WTI's request to correct inconsistencies identified in several sections of "Part B" of the permit application. The modification revised pages in Section D to include two already permitted units, the extruder and the pusher, as miscellaneous units and pages in Section C to include two already permitted units, the filter press and shredders, as miscellaneous units. This Class 1 permit modification request was acknowledged on March 18, 2004. On February 9, 2004, Ohio EPA received VRA/WTI's request to correct inconsistencies between the "Part A" and sections of the "Part B" of the permit application. This modification changed the classification of two units, the filter press and the shredder, from treatment units to miscellaneous units. This Class 1 permit modification request was acknowledged on March 2, 2004. As a result of these permit modifications, the extruder and pusher units were incorporated into Section F (Treatment in Miscellaneous Units) of the renewal permit.
- D) On January 14, 2003, Ohio EPA received Von Roll America's request to terminate carbon feed to the primary neutralization tank N -1. The addition of activated carbon to N -1 was intended to control mercury emissions from the incineration system. In order to control mercury emissions, VRA/WTI will limit the amount of mercury fed into the incineration system. Prior to approving this permit modification request, Ohio EPA required VRA/WTI to demonstrate through performance testing that this change would not affect the capability of the incinerator to meet permit emission limits for dioxin/furan emissions. This permit modification request was approved on February 5, 2003. As a result permit conditions I(A).1.(b)(xi) and I(A).3.(s)(iii) were marked "RESERVED" and Permit Attachments 1 & 3 revised.
- E) On January 14, 2003, Ohio EPA received VRA/WTI's request to reduce the activated carbon currently injected into the incineration train via the Enhanced Carbon Injection System. The activated carbon is intended to control emissions of dioxins and furans at the stack. On May 8, 2003, and July 30, 2003, Ohio EPA and U.S. EPA, respectively, approved a permit modification request to reduce the carbon flow rate that was injected into the incineration train via the Enhanced Carbon Injection System (ECIS). Prior to approving the modification, the Ohio EPA required VRA/WTI to conduct a mini-burn or stack test to demonstrate compliance

with dioxin/furan emissions at the reduced carbon feed rates. The test was conducted during the week of October 21-25, 2002. The test results, which were the lowest dioxin emissions ever recorded for VRAWTI, demonstrated emission levels well below all applicable limits established for hazardous waste incinerators during normal operating conditions. Terms and conditions were required as part of the modification approval. Language was included to require more frequent dioxin/furan testing than MACT requires and that will trigger additional testing if certain conditions occur. As a result of this permit modification, permit condition I(A).3.(h) was revised.

- F) On March 25, 2004, Ohio EPA received VRAWTI's request to feed activated carbon to the Enhanced Carbon Injection System at the rates demonstrated during the MACT Comprehensive Performance Test/Trial Burn (CPT/TB) conducted in September and December of 2003. The permit modification request was approved on April 8, 2004. As a result of this permit modification, permit condition I(A).3.(r) was revised.
- G) On September 4, 2003 Ohio EPA received VRAWTI's notification which implemented the change to the calibration frequency for the scales which monitor the feed rate of activated carbon to the Enhanced Carbon Injection System (ECIS). Ohio EPA acknowledged this change on September 24, 2003. As a result of this permit modification, the calibration frequency for the ECIS has been changed to monthly on Permit Attachment 3.
- H) On July 8, 2004, Ohio EPA received VRAWTI's request to store off-site generated Lab Pack waste for up to a year and beyond a year provided such storage is solely for the purpose of accumulation of such quantities of hazardous waste as are necessary to facilitate proper recovery, treatment, or disposal. This permit modification request was approved on November 26, 2004. As a result of this permit modification, permit condition C.1.(a) was revised.
- I) On June 28, 2004, Ohio EPA received VRAWTI's request to commence blending of containerized waste in the pump-out tanks for the purpose of off-site transfer or fuels blending. This permit modification request was approved on July 1, 2004. As a result of this permit modification, permit condition D.1.(c) was revised.

PERMIT CHANGES RESULTING FROM CORRECTIONS

Several other changes to the Permit were made as clarifications or corrections to the draft permit and are detailed below.

- A) Although VRAWTI cannot accept compressed gases as a waste stream, compressed gases used as a propellant in aerosol cans may be treated by incineration at the VRAWTI facility. This is clarified by making corrections to permit conditions I(A).2.(a)(iv) and I(A).2.(c)(vii).
- B) VRAWTI completed the Hazardous Waste Combustor MACT requirement to

perform a Comprehensive Performance Test and submitted a Notification of Compliance (NOC) on March 18, 2004. As a result permit condition I(A).11 has been removed.

- C)** Information on the "metal feed rates" system parameter was inadvertently left off of Attachment 3 to the Permit and has been included.

JN/ims
Responsiveness Summary VRA012805

Attachment A

**Letter from Halstead Harrison, Assoc. Professor of Atmospheric Sciences,
University of Washington, Seattle WA, dated April 6, 1999
(As referenced in the Response to Comment 16A.22)**

ATTACHMENT A

(From electronic copy of letter)

April 6, 1999

The Honorable Carol M. Browner
Director, US Environmental Protection Agency
401 M Street SW
Washington, DC 20460

Director Browner:

This letter is stimulated by my after-reflections upon two experiences serving with EPA's Risk Assessment Forum as an academic technical expert evaluating the risk-assessment process, and its resulting reports concerned with toxic waste incineration. These exercises, I judge, were not successful, and their results not likely to help with sensible decisions. I discuss the problems leading to this conclusion, and suggest reforms.

Respectfully,

Halstead Harrison
Associate Professor,
Atmospheric Sciences
University of Washington
Seattle, WA 98195-1640
<harrison@atmos.washington.edu>

Public concern and congressional mandate require assessments of risks to public health associated with toxic waste incineration. A consulting industry provides these assessments, following guidelines from the Environmental Protection Agency [EPA].

Responding to the national interest, new money flows into the science of risk assessments, and new research improves the precision and depth of the data and of our understanding of the many processes affecting risks. The evolution of public concerns is also dynamic, but this process has been marked by partiality and litigation. As each new guideline-influenced assessment appears... too often after the facilities are built and the momentum of commitment too ponderous to reverse ...critics appear to challenge both the assessment and the facilities on grounds of faulty protocols and neglected risks. This irritates managers facing pressing choices about what to do with the toxic wastes, who are frustrated by regulatory mandates that not unreasonably appear to be transitory and politicized.

The "Old Paradigm":

As they evolved through about 1996, guidelines for risk assessments of toxic waste incineration progressively concentrated on emissions of mercury, cadmium, and lead, and certain organic carcinogens, particularly dioxins, furans, and related chlorinated polycyclic molecules. Ironically, some of these molecules are not only inherent in the raw toxic wastes but may also be produced when chlorinated compounds [most plastics, insecticides, and herbistats] are burned at intermediate temperatures [400-600F].

It has been thought that the most likely pathway through which emitted metals and persistent carcinogens may affect human health is through deposition onto the soil and leafy food crops, followed by biological concentration and

accumulation in animal and human fatty tissue. Formal risk assessments typically estimate the incremental cancer risks through this path to be one or fewer "extra deaths" per million persons exposed over a lifetime [$1:10^6$]. Note for contrast that about a third of us die of cancer [1:3]. Many other natural risks in our lives [tornados, lightning, hurricanes, ..] also carry risks to the general population on the order of $1:10^6$, and this level is generally thought "acceptable", at least by those not living in affected communities.

These latter, however, typically divide into advocates concerned with business values and job production, which are not negligible benefits, and "nimby" critics who not unreasonably point out that increments of imposed risk, however small, are not voluntarily accepted by the local sub-population at greatest risk, and that if normalized by the smaller numbers of this at-highest-risk local group, the formal risk estimates increase beyond $1:10^6$, by orders of magnitude.

A Trap:

As it evolved, the "old paradigm" fell into a semantic, political, and statistical trap. In the presence of very large uncertainties ...both in the data and in the complex processes of emission, dispersion, deposition, ingestion, accumulation, and cancer induction .. it was initially hoped that if the risk-modelers were to accept pessimistic [through still plausible] upper-bound estimates at each step, and if the resulting risks then appeared acceptably small, [less than or on the order of $1:10^6$], then relatively quick, simple, and cheap modeling efforts would be adequate to assist decisions affecting proposed projects, before heavy commitments were made on their construction. In the jargon of the trade, such estimates are called "conservative".

In the last years of the "conservative" administration of President George H.W. Bush, however, [1990-1992], "fiscally conservative" economists in the Office of Management and Budget [OMB], correctly pointed out that "conservative" estimates carry costs of delay or exclusion of otherwise desirable projects, or of excessive investment in pollution control apparatus and governance. This is undeniably true.

Responding to the criticism, the EPA convened yet another panel of competent people to advise yet another revision of the guidelines to be followed in formal risk assessments. That panel advocated, in effect, that risk estimates should no longer be "conservative", but "central". That is, "best" guesses should be used at each step of a supposition chain, not plausibly worst guesses, and these should be accompanied by an additional formalism to assess the uncertainties of estimated risk factors. In 1994 directives from EPA mandated this practice, somewhat ambiguously, but as of 1999 the revised guidelines are not well specified, and recent risk assessments generally do not include specific, formal, and numerically expressed estimates of the uncertainties associated with estimated risks.

One reason for this regulatory lag is that the uncertainties are embarrassingly large. In the case of cancer risks from dioxin emissions through the complicated processes of dispersion, deposition, and ingestion into and through food chain, those uncertainties certainly exceed factors of 10, and likely exceed factors of 100. Thus, a "central" $1:10^6$ lifetime cancer risk might in fact plausibly lie in the range between $1:10^4$ and $1:10^8$. The first of these ratios is considered unacceptable, the second trivial, but how does one wisely choose between them? Are analyses with these uncertainties at all useful?

Another reason for regulatory lag is, interestingly, that the newer, "central", estimates are coming in at about the same levels as the older, "conservative" guesses. Newly perceived risk paths have been added at about the same rate as the older conservative risk estimates have been centralized. That $1:10^6$ ratio seems almost a constant of nature: obviously riskier facilities are cut-off early, and obviously safer ones bypass the formal process entirely.

In this situation, what should honorable decision makers do?

Of what value is a formal risk assessment with such broad uncertainties? Some of those studies cost millions. What do we get for our money?

A Shifting Paradigm:

Meanwhile, back at the scientific farm, the risk paradigm has been shifting from nearly exclusive concerns over cancers mediated by dioxins to expanded concerns over the hormone-like behavior of many of these and similar compounds, which appear to affect sperm production and fetal development in many species, including ours. The supporting evidence for these worries is somewhat ambiguous, and perhaps alarmist. But if the claims are approximately correct then other risks than cancers are significant, and should be accounted for.

Further, quite recent studies alert us to the high and growing incidence of childhood asthma, and to convincing associations between emergency-room admissions for asthma, bronchitis, and related stresses, and acute air-pollution episodes characterized by high levels of PM2.5 [aerosol particles with aerodynamic diameters less than 2.5 micrometers].

Unlike the cancers, where incremental risks even as large as $1:10^4$ cannot be detected in the presence of a natural back-ground of 1:3, it appears that childhood asthma [with a baseline incidence of 1:10] and adult congestive pulmonary distress [ACPD], which in many cases may be the same thing with a different label, are "canary" symptoms, where .. unlike the cancers .. statistically significant impacts of air pollution upon both health and mortality can be detected in cities with populations exceeding 10^5 . If this emerging paradigm proves correct ... as appears likely ... then asthma and ACPD should also be accounted for in formal risk assessments.

Dose-Damage Curves:

One confounding concern of the "new paradigm" is that acute distress ... as from asthma ... is sensitive to relatively rare

[a few events per year] episodes of severely degraded air quality, not just to cumulative exposures, as has been assumed

to be the case for the cancers. The dose-damage curve for asthma is likely non-linear, with lower thresholds below which our systems do not usually trigger strong immune responses, and higher dose levels at which progressively larger numbers of persons may be acutely affected, at rates that are more than proportional to added doses.

One effect of this non-linearity is to accentuate concern for disadvantaged sub-populations at higher-than-normal risk. Thus, a $1:10^6$ risk for the population at large, may be $1:10^5$ for all children, and $1:10^4$ for asthmatic children. [Cancers are so prevalent as generally to have been assumed a common blight, with approximately uniform risk to most people. Recent genetic studies question this, however.]

Another effect is to focus air-quality modeling on episodes, rather than long-term averages ... a distinctly harder task.

Forward and Backward Risk Estimates:

A "forward" risk estimate begins with a list of troubles, assigns probabilities to each, and combines these, using standard probability theory for serial and parallel processes. A "backward" estimate looks at a climate of troubles abstracted from real measurements of historical facilities and events. Insurance firms typically operate with backward risk estimates. New technologies are forced into the forward mode, because there are no historical data.

Interestingly, when the two approaches may finally be compared with one another, it too often appears that the forward estimates overlooked a set of serious troubles, or underestimated their severity. Egregious examples of this bias include the wildly optimistic estimates leading to the Challenger and Chernobyl tragedies. For both of these, forward estimates were low by factors of 10^2 . The common failing appears to have been neglect of stupidities, or "pilot error". We naively assume that the processes operate as we have designed them, that we are rational, and that others are too.

Note that risk analyses of toxic waste incineration are performed in the forward mode.

Cost-Benefit Analyses:

We all act upon informal and largely subconscious risk and benefit assessments, but economists stumble when trying to reduce these choices into quantifiable numbers. With toxic waste incinerators, some of the benefits may be measured in dollars that need not be spent in more expensive ways. Capital and labor costs can also be measured in dollars. But costs associated with externalized health risks are not well expressed in dollars, and attempts to do so risk Dr. Strangelove excesses and a repellent algebra when attempts are made to optimize "extra deaths per dollar".

What is the dollar cost of a premature cancer death? Do you count it as a benefit that social-security costs are diminished? [NO!]

What are the dollar costs of increased incidence of childhood asthma? Are these greater than with adult congestive pulmonary distress ... essentially the same disease ... because the child is young? Or less, because the society "saves" on educational costs? [NO!] What are the dollar denominated costs of degraded scenic views? Of eagle-shell fragility modulated by DDT?

Our tort system indeed struggles to assign dollar-measured prices to these costs, but the "coefficients" [dollars/death, dollars/view, dollars/eagle] are at best subjective, controversial, and unstable.

At The Margin:

In "Economics 101" it is taught as axiomatic that wise decisions are best made "at the margin". That is, one should consider the prospects of additional gain or loss, with respect to additional costs, and that "sunk" costs should not be weighed in present decisions for additional investment with prospect of gain, or additional insurance with prospect of loss.

This principle also holds with risk assessments: we are concerned with added risks above present baselines, and added costs of ameliorating those risks. But baseline data .. as for example of present air-pollution levels, or cancer rates, or asthma incidence .. are usually poorly known and not discussed. This is particularly poignant in rustbelt communities that are often characterized by lower-than-average educations and incomes, and a higher-than-average incidence of smoking and obesity, cancers, and childhood asthma.

"Peer" Reviews:

The stimulus to this essay was the author's involvement over several years as an external, scientific "peer reviewer" in two formal, EPA sponsored risk assessments, one concerned with a very large commercial toxic waste incinerator at East Liverpool, Ohio, the other with soil incineration at a superfund site at Lock Haven, Pennsylvania. The "peers" were narrowly charged with reviewing risk-assessment documents, prepared by engineering firms under contract with the EPA, primarily as to whether those contractors had adequately conducted their assigned tasks. Our participation in the definition of those tasks was minimal, and ineffectively late in the risk-assessment process. We were not asked to recommend acceptance or rejection of the assessments as a whole, or of their executive summaries, as would have been so were we "peer reviewing" papers submitted for publication, or research funding by federal agencies.

Community interest in our review process was high, and was somewhat misled into an expectation that these reviews provided a last "scientific" chance to deflect the projects. Sadly, a common theme in both communities was a projection onto the EPA as being more in alliance with the projects' sponsors than with protecting citizen interests.

This projection was cast with intense emotion and directed into personal attacks on the professionalism and integrity of EPA staff. Still more sadly, some of these charges were true.

My Opinions:

In the light of all these difficulties and concerns, it seems to me that:

1. The risk assessment process, as it presently operates, damages the EPA without assisting wise decisions.
2. The process is too late, too slow, and the uncertainties are too large. Diverse risks to health and the environment cannot sensibly be expressed in commensurate units. Health and deaths are not well measured by dollars, nor scenic views, nor eagles. Assessments that attempt non-dollar risks are intrinsically subjective. Assessments that neglect them are incomplete.
3. This facility is perceived by project sponsors, who largely ignore formal risk-assessments except as irritating regulatory interference: thus, we perpetuate a climate of managerial derision and evasion.
4. This facility is also perceived by regulators, where risk assessment processes grind on long after decisions have been effectively committed by heavy investments in the facilities assessed.
5. Citizens correctly perceive the process as "spin" for decisions already taken.
6. Costs and benefits are distributed to different populations. Some win, others lose. It is naive to assume that disparities between winners and losers impedes the historical, natural, and democratic process of dumping our troubles into others' back yards. Thus toxic waste incinerators are typically sited in already poor communities with high base rates for cancers and asthma.
7. There is an ethical difference between freely accepted risks, as from ski accidents, and imposed risks, as from toxic waste incineration. Stricter standards should be assumed when decision makers impose risks on non-consenting citizens who do not share in compensating benefits.
8. I have not discovered any approximately fair way around the problem of inequitably distributed costs and benefits. It is a reasonable seeming [at least to me] suggestion that compensating benefits might be invested within affected communities ... as for example through subsidies to emergency-room care and "Medic-One" services. But this suggestion is strongly rejected by all my acquaintances among the decent people who actively oppose toxic-waste incineration. If your child has cancer you want zero risks, the incinerator closed, and the rascals punished.

I recommend:

1. Risk assessments should be initiated before major capital investment, and compressed into weeks, not years. In the presence of large uncertainties, early and brief are better than late and wordy.
2. The EPA's guideline process for risk assessments excessively lags the science. Catch up is necessary.
3. Risks and benefits should be estimated at the margin. This requires baseline measurements of both air-quality and health in the affected communities. Usually, these data are missing. A vigorous program to collect and assess the baselines should be started in the earliest stages of any risk assessment process.
4. In addition to estimating risks to whole populations, we should estimate them also to identified sub-populations at exceptional risk, as for example asthmatic children.

5. The EPA should accept continuing responsibilities towards communities affected by toxic waste incineration. Health and air-quality studies should be improved where necessary .. often greatly improved .. to evaluate effects of the facilities on those communities.
6. Air-pollution modeling and observations should be tilted towards understanding the frequencies and severities of severely stagnant episodes, rather than towards longer-term averages and their standard deviations.
7. Peer reviewers of risk-assessment documents should be asked whether the executive summaries correctly reflect the peer consensus, and whether the assessments as a whole should be accepted or rejected, as usefully contributing to wise decisions.
8. The EPA should with high priority study the effects of aerosols and odors upon asthmatic children.
9. Toxic waste incinerators should not be located on flood plains of narrow river valleys, close to housing and schools.

.....End of Harrison Letter.....

Attachment B

**Memo from Timothy Fields Jr., Assistant Administrator for the Office of
Solid Waste, U.S. EPA, Washington D.C., dated January 19, 2001
(As referenced in the Response to Comments 7F and 15F)**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

JAN 19 2001

MEMORANDUM

SUBJECT: Response to the Preliminary National Ombudsman Report on Waste Technologies Industries (WTI) East Liverpool, Ohio dated October 20, 2000

FROM: Timothy Fields, Jr. *Timothy Fields, Jr.*
Assistant Administrator

TO: Robert J. Martin
National Ombudsman

I have reviewed the Preliminary National Ombudsman Report on Waste Technologies Industries (WTI), East Liverpool, Ohio, dated October 20, 2000. Although you have not responded to the questions I sent to you in my memorandum dated November 3, 2000, where I requested clarification on a number of issues in your report, I am nonetheless sending you my more detailed comments on the report. For purposes of today's memorandum, I will assume that my previous understanding of the facts in this matter is accurate, since you have sent me no reply to the contrary.

I fully support and am attaching the detailed comments of Francis Lyons, Regional Administrator, EPA Region 5, Elizabeth Cotsworth, Director, EPA Office of Solid Waste, and Dr. Dorothy A. Canter, Science Policy Advisor for OSWER.

My main concerns with your report fall into two categories, substantive concerns with the assumptions you use to support your findings, and procedural concerns with the way you conducted this investigation and released your preliminary draft report.

Substantive Concerns

In analyzing your report, it appears that your recommendations to cease feeding waste into the incinerator for a period of no less than six months, and schedule a re-test of the trial burn, are based on findings that are not supported by the facts in this case. I will summarize

several issues below; however, the attached, detailed comments further support my statements here.

1. On page 22 under the heading "Findings of Fact" you attribute to Congressman Kucinich of Ohio statements that WTI "continues to burn toxic waste and threaten the health of children" and that "[h]aving the WTI facility continue to burn 5 years after the expiration of its permit completely undermines the credibility of EPA's hazardous waste program." Your failure to comment in the report on the validity of the Congressman's statements leaves the impression that you endorse the comments as findings of fact.

I disagree with these statements. They are not supported anywhere in the report or in the administrative record. There is no discussion of any data or risk assessment that shows any threat to children's health. In fact, the WTI risk assessment included children's exposure pathways and parameters. These detailed analyses showed that no significant long-term cancer risks or adverse health effects would be expected for children potentially exposed to long-term emissions from WTI.

With regard to the permit expiration, we don't believe that having WTI operate under a permit that continues in effect pursuant to Congress' statutory design in any way undermines the credibility of the hazardous waste program. WTI is operating under a current legal Ohio permit. Also, the federal RCRA permit is still a fully-effective, enforceable federal document. The Administrative Procedure Act, 5 U.S.C. 558(c), and EPA's regulations, 40 CFR 270.51, provide that as long as the permittee files a timely and complete application for permit reissuance, the permit remains in effect even if the permitting authority does not issue a new permit by the expiration date. Therefore, as long as the permittee properly files for permit renewal (as WTI did), the facility is still subject to the conditions of its original permit and is still able to legally operate beyond the expiration date.

2. Throughout the report you confuse stack emissions measurements and ambient air monitoring. This leads to confusion and faulty conclusions.

You seem to believe that the trial burn was inconclusive, yielding compliance uncertainties, and uncertainties in the risk assessment. It appears that your finding that the trial burn was inconclusive is based on the presumption that NOVAA conducted the trial burn and/or that NOVAA conducted faulty ambient air monitoring that was part of the trial burn. As discussed below, it did not. In addition, you conclude that EPA's risk assessment and RCRA permit decisions were based on faulty data from quarterly lead testing. As discussed below, they were not.

I want to reply that we have thoroughly reviewed the decisions made at this site and find that there is no reason to question the trial burn, risk assessment or RCRA permit decisions for this facility. Nothing you provided in your preliminary report in any way changes our view of these decisions. As I will discuss in more detail in the section of the memorandum regarding procedural concerns, I believe that if you had reviewed more thoroughly the records regarding these issues, you would find that there is no evidence to support questioning the trial burn, risk

assessment, or the RCRA permitting decisions.

3. As to the issue of who conducted the trial burn. NOVAA did not conduct the trial burn. The trial burn was conducted by a company known as ENSR, based in Acton, Massachusetts under the oversight of EPA Region 5's hazardous waste program staff. ENSR both developed the trial burn plan which was approved by EPA Region 5 (after a public comment process), and conducted the trial burn testing. Although NOVAA may have been present as an observer, they played no role in the performance of the trial burn. The testing was also witnessed by the USEPA and its technical consultant, and by the Ohio EPA.
4. Also, ambient air monitoring was not required as part of the WTI trial burn, nor is it a regulatory requirement for hazardous waste incinerators. A trial burn is a test that measures stack emissions from an incinerator under certain operating conditions. Although ambient air monitoring was conducted at sites near the WTI incinerator simultaneously with the trial burn, it was not part of the trial burn process.
5. The WTI risk assessment was based on data from the trial burn as well as numerous performance tests conducted after the trial burn. The only use of ambient air monitoring in the calculation of risk in the WTI risk assessment was for background lead data. These data were one factor considered in calculating potential blood lead levels based on several exposure pathways. While EPA has not been able to rule out the possibility that these background lead data may have included data from testing done by NOVAA, EPA subsequently confirmed the risk assessment without resort to this data by using its traditional conservative default lead values.
6. Your report also discusses concerns regarding data from quarterly lead testing which you apparently believe were used in RCRA permit decisions and/or in the WTI risk assessment. The lead testing you refer to was not used in the RCRA permitting decisions or the risk assessment. EPA based its lead emission limits and lead risk calculations on lead emission information from the RCRA trial burn test conducted in 1993, not from the testing you refer to in your report.

As I stated above these issues and others are discussed in greater detail in the attached comments.

Procedural Concerns

As I discussed above, in general I believe that if you had reviewed more thoroughly the records regarding these issues, you would have found that there is no evidence to support the recommendations you made in the preliminary draft report. Regarding thoroughness, I have several specific concerns:

- Neither you nor your staff visited Region 5 or interviewed Region 5 staff, who are by far the most knowledgeable and have the most records regarding the key areas you examined, especially the trial burn and the risk assessment. (For example, Region 5 has records showing that ENSR

conducted the trial burn.)

- Neither you nor your staff consulted with peer reviewers of the risk assessment regarding your preliminary findings before you came to your conclusions. In addition, I believe that if you had consulted with experts in the field of incineration, you would have been able to correct flaws in your findings before completing your preliminary draft report. For example:

- Your report at times fails to adequately distinguish stack emissions measurements from ambient air monitoring when in fact the two are entirely different types of measurements.

- Your report links issues with each other that in fact have no connection to each other, for example, the emissions measurements and ambient air monitoring I mentioned above, the role of NOVAA in the areas you discuss, relationship of quarterly lead emissions testing to the RCRA permit decisions. If you had discussed your concerns with me or with Region 5 prior to releasing your report, we could have corrected your incorrect assumptions regarding these issues.

I am also concerned about how well you kept parties informed about the process you were following, and how much time you gave parties to respond to your requests, as follows:

- Failure to ensure that information submitted in response to your inquiries was distributed to the entire service list;

- Failure to give adequate notice of the public meeting and to notify people that they were expected to give testimony; and

- Failure to provide adequate time for responses to your inquiries.

Again, many of these concerns are also discussed in the attached, more detailed comments.

In the future, I would suggest that it would be better to give the necessary time and attention to these kinds of issues before publicly releasing findings, conclusions and recommendations.

Finally, I believe many of these problems could have been avoided if you had provided me, and perhaps others, with a draft of your report to review before you released it to the public. I believe that the release of this report with all of its inaccuracies and misleading information caused great concern and fear on the part of the community that was completely unwarranted by the facts in this matter.

I recommend that in preparing your final report on WTI and other matters you are investigating, that you seriously consider the recommendations I am making in this memorandum.

OSWER response to community concerns about the WTI incinerator

Although for the reasons I have stated above I disagree with the findings in your report, I continue to be committed to ensuring that we have the best data possible about this facility and

the community surrounding it. To ensure that, I have taken several steps.

1. Teams of experts have conducted 5 rounds of ambient air sampling and 2 rounds of soil testing in the East Liverpool community and specifically around East Elementary School. As the results of that sampling have come back from the laboratories and been checked for quality assurance and quality control, I have made those results available to the public by issuing press releases and posting the data on our web site at www.epa.gov/oswer under what's new.
2. I along with experts from Region 5, ERT, OAQPS, and my staff have reviewed the results of that sampling with the help of health experts at the Agency for Toxic Substances and Disease Registry (ATSDR). None of the results indicate that there are any immediate threats to the community.
3. Although not at levels of immediate concern, during the sampling I discuss in item 1 above, we did detect some constituents in our ambient air sampling that caused us to want to gather further information. Because of that, we sent information requests to several industries in the area that could be potential sources of the constituents we detected. We are analyzing the responses to our information requests, and will take appropriate action based on those responses.
4. Region 5, along with a team of experts, is discussing the possibility of longer term ambient air monitoring to provide us and the community with a thorough understanding of air quality issues in the East Liverpool area.
5. We observed the annual performance test of the WTI facility in the month of November, and have determined that we have no reason to question the procedures WTI used to conduct that test. We will thoroughly review the results of that test as soon as they are available.
6. We have met with members of the community to discuss any suggestions they have regarding future performance tests or trial burns at the facility, and have met with WTI, the Ohio EPA, and other experts to design a MACT comprehensive performance test that will provide us with useful information about the facility, and inform Ohio EPA's decision regarding WTI's pending permit renewal decision.
7. Finally, we have sent experts in the area of emergency preparedness and prevention to meet both with WTI and with the community emergency planning/response officials to discuss emergency preparedness and prevention issues, and we plan to continue to provide support to the facility and the community in these areas as well.

As is evident from these actions, I and the career staff at EPA both in headquarters and in Region 5 are committed to ensuring the continued well-being of the surrounding community and their environment. I hope these actions will reassure the community that everything possible is being done to alleviate their concerns.

Attachments

cc: Frank Lyons, EPA Region 5
Michael Shapiro, OSWER
Elizabeth Cotsworth, OSW
Dorothy Canter, OSWER
George Frampton, CEQ

Attachment C

**Memo from Francis X. Lyons, Regional Administrator of
U.S. EPA Region 5, dated December 4, 2000
(As referenced in the Response to Comment 17A)**



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

DEC 04 2000

REPLY TO THE ATTENTION OF

MEMORANDUM

SUBJECT: Region 5's Comments on Preliminary National Ombudsman Report - Waste Technologies Industries (WTI) East Liverpool, Ohio - October 20, 2000

FROM: Francis X. Lyons, Regional Administrator
Region 5 *[Handwritten signature]*

TO: Timothy Fields, Jr.
Assistant Administrator

Region 5 has had an opportunity to review the EPA Ombudsman's October 20, 2000, Preliminary Report regarding the Waste Technologies Industries facility in East Liverpool, Ohio, and offers the following comments.

The Ombudsman's recommendations to conduct a new trial burn test and to require WTI to cease burning hazardous waste are based on the Ombudsman's finding that the trial burn was inconclusive, yielding compliance uncertainties and uncertainties in the risk assessment (See page 3, line 6 *et seq.*). The Ombudsman's finding that the trial burn was inconclusive was based on a presumption that the trial burn data was compromised due to irregularities in the testing. (See page 28, line 12 *et seq.*) This presumption of irregularities is based, in the report, on the presumptions that (1) NOVAA conducted the trial burn stack testing, and/or that (2) NOVAA conducted ambient air monitoring that was part of the trial burn, and that (3) the USEPA's risk assessment was based on certain quarterly stack testing conducted in or before 1996 which did not include the feed of lead into the incinerator. However, these last three presumptions are at odds with documented facts in this matter, as discussed below.

Factual Errors in Preliminary Report:

1. Factual Error #1

The WTI Trial Burn included ambient air monitoring. (See Preliminary Report page 25 lines 35 *et seq.*, quoting Mr. Zumpano; page 28 lines 12 *et seq.*)

Region 5 Response: This is not the case. A trial burn is basically a performance test¹ which compares what goes into an incinerator to what comes out of the incinerator, or evaluates what comes out of the incinerator under certain operating conditions. As such, a trial burn consists of waste testing and stack testing. Because the RCRA incinerator regulations contain no requirements regarding monitored ambient air quality, there is no requirement for ambient air monitoring as part of a trial burn. While ambient air monitoring might have been conducted simultaneously with the conduct of the WTI trial burn, it was not part of the trial burn. Neither the regulations nor the WTI RCRA permit contain requirements regarding measured ambient air concentrations².

- A) The requirements for a trial burn are clearly spelled out in 40 C.F.R. §§ 270.62 and 264.343. We have enclosed copies of these for your convenience. 40 C.F.R. § 270.62 describes the elements of a trial burn, and 40 C.F.R. § 264.343 describes the performance standards that must be demonstrated via the trial burn. You will note that there is no mention of ambient air monitoring in these governing rules.
- B) A trial burn must follow an approved trial burn plan, which the applicant develops (WTI in this case) and submits for approval by the USEPA or authorized state. We have previously submitted to the Ombudsman's office a copy of the approved WTI trial burn

¹The purpose of the trial burn for an incinerator is to demonstrate that the incinerator system achieves the performance standards in 40 C.F.R. § 264.343, which are 99.99% DRE, the applicable hydrogen chloride emission/removal standard of either 99% removal or 4 lb/hr, and the .08 gr/dscf particulate emission standard. Trial burns for incinerators are generally also used to establish removal efficiencies for various heavy metals, and to establish emission rates of dioxins/furans and other products of incomplete combustion, for use in risk assessment (sometimes this latter testing is referred to as a "risk burn" to differentiate them from the "trial burn"; a trial burn is more concerned with verifying compliance with regulatory standards, and a risk burn collects additional information needed to conduct a risk assessment.). Because such tests verify the performance of the equipment, they are termed "performance tests."

²Note that the BIF rule, 40 C.F.R. § 266.100 *et seq.*, is imposed on WTI via the RCRA permit. Although the BIF rule back-calculates allowable stack emissions based on certain theoretical ground level ambient air concentrations (referred to as Reference Air Concentrations and Risk Specific Doses), the regulations do not allow the use of actual measurement of ambient air concentrations for establishing stack emission limits in the permit.

plan. We have, for your convenience, provided a copy of pages 1-14 and 1-15 from that Trial Burn Plan, which lists all sampling/analysis proposed to be conducted during the trial burn. You will find no reference to ambient air monitoring on these pages or elsewhere in the governing trial burn plan³.

It is important to note that specialists in this field tend to use the term "air monitoring" to mean ambient air monitoring, but not stack testing. Stack testing (i.e., sampling and analysis of combustion gases) would not be included in the common usage definition of "air monitoring" because combustion gases are not "air."

The Preliminary Report concludes that the trial burn was unreliable (see page 28, line 12 of the Preliminary Report) due, in part, to irregularities in ambient air monitoring conducted with the trial burn. However, since the WTI trial burn did not rely on the results of ambient air monitoring, irregularities in such monitoring - to the extent there were any - did not affect the reliability of the trial burn.

2. Factual Error #2

NOVAA conducted the trial burn. (Implied in Preliminary Report, See page 26 of the Preliminary Report, line 26 *et seq.*)

Region 5 Response: This is not true. WTI and a company known as ENSR, based in Acton, Massachusetts, conducted the trial burn. ENSR is a consultant that was hired by WTI, having recognized experience and specialization in the field of trial burns. ENSR both developed the trial burn plan and conducted the trial burn testing. NOVAA did not conduct the trial burn testing⁴.

A) Enclosed is a copy of the approved Trial Burn Plan. On page 8-31 *et seq.* of that trial burn plan (a copy of these pages have been enclosed for your convenience) you will find a section entitled "Field Strategy" which includes a listing of the field positions needed for conducting the WTI trial burn tests, as follows:

"The ENSR field team will consist of a crew of ten (10) people for the trial burn. Field personnel are required for the following

³Although it is possible that ambient monitoring could be negotiated as part of the trial burn review/approval process, this is generally not done and was not done in the specific case of WTI.

⁴It is probable that NOVAA personnel observed the trial burn test; however, the USEPA and its technical consultant, and the Ohio EPA also witnessed the testing. Although there is a reference in the Preliminary Report to NOVAA as being the "primary agency for compliance" and the "lead agency", this would have been limited to the State air program.

positions:

- Field team leader/sample train setup and recovery;
- Method MMTL Train (metals) operator;
- Method 5 Train (Hexavalent Chromium) operator;
- Method 0051 Train (HCl) operator;
- Method 0050 Train (Particulate and HCl/Cl₂) operator (at stack);
- Method 0010/23 Train (semivolatile POHC and PCDDs/PCDFs) operator;
- CEM operator;
- VOST operator
- Process Stream Sampling Observer/Sample Custodian; and
- Stack Assistant.”

- B) Mr. Victorine of my staff witnessed a large portion of the trial burn testing at WTI. Mr. Victorine states unequivocally that ENSR conducted the stack testing. The ENSR project manager who directed the effort was Mr. Douglas Roeck, and his staff operated the actual stack sampling trains.
- C) The reports submitted by WTI on the technical findings of the trial burn make no mention of NOVAA conducting sampling. See Trial Burn Reports dated May 1993 and April 1994, which were forwarded to the Ombudsman's office on October 4, 2000. Page 3-1 of the May 1993 Report and page 3-2 of the April 1994 Report (copies of these pages have been enclosed for your convenience) provide staffing lists for the March 1993 and February 1994 trial burn tests, providing names and responsibilities of the actual individuals. There is no mention of NOVAA conducting sampling.

The Preliminary Report cites the testimony of Vincent R. Zumpano in questioning the reliability of stack testing allegedly performed by NOVAA during the trial burn, and thus to question the reliability of both the trial burn (see page 26, line 43 of the Preliminary Report) and the risk assessment (see page 31, line 3 of the Preliminary Report). However, since NOVAA did not perform the stack testing for the trial burn, there is no reason to question either the trial burn or the risk assessment on this basis.

3. Factual Error #3

Data from quarterly lead emission testing was used in RCRA permit decisions or in the USEPA Risk Assessment.(Page 27 of the Preliminary Report, line 19 *et seq* and Page 31 line 5 *et seq*.)

Region 5 Response: This is not true. The USEPA based the lead emission⁵ information which

⁵ The WTI risk assessment predicted risks based on the calculated impact of stack emissions, not on ambient air concentrations. Only one of the pollutants studied in the risk

was used in the WTI Risk Assessment on the RCRA trial burn test conducted in 1993 (See WTI Risk Assessment Volume III, page III-7, enclosed). U.S. EPA used the results of that Risk Assessment in setting the current lead limits in the federal RCRA permit.

The approved Trial Burn Plan (previously submitted to the Ombudsman's office as part of the RCRA permit) includes a detailed protocol for maximizing and quantifying the feed of lead and certain other metals while the stack testing is performed (See Trial Burn Plan page 5-10 *et seq.*). This does not appear to be the case with the testing discussed on page 27 of the Preliminary Report by Ms. Hilkens (now VanWalsen) of the State air program. In addition, because Ms. VanWalsen is from the air program and not the RCRA program, she may not have knowledge of RCRA policies on requiring new trial burns. (A trial burn is a specific RCRA test program, but not a CAA test program.)

The Preliminary Report argues that the Risk Assessment cannot serve as an effective check on the protectiveness of the permit (see page 30, line 37 of the Preliminary Report), in part because of irregularities found by OEPA during quarterly lead emissions testing. (See page 27, lines 19 *et seq.*, and page 31, line 3 *et seq.*, of the Preliminary Report.) However, since data from quarterly lead emissions testing was not used in the Risk Assessment, there is no reason to question the reliability of the Risk Assessment on this basis.

Other Issues and Clarifications:

1. The Preliminary Report refers to concerns raised at the National Ombudsman Hearing that the Risk Assessment did not take into account a worst case scenario for air inversions of extended duration in the valley in which the WTI facility operates or meteorological and climatological data that is representative of the valley in which the facility operates. (Page 31 lines 44 *et seq.*, of the Preliminary Report.) This is apparently a reference to the testimony of Ashley Schannauer at the hearing. Mr. Schannauer included similar comments in a letter (dated October 2, 2000) that he addressed to the Ombudsman. Region 5 strongly disagrees with Mr. Schannauer's comments and testimony in this regard. Page 8 of Region 5's response (dated October 18, 2000) to the Ombudsman's fourth set of interrogatories and requests for documents addressed the comments in Mr. Schannauer's letter of October 2, as follows:

assessment (i.e., lead) required the input of an ambient air concentration. In order to calculate projected blood lead levels for the purposes of a risk assessment, values must be entered for background air lead concentration, background drinking water lead concentration, and background soil/dust lead concentration. When the measured background air concentration for lead was later called into question, EPA subsequently confirmed the risk assessment using its traditional conservative "default" value for ambient lead concentration. (See USEPA's response dated October 13, 2000, to the Ombudsman's third set of interrogatories and request for documents.) Thus, questions about the reliability of ambient air lead samples collected by NOVAA would not be a basis to conclude that the Risk Assessment was unreliable.

"On page 4 of his letter, Mr. Schannauer states that "Health risks associated with calm wind conditions and inversions were excluded." This is not true. Effects of calm winds with inversion/fumigation were addressed in Volume IV, pages IV-11 through IV-19. A copy of these pages are enclosed with our response. Mr. Schannauer later, on page 5, admits that calms/inversions were in fact analyzed, but as a sensitivity analysis (i.e., looking specifically at how this change affects the results) as opposed to totally re-running all calculations. Mr. Schannauer seems to imply that this "sensitivity analysis" technique was inferior to his suggested approach, without any real explanation as to why.

"Mr. Schannauer suggests that one year of meteorological data is insufficient, but does not suggest how much additional certainty might be gained from additional data. For on-site meteorological data, one year is the amount typically used in risk assessments. U.S. EPA requires in 40 CFR Part 51, Appendix W (Section 9.3.1.2) either five years of National Weather Service data or at least one year of site-specific data. Pamela Blakley of U.S. EPA Region 5 has indicated that because of the cost of additional monitoring, facilities have not been required to obtain more than one year of site data.

"On Page 5 of his letter, Mr. Schannauer discusses building downwash, and then states that the impacts of downwash were not included in the risk assessment calculations. However, the risk assessment did address both building downwash (see page II-10-13 of Volume IV) and terrain induced downwash (see page IV-19-21 of Volume IV). The terrain downwash was addressed via sensitivity analysis. The conclusion stated in the risk assessment is:

"These comparisons suggest that concentrations produced by the methods used to treat terrain in ISC-COMPDEP are sufficiently conservative, and that the changes in peak concentrations attributed to terrain downwash on the basis of the wind tunnel simulations are sufficiently minor, that the ISC-COMPDEP modeling performed for the WTI facility does not need any modifications related to terrain downwash."

Concerns raised by Mr. Schannauer regarding the alleged failure of the Risk Assessment to take into account air inversions and adequate meteorological data should not be a basis to question the reliability of the Risk Assessment.

2. On page 26 of the Preliminary Report, in discussing an ambient monitor operated during the trial burn, Mr. Zumpano is quoted as saying that "...it should have been on, but it wasn't." However, the fact that the monitor was not running on a particular day is not necessarily determinative of incorrect procedure, as seemingly implied in the Preliminary Report. There may be legitimate reasons (such as resources) why a monitoring organization might choose to only operate ambient air sampling equipment on certain days.

The Preliminary Report made no attempt to establish Mr. Zumpano's expertise or knowledge in the field of ambient air sampling or stack testing, nor detail his responsibilities for NOVAA. Mr.

Zumpano is quoted in the Preliminary Report as follows: " - let's get things straight. I don't know anything technically about the operation of WTI The only thing I did for NOVAA was took air samples. . . . I must have worked for NOVAA for five years, and ever since I worked at NOVAA, all I heard was problems at WTI. And Patsy [DeLuca] would make him run trial burns, whatever that meant, over and over again..." Mr. Zumpano's testimony clearly establishes that he knew nothing about trial burns. The Preliminary Report does not discuss the effect of Mr. Zumpano's guilty plea to criminal charges on his credibility as a witness.

3. On page 25, starting at line 20, the Preliminary Report says

"In response to a National Ombudsman question with respect to the retrieval of data from monitors and the role of NOVAA, Mr. Victorine of Region 5 stated:
'It's possible. I don't know what staff of NOVAA might have been involved.'"

The Preliminary Report appears to use this answer as evidence that NOVAA performed stack testing and ambient air monitoring at the WTI facility during the trial burn and in the years following. However, the transcript shows that this answer was in response to the following string of questions regarding the collection of meteorological data from Mr. Martin:

MR. MARTIN: (Page 267 line 17) "...was local meteorological data used in the development of the risk assessment for WTI?"

MR. MARTIN: (Page 268 line 22) "I have a related question. Who ran those monitors?"

MR. MARTIN: (Page 269 line 12) "So you're not certain, but it's possible that NOVAA may have worked on those monitors in terms of retrieval of data?"

MR. VICTORINE: "It's possible. I don't know what NOVAA staff might have been involved."

It's apparent that Mr. Victorine's response pertained to meteorological monitors, not ambient air monitors. This conclusion is further strengthened by the use of the term "retrieval of data", which is something that one would do with a meteorological station, but not something one would do with this type of an ambient air sampling⁶ device. The transcript subsequently discusses meteorological data after the above exchange, again confirming that Mr. Victorine, in the remarks quoted above, was referring to meteorological monitors.

⁶An ambient air monitor such as this is a simple sample collection device. It collects a physical sample of the contaminants in the air, which is then removed and sent to a laboratory for analysis. It does not collect data. There are some more sophisticated types of ambient air monitors, such as those used for NO-x and SO-x monitoring, which actually conduct chemical analysis at the monitor and record the results as data. However, it is our understanding that the discussion in this report deals with monitoring for Pb and other metals, not NO-x and SO-x.

As you know, since that time, we have researched the matter and provided you information in our October 13, 2000, letter to your office showing there is reason to believe that NOVAA did not oversee stations WTI-1, WTI-2, or WTI-3, which collected the subject meteorological data at that time.

While Region 5 does not doubt that NOVAA was indeed involved in at least some of the ambient air monitoring that occurred simultaneously with the WTI trial burn, Mr. Victorine's statement should not be considered as verification of this.

Procedural Issues:

1. Failure to Circulate Draft Preliminary Report Within EPA Before Releasing It to Public.

EPA personnel were not given an opportunity to review the draft Preliminary Report for errors before it was released to the public. Region 5 believes that most of the errors described above could have been rectified if that had been done. There is apparently precedent for circulating a draft report for review within EPA prior to release. It is Region 5's understanding that the National Ombudsman agreed to allow EPA to review the Preliminary National Ombudsman Recommendations for the Industrial Excess Landfill Case, dated October 20, 2000, prior to its release to the public.

2. Omission of Interviews and File Review

The Ombudsman's Office made no attempt to visit Region 5 to interview the many staff who have been involved in the WTI case over the years, or even to conduct a file review.

Rather than reviewing the actual file, the Ombudsman's office chose to request that Region 5 copy and submit certain documents from its RCRA file. Originally, only a small portion of the overall WTI file was requested. On September 25, 2000, less than one month before the Ombudsman issued the Preliminary Report, an e-mail message from an ombudsman staff employee to a Region 5 staff employee requested that a copy of virtually the entire RCRA file maintained by the Waste Management Branch be sent to the Ombudsman's office. The RCRA file contains more than 2800 documents, some of which are more than one hundred pages in length. In response, Region 5 has, to date, sent groupings of documents from the file on September 29, October 11, October 20, November 2, and November 8, and continues to work on this massive photocopying project. By the time the Ombudsman issued the Preliminary Report, we had had the opportunity to submit only a small portion of the RCRA file.

It would seem that the Preliminary Report was based on a small portion of the available documents, and on the one hearing.

3. Insufficient Notice of Public Hearing

On September 13, 2000, the Ombudsman's office issued a notice of a public hearing to be held "concerning EPA's activities regarding the WTI hazardous waste incinerator" That notice contained no agenda, and simply stated in pertinent part: "Parties to the WTI Service List as well as citizens and other stakeholders in this case are encouraged to give written testimony in addition to any oral testimony that may be given." It was unclear whether the Ombudsman expected or desired testimony from Agency representatives. Despite assurances from the Ombudsman in correspondence dated May 4, 2000 that public hearings would be scheduled with at least two weeks prior notice, the notice provided that the hearing would be held on Saturday September 23, only seven working days from the letter. The Ombudsman's office did not specify the topics about which Agency representatives would be expected to give testimony until later. This short time frame provided insufficient time to prepare testimony for the hearing, and to evaluate who should attend on behalf of Region 5 and who was available to attend. Nevertheless, during the hearing, Mr. Martin chastised the Region for failing, in his view, to send appropriate technical experts. As it turned out, the questions raised at the hearing would have necessitated an expert in the meteorological data and air dispersion modeling techniques used in the WTI risk assessment among others, which we could not have guessed.

As of this date, the Ombudsman's office has still made no attempt to contact the appropriate technical experts at Region 5.

4. Brief Response Deadlines

Response deadlines for interrogatories issued by the Ombudsman became unreasonably brief, especially during the period immediately before and after the issuance of the Preliminary Report:

- Request for Statement of Issues, Evidence and Legal Authorities, May 4, due May 19;
- First Set of Interrogatories and Requests for Documents, June 16, due July 7;
- Request for Briefs, June 19, due July 7;
- Second Set of Interrogatories and Request for Documents, September 26, due October 5;
- Third Set of Interrogatories and Request for Documents, September 29, due October 6;

- Fourth Set of Interrogatories and Request for Documents, October 5, due October 11;
- Fifth Set of Interrogatories and Request for Documents, October 26, due October 30;
- Sixth Set of Interrogatories and Request for Documents, November 2, due November 9 [No interrogatories or requests directed to Region 5];

In addition, the Ombudsman's office sent an e-mail message on September 20, requesting a response to several questions by close of business September 28, further overloading staff. On September 25, 2000, less than one month before the Ombudsman issued the Preliminary Report, an e-mail message from an Ombudsman staff employee to a Region 5 staff employee requested that a copy of virtually the entire RCRA file be sent to the Ombudsman's office.

The Ombudsman released the Preliminary Report on October 20.

Attachments

Subpart O—Incinerators

§ 264.340 Applicability.

(a) The regulations of this subpart apply to owners and operators of hazardous waste incinerators (as defined in § 260.10 of this chapter), except as § 264.1 provides otherwise.

(b) After consideration of the waste analysis included with part B of the permit application, the Regional Administrator, in establishing the permit conditions, must exempt the applicant from all requirements of this subpart except § 264.341 (Waste analysis) and § 264.351 (Closure),

(1) If the Regional Administrator finds that the waste to be burned is:

(i) Listed as a hazardous waste in part 261, subpart D, of this chapter solely because it is ignitable (Hazard Code I), corrosive (Hazard Code C), or both; or

(ii) Listed as a hazardous waste in part 261, subpart D, of this chapter solely because it is reactive (Hazard Code R) for characteristics other than those listed in § 261.23(a) (4) and (5), and will not be burned when other hazardous wastes are present in the combustion zone; or

(iii) A hazardous waste solely because it possesses the characteristic of ignitability, corrosivity, or both, as determined by the test for characteristics of hazardous wastes under part 261, subpart C, of this chapter; or

(iv) A hazardous waste solely because it possesses any of the reactivity characteristics described by § 261.23(a) (1),

(2), (3), (6), (7), and (8) of this chapter, and will not be burned when other hazardous wastes are present in the combustion zone; and

(2) If the waste analysis shows that

the waste contains none of the hazardous constituents listed in part 261, appendix VIII, of this chapter, which would reasonably be expected to be in the waste.

(c) If the waste to be burned is one which is described by paragraphs (b)(1)(i), (ii), (iii), or (iv) of this section and contains insignificant concentrations of the hazardous constituents listed in part 261, appendix VIII, of this chapter, then the Regional Administrator may, in establishing permit conditions, exempt the applicant from all requirements of this subpart, except § 264.341 (Waste analysis) and § 264.351 (Closure), after consideration of the waste analysis included with part B of the permit application, unless the Regional Administrator finds that the waste will pose a threat to human health and the environment when burned in an incinerator.

(d) The owner or operator of an incinerator may conduct trial burns subject only to the requirements of § 270.62 of this chapter (Short term and incinerator permits).

[46 FR 7678, Jan. 23, 1981, as amended at 47 FR 27532, June 24, 1982; 48 FR 14295, Apr. 1, 1983; 50 FR 665, Jan. 4, 1985; 50 FR 49203, Nov. 29, 1985; 56 FR 7207, Feb. 21, 1991]

§ 264.341 Waste analysis.

(a) As a portion of the trial burn plan required by § 270.62 of this chapter, or with part B of the permit application, the owner or operator must have included an analysis of the waste feed sufficient to provide all information required by § 270.62(b) or § 270.19 of this chapter. Owners or operators of new hazardous waste incinerators must provide the information required by § 270.62(c) or § 270.19 of this chapter to

the greatest extent possible.

(b) Throughout normal operation the owner or operator must conduct sufficient waste analysis to verify that waste feed to the incinerator is within the physical and chemical composition limits specified in his permit (under § 264.345(b)).

[46 FR 7678, Jan. 23, 1981, as amended at 47 FR 27532, June 24, 1982; 48 FR 14295, Apr. 1, 1983; 48 FR 30115, June 30, 1983; 50 FR 4514, Jan. 31, 1985]

§ 264.342 Principal organic hazardous constituents (POHCs).

(a) Principal Organic Hazardous Constituents (POHCs) in the waste feed must be treated to the extent required by the performance standard of § 264.343.

(b)(1) One or more POHCs will be specified in the facility's permit, from among those constituents listed in part 261, appendix VIII of this chapter, for each waste feed to be burned. This specification will be based on the degree of difficulty of incineration of the organic constituents in the waste and on their concentration or mass in the waste feed, considering the results of waste analyses and trial burns or alternative data submitted with part B of the facility's permit application. Organic constituents which represent the greatest degree of difficulty of incineration will be those most likely to be designated as POHCs. Constituents are more likely to be designated as POHCs if they are present in large quantities or concentrations in the waste.

(2) Trial POHCs will be designated for performance of trial burns in accordance with the procedure specified in § 270.62 of this chapter for obtaining trial burn permits.

[46 FR 7678, Jan. 23, 1981, as amended at 48 FR 14295, Apr. 1, 1983]

§ 264.343 Performance standards.

An incinerator burning hazardous waste must be designed, constructed, and maintained so that, when operated in accordance with operating requirements specified under § 264.345, it will meet the following performance standards:

(a)(1) Except as provided in paragraph (a)(2) of this section, an incinerator burning hazardous waste must achieve a destruction and removal efficiency (DRE) of 99.99% for each principal organic hazardous constituent (POHC) designated (under § 264.342) in its permit for each waste feed. DRE is determined for each POHC from the following equation:

$$\text{DRE} = \frac{(\text{Win} - \text{Wout})}{\text{Win}} \times 100\%$$

where:

Win=mass feed rate of one principal organic hazardous constituent (POHC) in the waste stream feeding the incinerator and

Wout=mass emission rate of the same POHC present in exhaust emissions prior to release to the atmosphere.

(2) An incinerator burning hazardous wastes FO20, FO21, FO22, FO23, FO26, or FO27 must achieve a destruction and removal efficiency (DRE) of 99.9999% for each principal organic hazardous constituent (POHC) designated (under § 264.342) in its permit. This performance must be demonstrated on POHCs, 139 Environmental Protection Agency, EPA § 264.344 that are more difficult to incinerate than tetra, penta, and hexachlorodibenzopdioxins and dibenzofurans. DRE is determined for

each POHC from the equation in § 264.343(a)(1). In addition, the owner or operator of the incinerator must notify the Regional Administrator of his intent to incinerate hazardous wastes FO20, FO21, FO22, FO23, FO26, or FO27.

(b) An incinerator burning hazardous waste and producing stack emissions of more than 1.8 kilograms per hour (4 pounds per hour) of hydrogen chloride (HCl) must control HCl emissions such that the rate of emission is no greater than the larger of either 1.8 kilograms per hour or 1% of the HCl in the stack gas prior to entering any pollution control equipment.

(c) An incinerator burning hazardous waste must not emit particulate matter in excess of 180 milligrams per dry standard cubic meter (0.08 grains per dry standard cubic foot) when corrected for the amount of oxygen in the stack gas according to the formula:

$$P_c = P_m \times \frac{14}{21 - Y}$$

Where P_c is the corrected concentration of particulate matter, P_m is the measured concentration of particulate matter, and Y is the measured concentration of oxygen in the stack gas, using the Orsat method for oxygen analysis of dry flue gas, presented in part 60, appendix A (Method 3), of this chapter. This correction procedure is to be used by all hazardous waste incinerators except those operating under conditions of oxygen enrichment. For these facilities, the Regional Administrator will select an appropriate correction procedure, to be specified in the facility permit.

(d) For purposes of permit enforcement,

compliance with the operating requirements specified in the permit (under § 264.345) will be regarded as compliance with this section. However, evidence that compliance with those permit conditions is insufficient to ensure compliance with the performance requirements of this section may be "information" justifying modification, revocation, or reissuance of a permit under § 270.41 of this chapter. [46 FR 7678, Jan. 23, 1981, as amended at 47 FR 27532, June 24, 1982; 48 FR 14295, Apr. 1, 1983; 50 FR 2005, Jan. 14, 1985]

§ 264.344 Hazardous waste incinerator permits.

(a) The owner or operator of a hazardous waste incinerator may burn only wastes specified in his permit and only under operating conditions specified for those wastes under § 264.345, except:

- (1) In approved trial burns under § 270.62 of this chapter; or
- (2) Under exemptions created by § 264.340.

(b) Other hazardous wastes may be burned only after operating conditions have been specified in a new permit or a permit modification as applicable. Operating requirements for new wastes may be based on either trial burn results or alternative data included with part B of a permit application under § 270.19 of this chapter.

(c) The permit for a new hazardous waste incinerator must establish appropriate conditions for each of the applicable requirements of this subpart, including but not limited to allowable waste feeds and operating conditions necessary to meet the requirements of § 264.345, sufficient to comply with the following standards:

- (1) For the period beginning with initial

introduction of hazardous waste to the incinerator and ending with initiation of the trial burn, and only for the minimum time required to establish operating conditions required in paragraph (c)(2) of this section, not to exceed a duration of 720 hours operating time for treatment of hazardous waste, the operating requirements must be those most likely to ensure compliance with the performance standards of § 264.343, based on the Regional Administrator's engineering judgment. The Regional Administrator may extend the duration of this period once for up to 720 additional hours when good cause for the extension is demonstrated by the applicant.

(2) For the duration of the trial burn, the operating requirements must be sufficient to demonstrate compliance with the performance standards of § 264.343 and must be in accordance with the approved trial burn plan:

(3) For the period immediately following completion of the trial burn, and only for the minimum period sufficient to allow sample analysis, data computation, and submission of the trial burn results by the applicant, and review of the trial burn results and modification of the facility permit by the Regional Administrator, the operating requirements must be those most likely to ensure compliance with the performance standards of § 264.343, based on the Regional Administrator's engineering judgement.

(4) For the remaining duration of the permit, the operating requirements must be those demonstrated, in a trial burn or by alternative data specified in § 270.19(c) of this chapter, as sufficient to ensure compliance with the performance standards of § 264.343.

[46 FR 7678, Jan. 23, 1981, as amended at 47 FR 27532, June 24, 1982; 48 FR 14295, Apr. 1, 1983; 50 FR 4514, Jan. 31, 1985]

§ 264.345 Operating requirements.

(a) An incinerator must be operated in accordance with operating requirements specified in the permit. These will be specified on a case-by-case basis as those demonstrated (in a trial burn or in alternative data as specified in § 264.344(b) and included with part B of a facility's permit application) to be sufficient to comply with the performance standards of § 264.343.

(b) Each set of operating requirements will specify the composition of the waste feed (including acceptable variations in the physical or chemical properties of the waste feed which will not affect compliance with the performance requirement of § 264.343) to which the operating requirements apply. For each such waste feed, the permit will specify acceptable operating limits including the following conditions:

- (1) Carbon monoxide (CO) level in the stack exhaust gas;
- (2) Waste feed rate;
- (3) Combustion temperature;
- (4) An appropriate indicator of combustion gas velocity;
- (5) Allowable variations in incinerator system design or operating procedures; and
- (6) Such other operating requirements as are necessary to ensure that the performance standards of § 264.343 are met.

(c) During startup and shutdown of an incinerator, hazardous waste (except wastes exempted in accordance with § 264.340) must not be fed into the incinerator unless the incinerator is

operating within the conditions of operation (temperature, air feed rate, etc.) specified in the permit.

(d) Fugitive emissions from the combustion zone must be controlled by:

(1) Keeping the combustion zone totally sealed against fugitive emissions;

or

(2) Maintaining a combustion zone pressure lower than atmospheric pressure;

or

(3) An alternate means of control demonstrated (with part B of the permit application) to provide fugitive emissions control equivalent to maintenance of combustion zone pressure lower than atmospheric pressure.

(e) An incinerator must be operated with a functioning system to automatically cut off waste feed to the incinerator when operating conditions deviate from limits established under paragraph (a) of this section.

(f) An incinerator must cease operation when changes in waste feed, incinerator design, or operating conditions exceed limits designated in its permit.

[46 FR 7678, Jan. 23, 1981, as amended at 47 FR 27532, June 24, 1982; 50 FR 4514, Jan. 31, 1985]

§ 264.346 [Reserved]

§ 264.347 Monitoring and inspections.

(a) The owner or operator must conduct, as a minimum, the following monitoring while incinerating hazardous waste:

(1) Combustion temperature, waste feed rate, and the indicator of combustion gas velocity specified in the facility permit must be monitored on a continuous basis.

(2) CO must be monitored on a continuous

basis at a point in the incinerator downstream of the combustion zone and prior to release to the atmosphere.

(3) Upon request by the Regional Administrator, sampling and analysis of the waste and exhaust emissions must be conducted to verify that the operating requirements established in the permit achieve the performance standards of § 264.343.

(b) The incinerator and associated equipment (pumps, valves, conveyors, pipes, etc.) must be subjected to thorough visual inspection, at least daily, for leaks, spills, fugitive emissions, and signs of tampering.

(c) The emergency waste feed cutoff system and associated alarms must be tested at least weekly to verify operability, unless the applicant demonstrates to the Regional Administrator that weekly inspections will unduly restrict or upset operations and that less frequent inspection will be adequate. At a minimum, operational testing must be conducted at least monthly.

(d) This monitoring and inspection data must be recorded and the records must be placed in the operating log required by § 264.73.

[46 FR 7678, Jan. 23, 1981, as amended at 47 FR 27533, June 24, 1982; 50 FR 4514, Jan. 31, 1985]

§§ 264.348—264.350 [Reserved]

§ 264.351 Closure.

At closure the owner or operator must remove all hazardous waste and hazardous waste residues (including, but not limited to, ash, scrubber waters, and scrubber sludges) from the incinerator site.

[Comment: At closure, as throughout the operating period, unless the owner or operator

can demonstrate, in accordance with § 261.3(d) of this chapter, that the residue removed from the incinerator is not a hazardous waste, the owner or operator becomes a generator of hazardous waste and must manage it in accordance with applicable requirements of parts 262 through 266 of this chapter.]

[46 FR 7678, Jan. 23, 1981]

§ 270.62 Hazardous waste incinerator permits.

(a) For the purposes of determining operational readiness following completion of physical construction, the Director must establish permit conditions, including but not limited to allowable waste feeds and operating conditions, in the permit to a new hazardous waste incinerator. These permit conditions will be effective for the minimum time required to bring the incinerator to a point of operational readiness to conduct a trial burn, not to exceed 720 hours operating time for treatment of hazardous waste. The Director may extend the duration of this operational period once, for up to 720 additional hours, at the request of the applicant when good cause is shown. The permit may be modified to reflect the extension according to § 270.42 of this chapter.

(1) Applicants must submit a statement, with part B of the permit application, which suggests the conditions necessary to operate in compliance with the performance standards of § 264.343 of this chapter during this period. This statement should include, at a minimum, restrictions on waste constituents, waste feed rates and the operating parameters identified in § 264.345 of this chapter.

(2) The Director will review this statement and any other relevant information submitted with part B of the permit application and specify requirements for this period sufficient to meet the performance standards of § 264.343 of this chapter based on his engineering judgment.

(b) For the purposes of determining feasibility of compliance with the performance standards of § 264.343 of this chapter and of determining adequate operating conditions under § 264.345 of this chapter, the Director must establish conditions in the permit for a new hazardous waste incinerator to be effective during the trial burn.

(1) Applicants must propose a trial burn plan, prepared under paragraph (b)(2) of this section with a part B of the permit application.

(2) The trial burn plan must include the following information:

(i) An analysis of each waste or mixture

of wastes to be burned which includes:

(A) Heat value of the waste in the form and composition in which it will be burned.

(B) Viscosity (if applicable), or description of the physical form of the waste.

(C) An identification of any hazardous organic constituents listed in part 261, appendix VIII of this chapter, which are present in the waste to be burned, except that the applicant need not analyze for constituents listed in part 261, appendix VIII, of this chapter which would reasonably not be expected to be found in the waste. The constituents excluded from analysis must be identified, and the basis for the exclusion stated. The waste analysis must rely on analytical techniques specified in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication SW-846, as incorporated by reference in § 260.11 of this chapter and § 270.6, or other equivalent.

(D) An approximate quantification of the hazardous constituents identified in the waste, within the precision produced by the analytical methods specified in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication SW-846, as incorporated by reference in § 260.11 of this chapter and § 270.6, or their equivalent

(ii) A detailed engineering description of the incinerator for which the permit is sought including:

(A) Manufacturer's name and model number of incinerator (if available).

(B) Type of incinerator.

(C) Linear dimensions of the incinerator unit including the cross sectional area of combustion chamber.

(D) Description of the auxiliary fuel system (type/ feed).

(E) Capacity of prime mover.

(F) Description of automatic waste feed cutoff system(s).

(G) Stack gas monitoring and pollution control equipment.

(H) Nozzle and burner design.

(I) Construction materials.

(J) Location and description of temperature, pressure, and flow indicating and control devices.

(iii) A detailed description of sampling and monitoring procedures, including sampling and monitoring locations in the system, the equipment to be used, sampling and monitoring frequency.

and planned analytical procedures for sample analysis.

(iv) A detailed test schedule for each waste for which the trial burn is planned including dates, duration, quantity of waste to be burned, and other factors relevant to the Director's decision under paragraph (b)(5) of this section.

(v) A detailed test protocol, including, for each waste identified, the ranges of temperature, waste feed rate, combustion gas velocity, use of auxiliary fuel, and any other relevant parameters that will be varied to affect the destruction and removal efficiency of the incinerator.

(vi) A description of, and planned operating conditions for, any emission control equipment which will be used.

(vii) Procedures for rapidly stopping waste feed, shutting down the incinerator, and controlling emissions in the event of an equipment malfunction.

(viii) Such other information as the Director reasonably finds necessary to determine whether to approve the trial burn plan in light of the purposes of this paragraph and the criteria in paragraph (b)(5) of this section.

(3) The Director, in reviewing the trial burn plan, shall evaluate the sufficiency of the information provided and may require the applicant to supplement this information, if necessary, to achieve the purposes of this paragraph.

(4) Based on the waste analysis data in the trial burn plan, the Director will specify as trial Principal Organic Hazardous Constituents (POHCs), those constituents for which destruction and removal efficiencies must be calculated during the trial burn. These trial POHCs will be specified by the Director based on his estimate of the difficulty of incineration of the constituents identified in the waste analysis, their concentration or mass in the waste feed, and, for wastes listed in part 261, subpart D, of this chapter, the hazardous waste organic constituent or constituents identified in appendix VII of this part as the basis for listing.

(5) The Director shall approve a trial burn plan if he finds that:

(i) The trial burn is likely to determine whether the incinerator performance standard required by § 264.343 of this chapter can be met;

(ii) The trial burn itself will not

present an imminent hazard to human health or the environment.

(ii) The trial burn will help the Director to determine operating requirements to be specified under § 264.345 of this chapter; and

(iv) The information sought in paragraphs (b)(5) (i) and (ii) of this section cannot reasonably be developed through other means.

(6) The Director must send a notice to all persons on the facility mailing list as set forth in 40 CFR 124.10(c)(1)(ix) and to the appropriate units of State and local government as set forth in 40 CFR 124.10(c)(1)(x) announcing the scheduled commencement and completion dates for the trial burn. The applicant may not commence the trial burn until after the Director has issued such notice.

(i) This notice must be mailed within a reasonable time period before the scheduled trial burn. An additional notice is not required if the trial burn is delayed due to circumstances beyond the control of the facility or the permitting agency.

(ii) This notice must contain:

(A) The name and telephone number of the applicant's contact person;

(B) The name and telephone number of the permitting agency's contact office;

(C) The location where the approved trial burn plan and any supporting documents can be reviewed and copied;

and
(D) An expected time period for commencement and completion of the trial burn.

(7) During each approved trial burn (or as soon after the burn as is practicable), the applicant must make the following determinations:

(i) A quantitative analysis of the trial POHCs in the waste feed to the incinerator.

(ii) A quantitative analysis of the exhaust gas for the concentration and mass emissions of the trial POHCs, oxygen (O₂) and hydrogen chloride (HCl).

(iii) A quantitative analysis of the scrubber water (if any), ash residues, and other residues, for the purpose of estimating the fate of the trial POHCs.

(iv) A computation of destruction and removal efficiency (DRE), in accordance with the DRE formula specified in § 264.343(a) of this chapter.

(v) If the HCl emission rate exceeds 1.8 kilograms of HCl per hour (4 pounds

per hour), a computation of HCl removal efficiency in accordance with § 264.343(b) of this chapter.

(vi) A computation of particulate emissions, in accordance with § 264.343(e) of this chapter.

(vii) An identification of sources of fugitive emissions and their means of control.

(viii) A measurement of average, maximum, and minimum temperatures and combustion gas velocity.

(ix) A continuous measurement of carbon monoxide (CO) in the exhaust gas.

(x) Such other information as the Director may specify as necessary to ensure that the trial burn will determine compliance with the performance standards in § 264.343 of this chapter and to establish the operating conditions required by § 264.345 of this chapter as necessary to meet that performance standard.

(8) The applicant must submit to the Director a certification that the trial burn has been carried out in accordance with the approved trial burn plan, and must submit the results of all the determinations required in paragraph (b)(6) of this section. This submission shall be made within 90 days of completion of the trial burn, or later if approved by the Director.

(9) All data collected during any trial burn must be submitted to the Director following the completion of the trial burn.

(10) All submissions required by this paragraph must be certified on behalf of the applicant by the signature of a person authorized to sign a permit application or a report under § 270.11.

(11) Based on the results of the trial burn, the Director shall set the operating requirements in the final permit according to § 264.345 of this chapter. The permit modification shall proceed according to § 270.42.

(c) For the purposes of allowing operation of a new hazardous waste incinerator following completion of the trial burn and prior to final modification of the permit conditions to reflect the trial burn results, the Director may establish permit conditions, including but not limited to allowable waste feeds and operating conditions sufficient to meet the requirements of § 264.345 of this chapter, in the permit

to a new hazardous waste incinerator. These permit conditions will be effective for the minimum time required to complete sample analysis, data computation and submission of the trial burn results by the applicant, and modification of the facility permit by the Director.

(1) Applicants must submit a statement with part B of the permit application, which identifies the conditions necessary to operate in compliance with the performance standards of § 264.343 of this chapter, during this period. This statement should include, at a minimum, restrictions on waste constituents, waste feed rates, and the operating parameters in § 264.345 of this chapter.

(2) The Director will review this statement and any other relevant information submitted with part B of the permit application and specify those requirements for this period most likely to meet the performance standards of § 264.343 of this chapter based on his engineering judgment.

(d) For the purpose of determining feasibility of compliance with the performance standards of § 264.343 of this chapter and of determining adequate operating conditions under § 264.345 of this chapter, the applicant for a permit for an existing hazardous waste incinerator must prepare and submit a trial burn plan and perform a trial burn in accordance with § 270.19(b) and paragraphs (b)(2) through (b)(5) and (b)(7) through (b)(10) of this section or, instead, submit other information as specified in § 270.19(c). The Director must announce his or her intention to approve the trial burn plan in accordance with the timing and distribution requirements of paragraph (b)(6) of this section. The contents of the notice must include: the name and telephone number of a contact person at the facility; the name and telephone number of a contact office at the permitting agency; the location where the trial burn plan and any supporting documents can be reviewed and copied; and a schedule of the activities that are required prior to permit issuance, including the anticipated time schedule for agency approval of the plan and the time period during which the trial burn would be conducted. Applicants submitting information under § 270.19(a)

are exempt from compliance with 40 CFR 264.343 and 264.345 and, therefore, are exempt from the requirement to conduct a trial burn. Applicants who submit trial burn plans and receive approval before submission of a permit application must complete the trial burn and submit the results, specified in paragraph (b)(7) of this section, with part B of the permit application. If completion of this process conflicts with the date set for submission of the part B application, the applicant must contact the Director to establish a later date for submission of the part B application or the trial burn results. Trial burn results must be submitted prior to issuance of the permit. When the applicant submits a trial burn plan with part B of the permit application, the Director will specify a time period prior to permit issuance in which the trial burn must be conducted and the results submitted.

[48 FR 14228, Apr. 1, 1983, as amended at 53 FR 37939, Sept. 28, 1988; 58 FR 46051, Aug. 31, 1993; 60 FR 63433, Dec. 11, 1995]

From Trial
Burn Plan

TABLE 1-3
TRIAL BURN SAMPLING AND ANALYTICAL PROGRAM SUMMARY

Process Stream and Flue Gas Sampling Parameters	Sampling Methods	Analytical Parameters	Sampled During
FEED STREAMS			
<i>High Btu Liquids</i> (To be fed during Conditions 1, 2, & 3)	Grab/Comp	Heat Content Ash Water Viscosity Total Chlorides Flash Point	All Runs/All Conditions All Runs/All Conditions All Runs/All Conditions All Runs/All Conditions All Runs/All Conditions All Runs/All Conditions
<i>Organic Liquids</i> (To be fed during Conditions 1, 2, & 3) (a)	Grab/Comp	Heat Content Ash Water Viscosity Total Chlorides Flash Point	Runs 1,2,3,7,8,9 Runs 1,2,3,7,8,9 Runs 1,2,3,7,8,9 Runs 1,2,3,7,8,9 Runs 1,2,3,7,8,9 Runs 1,2,3,7,8,9
<i>Organic Slurry</i> (To be fed during Conditions 1 & 2)	Grab/Comp	Heat Content Ash Water Total Chlorides Viscosity	Runs 1,2,3,4,5,6 Runs 1,2,3,4,5,6 Runs 1,2,3,4,5,6 Runs 1,2,3,4,5,6 Runs 1,2,3,4,5,6
<i>Organic Sludge</i> (To be fed during Condition 2 only)	Grab/Comp	Heat Content Ash Water Viscosity Total Chlorides	Runs 4,5,6 Runs 4,5,6 Runs 4,5,6 Runs 4,5,6 Runs 4,5,6
<i>Bulk Solids</i> (To be fed during Condition 3 only)	Grab at beginning and end of each run, then composite for one sample/run	Heat Content Ash Water Total Chlorides	Runs 7,8,9 Runs 7,8,9 Runs 7,8,9 Runs 7,8,9
<i>Containerized Waste</i> (To be fed during Conditions 1 & 3)	Predetermined Analysis	Heat Content Ash Water Total Chloride Total Sulfur	See Note Below
<i>Aqueous Liquids</i> (To be fed during Conditions 1 & 2)	Grab/Comp	Ash	Runs 1,2,3,4,5,6

October 22, 1991
Denson

From Trial
Burn Plan

TABLE 1-3 (continued)
TRIAL BURN SAMPLING AND ANALYTICAL PROGRAM SUMMARY

Process Stream and Flue Gas Sampling Parameters	Sampling Methods	Analytical Parameters	Sampled During
PROCESS STREAMS ---			
Wet Kiln Ash/Slag	Grab/Comp	POHCs Metals PCDD/PCDF	(b) (c) All Runs/All Conditions Runs 1,2,3 Runs 1,2,3
Combined Ash Discharge (Boiler, Spray Dryer, and ESP)	Grab/Comp	POHCs Metals PCDD/PCDF	(b) (c) All Runs/All Conditions Runs 1,2,3 Runs 1,2,3
Scrubber Makeup Water	Grab/Comp	POHCs	(b) All Runs/All Conditions
Spray Dryer Feed Liquids	Grab Grab	Total Solids Metals	(c) All Runs/All Conditions (d) Runs 1,2,3
Quench Blowdown	Grab	Total Solids	(c) All Runs/All Conditions
FLUE GAS (ESP Outlet) --			
Gaseous HCl	EPA M0051	HCl	All Runs/All Conditions
FLUE GAS (Stack) --			
Particulate Matter (M5)	EPA M0090	Particulate	All Runs/All Conditions
Gaseous HCl/Cl ₂ (M5)	EPA M0090	HCl & Cl ₂	All Runs/All Conditions
Metals (BIF/M5)	EPA MMTL	Metals	(d) Runs 1,2,3
Hexavalent Chromium	EPA Cr ⁶⁺	Cr ⁶⁺	Runs 1,2,3
Volatiles (VOST)	EPA M0030	POHCs/PICs	(b,e) All Runs/All Conditions
VOST Condensate	EPA M0030	POHCs/PICs	(b,e) All Runs/All Conditions
Semivolatiles (MM5)	EPA M0010	PCDDs/PCDFs SVOC POHCs SVOC PICs	All Runs/All Conditions (b) Runs 7,8,9 (e) All Runs/All Conditions
Carbon Dioxide (CO ₂)	EPA M 3A	CO ₂	All Runs/All Conditions
Oxygen (O ₂)	EPA M 3A	O ₂	All Runs/All Conditions
Sulfur Dioxide (SO ₂)	EPA M 8C	SO ₂	All Runs/All Conditions
Oxides of Nitrogen (NO _x)	EPA M 7E	NO _x	All Runs/All Conditions
Carbon Monoxide (CO)	EPA M 1D	CO	All Runs/All Conditions
Total Hydrocarbons (THC)	EPA M 25A	THC	All Runs/All Conditions
<p>(a) The Condition 2 organic liquid feed is precharacterized trichlorobenzene. This stream will therefore not be sampled during condition 2.</p> <p>(b) Volatile POHCs include: carbon tetrachloride, monochlorobenzene, and trichloroethylene. Semivolatile POHC is 1,2,4-trichlorobenzene.</p> <p>(c) Sampled hourly and analyzed on site for steady state verification.</p> <p>(d) Metals are: arsenic, antimony, beryllium, cadmium, chromium, lead, and mercury.</p> <p>(e) Volatile PICs include benzene, tetrachloroethylene and chloroform; semivolatile PICs include p-, o-, and m-dichlorobenzene and hexachloroethane. See Section 8.3 for a complete list of volatile and semivolatile PICs.</p> <p>NOTE: Drums will not be sampled during the Trial Burn, rather a predetermined amount of material with known characteristics will be added to each drum prior to the program.</p>			

the same reagents as described previously in Section 8.4.4.2.

8.4.4.8 Process Stream Sampling

Composite feed and process streams will be sampled every 30 minutes at locations where the stream is well-mixed and representative. Two types of samples will be collected:

- For *volatile* POHC analyses, one 40 mL VOA vial (for liquids) and 1-4 oz glass jar (for solids) will be collected at each sampling time for each stream for later compositing. Every attempt will be made to minimize headspace to reduce volatile losses.
- For all other parameters, ~55 mL of liquid will be collected in a 100 mL beaker at each sampling point and emptied into a 500-mL amber glass jar. This composite will be used for analysis of non-VOC parameters.

Bulk solids will be sampled at the beginning *and end* of each run with a *scoop and composited*. For other solids, (e.g., the kiln ash/slag discharge) a 100 mL beaker will be filled and emptied into a 1000-mL glass sampling container every 30 minutes. A total of approximately 11 samplings will occur over the 5 hour run time.

8.4.4.9 Sample Preservation and Holding Times

Table 8-5 lists sample preservations and holding times for applicable matrices.

8.4.5 Field Strategy

The ENSR field team will consist of a crew of ~~nine (9)~~ *ten (10)* people for the trial burn. Field personnel are required for the following positions:

- Field team leader/sample train setup and recovery;
- Method *MMTL* Train (metals) operator;
- Method 5 Train (Hexavalent Chromium) operator;
- *Method 0051 Train (HCl) operator (at Quench Inlet);*
- Method 0050 Train (Particulate and HCl/Cl₂) operator *(at stack);*
- Method *0010/23* Train (semivolatile POHC and PCDDs/PCDFs) operator;
- CEM operator;
- VOST operator;

TABLE 8-5

Sample Preservation and Holding Times

Parameter	Matrix	Preservation	Holding Time
Volatile Organics	Aqueous	Cool	14 days
	Solid	Cool	14 days
	Tenax (VOST)	Cool	14 days
	Organic Liquid	Cool	14 days
PCDD/PCDF	XAD	Cool	6 months
Metals	Aqueous	HNO ₃ to pH<2	6 months
	Solid	Cool	6 months
	Organic Liquid	Cool	6 months
Metals - Mercury	Aqueous	HNO ₃ to pH<2	28 days
	Solid	Cool	28 days
	Organic Liquid	Cool	28 days
Metals - Cr ⁶	Aqueous	Cool	3 weeks
Total Chlorides	Aqueous	Cool	30 days
	Solid	Cool	30 days
	Organic Liquid	Cool	30 days
HCl (gaseous)	Aqueous	Cool	28 days
Physical Parameters	Aqueous	Cool	None Specified
	Organic Liquid	Cool	None Specified
	Solid	Cool	None Specified

- Process Stream Sampling Observer/Sample Custodian; and
- Stack Assistant.

All of the team members planned for this effort have extensive previous experience at other facilities where trial burns have been performed.

ENSR will make every effort possible to arrange overnight delivery of all samples at the conclusion of each *test condition sample day* to ensure sample integrity and maximize analytical turnaround time.

8.4.6 Sample Traceability

The purpose of sample traceability procedures is to document the identity of the sample and its handling from its first existence as a sample until analysis and data reduction are completed.

Custody records trace a sample from its collection through all transfers of custody until it is transferred to the analytical laboratory. Internal laboratory records then document the custody of the sample through its final disposition.

8.4.6.1 Field Sampling Operations

The importance of uncontaminated reagents, collection media and sample containers in collecting valid samples is well recognized by ENSR. The collection medium actually becomes part of the sample itself.

Sample integrity will be maintained throughout all sampling and analysis programs. Samples will be held within sight of the samplers or sample custodian, or will be kept in sealed or secured containers at all times. Sealed coolers will be used to ship samples to the appropriate laboratory.

Preprinted sample identification labels are used by ENSR to ensure that the required information is entered in the field. When sample batches are shipped to the specified laboratory, a sample packing list (similar to that shown in Figure 8-8) accompanies the shipment. This form is based on established laboratory format and will be used to document sample transfer in the field and from sampling personnel to the laboratory.

The ENSR Sample Custodian will coordinate the packing and shipment of all samples. Worksheets specifically designed for this program will be generated prior to the field effort. These



3.0 PROGRAM OVERVIEW

3.1 Project Schedule and Organization

The Trial Burn Plan for the WTI facility was approved by the regulatory agencies in January 1993. During the first week of January, ENSR performed the CEM certification program for WTI's continuous monitors located at the ESP outlet (quench inlet) and at the stack.

The trial burn was scheduled to begin on January 13, but due to circumstances beyond the control of WTI or ENSR, a delay was necessary. The trial burn was subsequently completed during March. The overall program was implemented by a team consisting of WTI, Von Roll Ohio, Von Roll, Inc., ENSR Consulting and Engineering and B³ Systems of Texas, Inc. Operation of the facility, logging of all process data, and collection of process stream samples was the responsibility of WTI, Von Roll Ohio, and Von Roll, Inc. B³ Systems was responsible for injection of POCs and metals into the appropriate feed lances and associated data reporting. ENSR was responsible for supervision of process stream sampling, collection of all samples at the ESP outlet and stack exhaust, and associated laboratory analysis and data reporting. ENSR field crew personnel and responsibilities varied slightly over the course of the entire program and were as follows:

Douglas Roeck	- Program Manager; process stream sampling and sample custodian
Richard Graziano and James Gallagher	- Volatile Organic Sampling Train (VOST) operators
James Morris and David Cameron	- Semivolatile Organics Sampling Train Operators
David Moll and David Caron	- ENSR CEM System Operators
Luke Ford	- Hexavalent chromium sampling train operator
James Gallagher	- Multimetals sampling train operator
Frederick Sanguedolce and James Gallagher	- Particulate/HCl/Cl ₂ sampling train operators (stack)
David Caron and Bruce Maisel	- HCl sampling train operators (ESP outlet)
C. Gregg Smith	- Sample train setup and recovery



feed lances and associated data reporting. ENSR was responsible for supervision of process stream sampling, collection of all samples at the ESP outlet and stack exhaust, and associated laboratory analysis and data reporting. ENSR field crew personnel and associated responsibilities over the course of the program were as follows:

- Douglas Roeck - Program Manager; process stream sampling and sample custodian
- Louis Pounds - Volatile Organic Sampling Train (VOST) operator
- Luke Ford - Semivolatile Organics Sampling Train operator
- David Moll - ENSR CEM System operator
- Jon Hays - Particulate/HCl/Cl₂ sampling train operator (stack)
- David Caron - HCl sampling train operator (ESP outlet)
- James Morris - Sampling train setup and recovery

The remainder of this section provides a generalized discussion of process operations, sampling locations, parameters, and methodologies. A more in-depth discussion of specific protocols followed is available in the approved TBP.

3.2 Process Operating Conditions

The trial burn demonstrated the ability of the WTI incineration system to comply with all applicable limits when operated under worst case operating conditions. Condition 2 (Runs 2-4) demonstrated maximum feed rates for slurry, sludge, and pumpable ash and minimum SCC temperature. Table 3-1 provides an overall summary of actual process parameters during the trial burn. Similar data for Run 1 are provided in Table 3-1A. A complete listing of all relevant system operating parameters is provided in Appendix A.

From Risk Assessment

The general equation being used to calculate metal emission rates for the incinerator stack is the following:

$$E_i = (1 - SRE_i) \times F_i \quad (III-2)$$

where:

- E_i = annual average stack emission rate for metal i, lb/yr
- F_i = annual feed rate for metal i, lb/yr
- SRE = system removal efficiency, %/100

The trial burn conducted at the facility in March 1993 prior to installation of the ECIS provided SREs for seven metals (antimony, arsenic, beryllium, cadmium, chromium, lead, and mercury). Trial burn data are not available, however, to estimate SREs for the remaining eight metals evaluated in this risk assessment (aluminum, barium, copper, nickel, selenium, silver, thallium, and zinc). For metals where direct SRE measurements were made during the trial burns, the average SRE value from the various sampling runs is used. For metals not analyzed in the March 1993 trial burns, SRE values are extrapolated from the trial burn data for the metals that were tested, considering the results of thermodynamic modeling, as described below.

The behavior of metals in the incinerator train is modeled based on mechanistic theories of metal reactions and particle formation (Barton et al. 1990). Figure III-1 illustrates the pathways metals may take through the WTI incinerator. As illustrated in Figure III-1, metals present in the waste feed may first volatilize, become entrained as particles in the combustion gas stream, or enter the slag. Complex oxidation and reduction reactions can then occur between metals and other reactive elements in the combustion gases in the primary and secondary chamber, creating newly formed metal species with different physical/chemical properties than the metals introduced with the waste feed. When metal speciation is expected to occur, the worst case scenario for oxidation state is assumed. For example, all chromium emissions are assumed to be in the Chromium VI oxidation state (the most toxic form of chromium). Chromium speciation is further discussed in Chapter V.

As the combustion gas cools after it exits the secondary combustion chamber, a portion of the metals will condense to form new particles, or condense on the surfaces of the entrained ash particles. The formed particles collide with one another and with the entrained

Attachment D

**Document entitled EPA's Draft Final Guidelines for
Carcinogenic Risk Assessment, issued 2003
(As referenced in the Response to Comment 16B.14)**

ATTACHMENT D

EPA's Draft Final Guidelines for Carcinogen Risk Assessment

Questions and Answers

The following questions and answers provide general information and a summary of key points in EPA's Draft Final "Guidelines for Carcinogen Risk Assessment" (cancer guidelines or draft final *Guidelines*). The draft final *Guidelines* are available for public review and comment.

SECTION I. GENERAL

1. What are EPA's "Guidelines for Carcinogen Risk Assessment"?

EPA's cancer guidelines set forth recommended principles and procedures to guide EPA scientists in assessing the cancer risks from chemicals or other agents in the environment. They also inform EPA decision makers and the public about these procedures. The cancer guidelines are used with other risk assessment guidelines that the Agency has developed, such as guidelines for exposure assessment, in developing an overall characterization of risk to human health. Collectively, all the risk assessment guidelines are intended to promote consistency and technical quality in EPA risk assessments while leaving EPA free to utilize yet-to-be-developed information and procedures.

2. What is the history of the cancer guidelines?

EPA published final cancer guidelines in 1986. As with other risk assessment guidelines, EPA has been working to revise the cancer guidelines to reflect advances in scientific understanding as well as experience in using them. Milestones in the revisions to the guidelines include the following:

- In 1996, EPA issued proposed revisions to the cancer guidelines. The proposed guidelines have been subject to extensive public comment and scientific peer review, including three reviews by EPA's Science Advisory Board (SAB).
- In 1997, the SAB completed comments from its first review of the proposed guidelines.
- In January 1999, the SAB reviewed key sections of the proposed guidelines that had been revised to address prior SAB and public comments.
- In July 1999, the SAB began a third review that focused on revisions of the guidelines addressing risks to children. EPA received the report from this review in 2000.
- In November 2001, EPA published in the *Federal Register* a Notice of Intent to finalize the cancer guidelines, and provided an opportunity to provide additional information and comment. At the same time EPA identified the draft 1999 guidelines as interim EPA guidance pending issuance of final revised guidelines.

Since 2001, EPA has been revising the cancer guidelines in light of the SAB reviews, public comments, and recent scientific workshops EPA has hosted on children's cancer risks.

3. What are the major principles and issues EPA has considered in its revisions to the *cancer guidelines*?

EPA's guiding principle for revisions to the cancer guidelines is that EPA cancer risk assessments be both public health protective and scientifically sound. By public health protective, EPA means that risk assessments should consider a range of susceptibilities among the human population and, in the absence of complete knowledge, employ assumptions that will reflect the risks to susceptible subpopulations and lifestages. By scientifically sound, EPA means that risk assessments should reflect current and evolving scientific practice and describe risks in a clear, consistent, and reasonable manner. In particular, the revisions to the cancer guidelines are intended to promote greater use of the increasing scientific understanding of the mechanisms that underlie the carcinogenic process.

In applying these principles to the revision of the Guidelines, four interrelated issues have been the focus of EPA deliberation and are each discussed further below. These issues are: 1) use of default assumptions, 2) consideration of differences in susceptibilities to carcinogens among people, 3) use of mode-of-action information in the risk assessment process, and 4) weighing the evidence to characterize human carcinogen potential.

4. What is the approach used in the draft final *Guidelines* for "default options"?

Default options are approaches that EPA can apply in risk assessments when critical information about the effects of a substance on human health is unavailable, limited, or of insufficient quality. For example, if no information is available on the effects of a chemical on humans, a common default option is that adverse effects observed in animals due to chemical exposure have the potential to occur in humans as well. In the draft final *Guidelines*, EPA has more clearly articulated its policy on when it is appropriate to invoke various default assumptions, based on comments from the SAB and others. EPA's recommended approach is to begin with a critical analysis of available information, and then invoke default options if needed to address uncertainty or the absence of critical information. Use of default options is intended to be health protective while also being scientifically defensible. Specific examples of default options are discussed in additional questions below.

5. How do the draft final *Guidelines* account for the variability in susceptibility to carcinogens among the human population?

EPA's draft final *Guidelines* explicitly recognize that variability exists among people in their susceptibility to carcinogens. Individuals in some *subpopulations* may experience increased susceptibility to carcinogens throughout their lives, such as people who have an inherited predisposition to certain cancer types or reduced capacity to repair genetic damage. Also, during certain *lifestages* the entire population may experience heightened susceptibility to carcinogens. In particular, EPA notes that childhood may be a lifestage of greater susceptibility for a number of reasons, such as that related to the rapid growth and development that occurs prenatally and after birth. Some of the aspects of the draft final *Guidelines* that account for potentially susceptible subpopulations and lifestages include the following:

- The draft final *Guidelines* recommend estimating the internal dose of chemicals experienced by children to predict the toxic effects from such doses.

- The draft final *Guidelines* encourage and provide guidance for developing separate risk estimates for children when pertinent data are available.
- The draft final *Guidelines* encourage consideration of differences in diet and behavior patterns among subpopulations and lifestages that may increase exposure to potential carcinogens.
- In the absence of information on susceptibility, the default option that may be invoked result in a risk assessment that is expected to be public health protective for the general population. These include the default option that there is no threshold below which cancer risks are not present (i.e., linear extrapolation to low doses).

6. How do the draft final *Guidelines* incorporate our knowledge of how a chemical causes cancer into the risk assessment process?

Cancer refers to a group of diseases involving abnormal, malignant tissue growth. Research has revealed that the development of cancer involves a complex series of steps and that carcinogens may operate in a number of different ways. Ultimately, cancer results from a series of defects in genes controlling cell growth, division, and differentiation. Genetic defects leading to cancer may occur because a chemical (or other carcinogenic agent) damages DNA directly.

Alternatively, an agent may have indirect effects that increase the likelihood, or accelerate the onset, of cancer without directly interacting with DNA. For example, an agent might interfere with DNA repair mechanisms, thereby increasing the likelihood that cell division will give rise to cells with damaged DNA. An agent might also increase rates of cell division, thus increasing the potential for genetic errors to be introduced as cells replicate their DNA in preparation for division.

The draft final *Guidelines* emphasize the value of understanding the biological changes that the chemical can cause and how these changes might lead to the development of cancer. They also discuss methods to evaluate and use such information, including information about a chemical's postulated *mode of action*, or the series of steps and processes that lead to cancer formation. Mode-of-action data, when available and of sufficient quality, may be useful in drawing conclusions about the potency of a chemical, its potential effects at low doses, whether findings in animals are relevant to humans, and which populations or lifestages may be particularly susceptible. In the absence of mode-of-action information, default options are available to address uncertainty.

7. How does EPA characterize a chemical's potential for human carcinogenicity under the draft final *Guidelines*?

The draft final *Guidelines* recommend that an agent's human carcinogenic potential is described in a *weight-of-evidence narrative*. The narrative summarizes the full range of available evidence and describes any conditions associated with conclusions about an agent's hazard potential. For example, the narrative may explain that a chemical appears to be carcinogenic by some routes of exposure but not others (e.g., by inhalation but not ingestion). Similarly, a hazard may be attributed to exposures during sensitive lifestages of development but not at other times. The narrative also summarizes uncertainties and key default options that have been invoked.

To provide additional clarity and consistency in weight-of-evidence narratives, the draft final *Guidelines* suggest a set of standard *weight-of-evidence descriptors* to accompany the narratives. The draft final *Guidelines* emphasize that risk managers should consider the full range of information in the narratives and not focus exclusively on the descriptors. As in the case of the narratives, descriptors may apply only to certain routes of exposure, dose ranges, and durations of exposure. The five descriptors are:

- *Carcinogenic to Humans*
- *Likely To Be Carcinogenic to Humans*
- *Suggestive Evidence of Carcinogenic Potential*
- *Inadequate Information to Assess Carcinogenic Potential*
- *Not Likely To Be Carcinogenic to Humans*

This proposed approach differs from that used in EPA's 1986 cancer guidelines in its recommendation that carcinogenic potential be discussed in a narrative and in the particular descriptors employed.

8. **What is the status of the *Guidelines* revision process?**

On March 3, 2003, EPA issued a *Federal Register* notice announcing the public availability of the draft final *Guidelines* and the start of a 60-day public comment period. EPA issued final cancer risk assessment guidelines in 1986. This is the third time (1996, 1999, 2003) since 1986 that the Agency has disseminated revised cancer guidelines for public review and comment. This current draft final *Guidelines* reflects the extensive public comment received on earlier drafts, as well as multiple rounds of expert scientific review by EPA's SAB. Therefore, EPA is requesting that public comments focus on issues that are substantively revised or newly addressed since the publication of the 1999 revised draft cancer guidelines. These issues include:

- the nature and use of default options;
- definition and application of hazard descriptors;
- identification of carcinogenic modes of action (in particular consideration of relevancy for children, for instance, the potential for differential lifestage susceptibility); and
- the default low-dose extrapolation approach for non-linear carcinogens.

Because the draft final *Guidelines* recommend consideration of possible sensitive subpopulations and lifestages (such as childhood), EPA is also releasing for public comment a draft supplemental guidance, entitled, "Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens," describing possible approaches that could be used to assess risks resulting from early life exposure to environmental contaminants (Supplemental Guidance is discussed in more detail in Section II). As with the draft final *Guidelines* themselves, the draft Supplemental Guidance is intended as a non-binding statement of policy. Risk assessments may employ different methods for a variety of reasons, including new information, methods, or scientific judgment.

After receipt of public comments and comments from other agency scientists, EPA will address those comments in its final revised *Guidelines for Carcinogen Risk Assessment*. After public

comments and comments from other agency scientists are received and considered for the draft Supplemental Guidance, it will be reviewed by EPA's Science Advisory Board.

9. What is new in the draft final *Guidelines* when compared to the July 1999 Draft Revised Guidelines?

The draft final *Guidelines* reflect public comments received in response to the November 2001 *Federal Register* notice as well as EPA's experience in applying the July 1999 Draft Revised Guidelines. Specific changes include:

- Clarification that assessments should begin with a critical analysis of the available data and that default options are invoked on an as needed basis when there is too much uncertainty or critical data are missing.
- Refinement of the guidance addressing the weight of evidence narrative and use of the associated descriptors. The draft final *Guidelines* emphasize the importance of weighing all of the evidence in reaching conclusions about the human carcinogenic potential of agents. This is accomplished in a single step after assessing all of the individual lines of evidence. Examples of the kinds of results that can lead to the use of a particular descriptor are included in the draft final *Guidelines*.
- Understanding of mode of action can be a key to identifying processes that may cause chemical exposures to differentially affect a particular population segment or lifestage. The framework for analysis of mode of action data has been revised to explicitly recommend consideration of any populations or lifestages that can be particularly sensitive in light of the hypothesized mode of action.
- In keeping with the goal of harmonizing cancer and noncancer risk assessment practices, the draft final *Guidelines* recommend the use of EPA's approach to setting noncancer reference values (oral reference doses [RfD] and inhalation reference concentrations [RfC]; See SECTION III: IRIS) in situations where the carcinogenic mode of action is determined to be nonlinear.
- In the absence of agent-specific data, there is some general information to indicate that childhood can be a susceptible lifestage for exposure to some carcinogens; this warrants explicit consideration in each assessment. The potential for susceptibility from early-life exposure is expected to vary among specific agents and chemical classes. Draft *Supplemental Guidance* has been developed as a possible approach for addressing early lifestage susceptibility in situations of less than lifetime exposure.

10. Why is EPA revising its 1986 final cancer guidelines?

EPA began revising the 1986 cancer guidelines in light of significant advances in our understanding of the processes of carcinogenesis and the modes of actions of disease at the cellular level. Revising the cancer guidelines is in keeping with EPA's original intent when it issued the first set of final risk assessment guidelines in 1986. The risk assessment guidelines were meant to be dynamic, flexible documents that would evolve to reflect the current state of the science and risk assessment practices.

11. What version of the EPA's cancer guidelines is currently being used in EPA human health risk assessment activities?

On December 20, 2001, Linda J. Fisher, EPA Deputy Administrator, issued a memorandum regarding steps for finalizing the *Guidelines for Carcinogen Risk Assessment*. A key part of that memorandum designated the July 1999 Draft Revised Guidelines for Carcinogen Risk Assessment as interim guidance to EPA risk assessors in preparing cancer risk assessments, superseding all previous versions of the Guidelines. The Deputy Administrator's December 2001 memorandum identifying the July 1999 Draft Revised Guidelines for Carcinogenic Risk Assessment as EPA's operative guidance remains in effect until these draft guidelines are finalized.

SECTION II. DRAFT SUPPLEMENTAL GUIDANCE ON EARLY-LIFE EXPOSURE

12. What is the draft *Supplemental Guidance*? Why is it necessary?

The draft *Supplemental Guidance* entitled, "Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens," describes possible approaches that EPA could use in assessing risks from early-life exposure to potential carcinogens. A final decision by EPA on the use of this or any alternative approach will reflect public comments and recommendations from the SAB's review of this document.

The draft *Supplemental Guidance* is part of EPA's response to the recommendation of the National Research Council (1994) that "EPA should assess risks to infants and children whenever it appears that their risks might be greater than those of adults." For several potential carcinogens, there is some evidence of higher cancer risks following early-life exposure. Accordingly, the potential for higher risks from early-life exposure warrants explicit consideration in each assessment.

13. What does the draft *Supplemental Guidance* contain? How will it be used?

The draft *Supplemental Guidance* describes the possible approaches that EPA could use in assessing cancer risks following early-life exposures. The draft *Supplemental Guidance* also summarizes the results of the cancer studies that investigated early-life exposure, along with EPA's analysis of those studies.

When final, EPA's headquarters and regional offices will refer to the draft *Supplemental Guidance* when assessing exposure scenarios that include exposure during childhood. Several examples in the draft *Supplemental Guidance* illustrate how early-life exposures can be assessed.

14. Why has the draft *Supplemental Guidance* been issued separately rather than included in the draft final *Guidelines*?

The draft *Supplemental Guidance* appears as a separate document because EPA intends to update this guidance as new research results increase understanding about the effects of early-life exposures. A separate guidance focused on early-life exposures will be more amenable to being updated in a timely manner. Frequent updates will likely be needed to help risk assessors

reflect new scientific understanding in their risk assessments, particularly for chemical classes (for example, endocrine-disrupting chemicals) where new information is rapidly emerging. Also, the draft *Supplemental Guidance* will undergo review by EPA's Science Advisory Board (SAB) following the comment period, whereas the draft final *Guidelines* will not.

15. Does the draft *Supplemental Guidance* address all potential carcinogens?

The draft *Supplemental Guidance* recommends consideration of all studies on the effects of early-life exposures. For the common case where there are no early-life studies on a potential carcinogen, the draft final *Guidelines* suggest consideration of the carcinogen's mode of action. The draft *Supplemental Guidance* addresses carcinogens with a mutagenic mode of action in detail because currently most early-life studies are for carcinogens with a mutagenic mode of action. As new research leads to more conclusive evidence, EPA intends to update this guidance to address other modes of action. Furthermore, risk assessments should reflect emerging science even if the draft *Supplemental Guidance* has not been updated to reflect it.

16. Do the draft final *Guidelines* or the draft *Supplemental Guidance* recommend development of specific data on children's risk?

Both the draft final *Guidelines* and the draft *Supplemental Guidance* discuss general ways of proceeding when there are no early-life studies on a potential carcinogen. Nonetheless, there may be cases where these general approaches may not adequately reflect differential risks to children. As in all cases, specific data on the effects of early-life exposures is valuable in improving the assessment.

17. How and when will the draft *Supplemental Guidance* be finalized?

Soon after the close of the public comment period, the scientific data and rationale that support the *Supplemental Guidance* will be peer-reviewed by EPA's Science Advisory Board (SAB) in a public meeting. Details of the SAB's review will be available in the *Federal Register* and through the internet at www.epa.gov/sab. The SAB will provide written advice to EPA. After EPA considers that advice and makes appropriate changes, it will publish final *Supplemental Guidance*.

SECTION III. IRIS AND THE CANCER GUIDELINES

18. What is IRIS (www.epa.gov/IRIS)?

IRIS, the Integrated Risk Information System, is an EPA data base containing EPA's consensus position on the potential adverse human health effects that may result from chronic (or lifetime) exposure to specified chemical substances found in the environment. IRIS currently provides health effects information on over 500 specific chemical substances. IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of the first two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. IRIS information includes the reference dose for noncancer health effects resulting from oral exposure, the reference concentration for noncancer health effects resulting from inhalation exposure, and the cancer assessment for both oral and inhalation exposure. Combined with

specific situational exposure assessment information, the summary health hazard information in IRIS may be used as a source in evaluating potential public health risks from chemical substances found in the environmental.

19. How is the information in IRIS developed?

EPA's current process for developing IRIS information consists of: (1) an annual *Federal Register* announcement of EPA's IRIS agenda and call for scientific information from the public on the selected chemical substances, (2) a search of the current literature, (3) development of health assessments and draft IRIS summaries, (4) peer review within EPA, (5) peer review outside EPA, (6) EPA consensus review and management approval, (7) preparation of final IRIS summaries and supporting documents, and (8) entry of summaries and supporting documents into the IRIS data base.

20. What is the relationship between EPA's IRIS and the cancer guidelines?

Currently an IRIS file may include descriptive and quantitative human health risk information on both noncancer and cancer effects. EPA's cancer guidelines provide guidance to Agency risk assessors in developing the cancer risk assessment portion of the IRIS file. Since the mid-1980s, when IRIS was developed, the cancer summary files were based first on the 1984 proposed cancer guidelines and then on the 1986 final guidelines. While the 1986 guidelines have guided the development of the IRIS cancer risk information for many years, cancer risk assessments have been informed by other considerations such as evolving science, the facts of the particular case, and scientific judgment.

On November 29, 2001, EPA issued a *Federal Register* notice announcing: 1) an opportunity to provide additional information and comment on the July 1999 Draft Revised Guidelines for Carcinogen Risk Assessment, 2) the availability of the draft revised *Guidelines*, and 3) the adoption of the 1999 draft revised *Guidelines* as interim guidance. The *Federal Register* notice states that until final cancer guidelines are issued, the July 1999 Draft Revised Guidelines will serve as EPA's interim guidance to EPA risk assessors preparing new cancer risk assessments or revising old assessments. This notice is posted on the IRIS website. In order to provide consistency for IRIS users during the transition period from the use of the 1986 guidelines to the July 1999 Draft Revised Guidelines, new or revised cancer risk information on IRIS has been developed using both the 1986 final and July 1999 Draft Revised Guidelines. Recently a decision was made to discontinue the application of the 1986 guidelines and exclusively apply the July 1999 Draft Revised Guidelines. When the draft final *Guidelines* are finalized, the IRIS program will begin using the final version in new or revised assessments.

SECTION IV. ROLE OF CANCER GUIDELINES IN EPA DECISIONS

21. How will EPA use the final cancer guidelines?

EPA scientists will refer to the cancer guidelines as a framework for evaluating information on the carcinogenic potential of various chemicals. The resulting cancer risk assessments will then be considered in making regulatory decisions under various statutes.

22. How will EPA manage the transition to the new cancer guidelines? What are the implications of the new cancer guidelines for EPA's regulatory programs?

Since the publication of the 1986 guidelines, EPA's cancer assessment methodology has continued to evolve as new science and data have become available. EPA is currently using the July 1999 Draft Revised Guidelines as its operative guidance for conducting cancer risk assessments. Once the draft final *Guidelines* and draft *Supplemental Guidance* are finalized, cancer risk assessments will incorporate EPA's up-to-date guidance. Given the large number of substances for which cancer assessments have been conducted (for example those in the IRIS database), EPA will have to address a range of issues associated with making the transition to the new cancer guidelines. For example, under what circumstances will the EPA prepare a reassessment under the new cancer guidelines. This and other implementation issues will be evaluated and addressed by EPA over the next several months, as well as when the draft final *Guidelines* are finalized.

SECTION V. CANCER RESEARCH ACTIVITIES

23. What is EPA doing to reduce both its reliance on default options and the uncertainties that, to date, have been inherent in human health risk assessment?

EPA began revising the 1986 cancer guidelines in light of significant advances in our understanding of the processes of carcinogenesis and the modes of action of disease at the cellular level. Some of the work in these areas that led to these advances is the result of EPA research efforts over the past several years. Because our understanding of carcinogenicity, causation of disease, and effects on susceptible lifestages and populations are constantly and quickly evolving, EPA will continue research work in this area, as well as collaborate with other research organizations to produce research that ultimately serves to reduce both uncertainties in cancer risk assessments and reduce EPA's reliance on default options.

24. What is the cancer research area that EPA intends to focus on next?

To enhance EPA's understanding of age-related cancer susceptibility, EPA's Office of Research and Development (ORD) is expanding its research through an initiative that focuses on appropriate measures of dose, response characteristics, and exposure variables that may be affected by age. This research will be done via a combination of studies in EPA laboratories, ORD's Science to Achieve Results (STAR) grants program, and collaborations with other federal agencies.



Attachment E

**Document entitled A Review of the Reference Dose and Reference Concentrate Process, Final Draft, Prepared by the Risk Assessment Forum of the U.S. EPA, Washington D.C., dated November 2002
(As referenced in the Response to Comment 16B.14)**

**A REVIEW OF THE REFERENCE DOSE AND
REFERENCE CONCENTRATION PROCESSES**

Prepared for the
Risk Assessment Forum
U.S. Environmental Protection Agency
Washington, DC

Reference Dose/Reference Concentration (RfD/RfC) Technical Panel

Bob Benson (OPRA/Region 8)
Gary Foureman (NCEA/ORD)
Lee Hofmann (OERR/OSWER)
Carole Kimmel (NCEA/ORD)*
Gary Kimmel (NCEA/ORD)
Susan Makris (OPP/OPPTS)
Deirdre Murphy (OAQPS/OAR)

Edward Ohanian (OST/OW)
Jennifer Orme-Zavaleta (NHEERL/ORD)
Deborah Rice (NCEA/ORD)
Jennifer Seed (OPPT/OPPTS)
Hugh Tilson (NHEERL/ORD)
Vanessa Vu (OSCP/OPPTS)

*Technical Panel Chair

Technical Advisors

Amy Mills, IRIS Director, NCEA/ORD
Bill Wood, RAF Director, NCEA/ORD

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

PREFACE

The U.S. Environmental Protection Agency (EPA) Risk Assessment Forum was established to promote scientific consensus on risk assessment issues and to ensure that this consensus is incorporated into appropriate risk assessment guidance. To accomplish this, the Risk Assessment Forum assembles experts throughout EPA in a formal process to study and report on these issues from an Agencywide perspective. For major risk assessment activities, the Risk Assessment Forum has established Technical Panels to conduct scientific reviews and analyses. Members are chosen to assure that necessary technical expertise is available.

The RfD/RfC Technical Panel (hereafter the Technical Panel) was established by EPA's Risk Assessment Forum in early 1999 in response to a request from the Agency's 10X Task Force¹⁵ to the Science Policy Council and the Risk Assessment Forum. In the process of developing a strategy for implementation of the Food Quality Protection Act (FQPA) relative to protecting children's health and application of the 10X safety factor, the 10X Task Force produced two draft reports (one on toxicology and one on exposure data requirements [EPA, 1999a, b] that were used by the Office of Pesticide Programs (OPP) to develop a policy document for implementation of the FQPA safety factor (EPA, 1999c, 2002b). The draft 10X toxicology report (EPA, 1999a) raised a number of issues that relate to the derivation of the oral reference dose (RfD) and inhalation reference concentration (RfC). Examples of these issues include the following. (1) Appropriate application of a database uncertainty factor (UF) or modifying factor for studies that are considered necessary but are absent or judged inadequate that may show children to be significantly more sensitive or susceptible than adults. Addressing this issue also implicates aspects of other UFs that relate to children's health, including the factor for inter-individual variability in humans (e.g., response of the aged versus response of the younger adult or child), and the inter-species UF (e.g., young animals versus young humans). (2) How to account for degree of concern for potential toxicity to children in the RfD/RfC process. Degree of concern, as used in the 10X toxicology report, refers to the characterization of the database as to the likelihood that the agent under review would have effects in humans, within the context of dose, route, duration, and timing of exposure. (3) The use of developmental toxicity data as the basis for reference values¹⁶ of chronic duration (RfDs or RfCs) and the appropriate setting of acute, short-term, and longer-term reference values, including the application of developmental toxicity data for these shorter duration reference values. (4) The appropriateness and/or rationale for

¹⁵The 10X Task Force was created by the Administrator, EPA, to explore the adequacy of current testing approaches for pesticides for protecting children's health, and to recommend approaches for implementation of the additional 10X safety factor mandated by the 1996 FQPA.

¹⁶The term reference value is used generically here to refer to values such as the RfD, RfC, acute reference exposure (ARE), Health Advisory (HA), acute exposure guideline level (AEGl), minimal risk level (MRL), or other similar values.

adjustment of the no-observed-adverse-effect level (NOAEL) or the benchmark dose (BMD) from developmental toxicity data with inhalation exposures using a concentration times time (C x t) adjustment as is done for other study types.

The Technical Panel also was asked to consider the need for additional toxicity test protocols related to children's health as recommended by the 10X Task Force, when they should be required, and interpretation of the data for risk assessment purposes. These include (1) collection of toxicokinetic data, both in adults and at different developmental stages; (2) direct dosing of neonates, especially when early exposure is of concern; (3) perinatal carcinogenesis studies and appropriate triggers for when they should be required; (4) developmental immunotoxicity testing and appropriate triggers; (5) advanced developmental neurotoxicity (DNT) testing, in particular, cognitive testing that is more similar to that used in humans; and (6) exposure assessments that are more compatible with the dose-response assessment. See Appendix A for more a detailed discussion of the issues raised by the 10X Task Force.

The Science Policy Council and the Risk Assessment Forum agreed that these issues should be examined on a broader scale than just for pesticides, with input from various program offices within the Agency and from the outside scientific/policy community. This charge was expanded by the Forum to include a more in-depth review of a number of issues related to the RfD/RfC process, in part because of several other Forum activities that were underway. These activities included development of the Framework for the Harmonization of Cancer and Noncancer Risk Assessment, revision of the Benchmark Dose Guidance Document, and revision of the Cancer Risk Assessment Guidelines. In addition, the RfD/RfC derivation process had not been evaluated in detail for a number of years, and several scientific issues concerning children's health, e.g., neurotoxicity and immunotoxicity, have become increasingly important in risk assessment. These various but related activities have prompted the need to re-examine the RfD/RfC process and to coordinate these efforts with other related activities. In particular, it was important that efforts continue to focus on moving toward the goal of harmonization of risk assessment approaches for all health endpoints. This document represents the review and deliberations of the RfD and RfC processes by the Risk Assessment Forum Technical Panel.

EXECUTIVE SUMMARY

This document summarizes the review and deliberations of the Technical Panel and its recommendations for improvements in the process as well as additional efforts that are needed. It discusses revisions to the framework for the derivation of reference values. The document is a review, and not guidance, but does make recommendations that should be considered in the implementation of changes in the current process and/or development of needed guidance.

The Technical Panel reviewed most of the issues relating to hazard characterization for developing reference values, and the need for developing reference values for different durations of exposure, as well as the process of deriving reference values, but it did not go into detail on the quantitative aspects of the dose-response process, which is being covered in other Forum activities. The Technical Panel views the RfD/RfC process as one that should be continually evolving as new information becomes available and new scientific and risk assessment approaches are developed. This does not mean that current RfDs or RfCs are invalid, but these new scientific issues should be included in the process of re-evaluation of current reference values.

This report reviews and discusses a number of issues and provides conclusions and recommendations that are intended to improve the RfD/RfC process. The Technical Panel has provided specific recommendations for the development of guidance in some cases and more general conclusions and recommendations in others. In the latter cases, the Technical Panel felt that development of specific recommendations was beyond the scope of its efforts or that policies needed to be further developed before specific guidance could be written to implement the recommendations.

The report is divided into five chapters:

Chapter 1 provides an introduction, background, purpose and scope for the project.

Chapter 2 reviews current approaches to developing acute, short-term, and longer-term reference values as well as the chronic reference values, the RfD and the RfC. This chapter incorporates the presentations and discussions on developing less-than-lifetime values from briefings to the Technical Panel and a colloquium held August 2, 2000. These include discussions of the proposed Acute Reference Exposure (ARE) methodology for acute inhalation exposures, the Acute Exposure Guideline Level (AEGLE) Program, the Office of Pesticide Programs' (OPP's) procedures for setting acute and longer-term duration RfDs, the Office of Water's (OW's) Health Advisories, and the Agency for Toxic Substances and Disease Registry's Minimal Risk Levels (MRLs). On the basis of a review of the various approaches to setting acute, short-term, and longer-term reference values, the Technical Panel concurred with the recommendation of the 10X Task Force that acute, short-term, and longer-term reference values should be set, where possible, and that they should be incorporated into the Integrated Risk Information System (IRIS) database. In addition, the Technical Panel recommended that this process be done in a consistent manner, using standardized definitions

for acute, short-term, longer-term, and chronic durations that are consistent with current practice. These values can then be used by various program offices, where applicable. A framework for deriving these additional values is presented in Chapter 4.

Chapter 3 reviews the current Office of Prevention, Pesticides and Toxic Substances' (OPPTS') harmonized health effects testing guidelines for the purpose of determining the data available for setting various duration reference values. The intent of this review is not to suggest that additional testing be conducted for each and every chemical in order to fill in the information gaps identified for those organ systems evaluated. Nor is it suggested that alternative testing protocols that are discussed in this chapter should be conducted for every chemical or become part of current toxicology testing requirements, or that these alternative protocols are the only options available. Rather, it is the goal of this document to provide a basis for the development of innovative alternative testing approaches and the use of such data in risk assessment, and to then illustrate some aspects of this concept with a few examples. In reviewing the current testing protocols, target organs/systems that are evaluated were reviewed along with how thorough the testing is with respect to life stage assessment, endpoint assessment, route, timing and duration of exposure, and latency to response. These issues were all considered important in evaluating potentially susceptible subpopulations, including life stages. The testing guideline protocols were reviewed overall for these issues; in addition, four biological systems were evaluated in depth, two that are fairly thoroughly evaluated (the reproductive and nervous systems) and two that are evaluated to a more limited extent (the immune and cardiovascular systems). In each case, an overview of the tests for the particular system is given, as well as a more specific discussion of gaps in life stage of assessment, gaps in assessment endpoints, and gaps in duration and latency assessment.

The Technical Panel has made a number of recommendations concerning toxicity testing: for example, to develop a strategy for approaches to toxicity testing, with guidance on how and when to use existing and newly recommended guidelines; to develop guidelines or guideline study protocols that will provide more systematic information on toxicokinetics and toxicodynamics (i.e., mechanism or mode of action) including at different life stages; to develop protocols for acute and short-term studies that provide more comprehensive data for setting reference values; to modify existing guideline study protocols to provide more comprehensive coverage of life stages for both exposure and outcomes; to collect more information from less-than-lifetime exposure to evaluate latency to effect and to evaluate reversibility of effect; to develop guidelines or guideline study protocols to assess immunotoxicity, carcinogenicity, and cardiovascular toxicity at different life stages; and to explore the feasibility of setting dermal reference values for direct toxicity at the portal of entry, including sensitization.

A primary goal of this review was to provide the basis for recommendations for the development of a strategy for approaches to toxicity testing and for innovative alternative testing approaches to provide data for risk assessment. The Technical Panel is suggesting that alternative strategies and

guidance for testing approaches be developed that incorporate information on toxicokinetics and mode of action early in the process, thus allowing a more targeted testing approach. In addition, alternative protocols are discussed that are aimed at more efficient use of animals and resources in combined studies that would provide more extensive data on life stages, endpoints and other factors not well characterized in current testing approaches. Recommendations are also made about research areas that should be encouraged to aid in better study design and interpretation of data for risk assessment.

Finally, an example of an alternative testing protocol for acute exposure and evaluation that incorporates the types of endpoints and evaluations optimal for setting acute reference values is discussed. Two sample alternative protocols are presented for chronic exposures and options are discussed for combining studies and evaluations to include a wider array of life stage and endpoint assessments.

Chapter 4 discusses a number of modifications to the existing framework for use in the derivation of reference values, both for the current chronic reference values (RfD and RfC) as well as for acute, short-term, and longer-term reference values. The approach to reference values discussed here is intended for risk assessments of any type of health effect known or assumed to be produced through a nonlinear and/or threshold mode of action (which may include U-shaped or other nonmonotonic dose-response curves as well as thresholds). Thus, the Technical Panel recommends moving away from the dichotomy between "cancer" and "noncancer." The term "noncancer" has been removed from the reference value definition, denoting the move toward defining approaches for low-dose estimation or extrapolation based on mode of action. Two case studies that illustrate many of the concepts discussed in this chapter are presented in more detail in Appendix B. The Technical Panel recommends including the acute, short-term, longer-term, and chronic reference values derived on the basis of the recommendations in this report in IRIS after appropriate internal, external, and consensus review. Standard exposure durations are proposed, as is a definition for the reference value, including a designation for route and duration of exposure.

The Technical Panel is aware that there will be data limitations for an individual chemical that may preclude development of all four reference values, and is aware that time and resources need to be considered when implementing these recommendations. The IRIS program has begun to implement a pilot program to test whether development of the expanded array of reference values is practical and can be accomplished without unduly delaying the completion of an IRIS file. As a part of the pilot, the IRIS Program will need to identify the methods to be used in deriving these additional values.

The Technical Panel recommends that endpoint-specific reference values should not be developed, including the reference dose for developmental toxicity, RfD_{DT} (EPA, 1991). Rather, a sample reference value should be calculated for each relevant and appropriate endpoint and these

should be considered in the derivation of various duration reference values. The reference values should be derived to be protective of all types of effects for a given duration of exposure.

An expanded approach to the evaluation of studies and characterization of the extent of the database as a whole is recommended; in particular, several factors are discussed that should be considered in a weight-of-evidence approach for characterizing hazard for the population as a whole as well as for potentially susceptible subpopulations. Those considerations for assessing level of concern raised by the Toxicology Working Group of the 10X Task Force (EPA, 1999a) have been incorporated into this approach. In the context of this framework, the Technical Panel recommends a somewhat different approach to characterizing the extent of the database for reference values. Instead of specifying particular studies, this approach emphasizes the types of data needed (both in terms of human and animal data) for deriving reference values, and it recommends the use of a narrative description of the extent of the database rather than a single confidence ranking of high, medium, or low. To characterize the database, the Technical Panel has developed a description of a "minimal" database and a "robust" database as a way of describing the range of data that can be used for deriving a reference value, and the Panel urges the use of a great deal of scientific judgement in the process of summarizing the extent of the database, including its strengths and limitations. The narrative approach is intended to emphasize the types of data available (both human and animal data) as well as the data gaps that could improve the derivation of reference values. This approach should encourage a wider range of information to be used in deriving reference values, taking into consideration the issues of duration, timing, and route of exposure, the types and extent of endpoint assessments (i.e., structure and function), the life stages evaluated, and the potential for latent effects and/or reversibility of effects.

Dosimetric adjustment of values for deriving a human equivalent concentration (HEC) for inhalation exposure is discussed, as well as the derivation of a human equivalent dose (HED) for oral or dermal exposure. The Technical Panel recommends that duration adjustment procedures to continuous exposures based on $C \times t$ be used as a default procedure for inhalation developmental toxicity studies as for other health effects from inhalation exposures. In addition, further evaluation of current dosimetric adjustments for deriving HECs should be pursued to confirm or assess the relevance for population subgroups (particularly for children).

Because of the recommendation for deriving several duration reference values, the Technical Panel recommends that the data for the point of departure (POD) be evaluated based a comparison of all relevant endpoints carried through the derivation of sample reference values, with selection of the limiting value(s) as the final step rather than based on selection of a single "critical study" and "critical effect." To aid in this evaluation, the use of an exposure-response array is recommended as a visual display of all relevant and appropriate endpoints and durations of exposure in order to determine the range of numerical values for each reference value.

The Technical Panel makes a number of recommendations concerning the application of uncertainty factors (UFs) for reference value derivation. In particular, it is imperative that the IRIS documentation contain a justification for the individual factors selected for each chemical or assessment because rigid application of UFs could lead to an illogical set of reference values. Although default factors of 10 are recommended, with 3 used in place of half-power values (i.e., $10^{0.5}$) when occurring singly, the exact value of the UF chosen should depend on the quality of the studies available, the extent of the database, and scientific judgment. Sound scientific judgment should be used in the application of UFs to derive reference values which are applied to the value chosen for the POD derived from the available database (BMDL, NOAEL, or LOAEL).

The Technical Panel recommends that if there is uncertainty in more than four areas of extrapolation, it is unlikely that the database is sufficient to derive a reference value. Even when there is uncertainty in four areas, the database should be carefully evaluated to determine whether the derivation of a reference value is appropriate. In addition, the Technical Panel recommends limiting the total UF applied to a chronic reference value for any particular chemical to 3,000. This maximum of 3,000 applies only to the UFs and does not include the various adjustment factors discussed in Chapter 4.

The intraspecies UF is applied to account for variations in susceptibility within the human population (interhuman variability) and the possibility (given a lack of relevant data) that the database available is not representative of the dose/exposure-response relationship in the subgroups of the human population that are most sensitive to the health hazards of the chemical being assessed. As the reference concentration/dose is defined to be applicable to "susceptible subgroups," this uncertainty factor was established to account for uncertainty in that regard. In general, the Technical Panel reaffirms the importance of this uncertainty factor, recommending that reduction of the intraspecies UF from a default of 10 be considered only if data are sufficiently representative of the exposure/dose-response data for the most susceptible subpopulation(s). At the other extreme, a 10-fold factor may sometimes be too small because of factors that can influence large differences in susceptibility, such as genetic polymorphisms. The Technical Panel urges the development of data to support the selection of the appropriate size of this factor, but recognizes that often there are insufficient data to support a factor other than the default. The Technical Panel urges continued research and evaluation of the similarities and differences between the general population and susceptible subpopulations, particularly children and the elderly, in their responses to particular agents. From such evaluations, the protectiveness of the 10-fold default factor should continue to be assessed. The Technical Panel urges the development of data to support the selection of the appropriate size of this factor, but recognizes that often there are insufficient data to support a factor other than the default. The database UF is intended to account for the potential for deriving an underprotective RfD/RfC as a result of an incomplete characterization of the chemical's toxicity. In addition to the identification of toxicity information that is lacking, review of existing data may also

suggest that a lower reference value might result if additional data were available. Consequently, in deciding to apply this factor to account for deficiencies in the available data set, and in identifying its magnitude, the assessor should consider both the data lacking and the data available for particular organ systems as well as life stages. The Panel considers the purpose of the modifying factor (MF) to be sufficiently subsumed in the general database UF, and recommends discontinuance in the use of the MF.

Given that there are several UFs that can be used to deal with data deficiencies as part of the current reference value process, and given that these are assumed to overlap to some extent, the Technical Panel agrees with the 10X Task Force Toxicology Working Group that the current interspecies, intraspecies, and database deficiency UFs, if appropriately applied using the approaches recommended in this review, will be adequate in most cases to cover concerns and uncertainties regarding the potential for pre- and postnatal toxicity and the completeness of the toxicology database. In other words, an additional uncertainty factor is not needed in the RfC/RfD methodology as the currently available factors are considered sufficient to account for uncertainties in the database from which the reference values are derived (and does not exclude the possibility that these UFs may be decreased or increased from the default value of 10). The approach to using chemical-specific data for toxicokinetic and toxicodynamic components of the interspecies UF is part of the current RfC methodology (EPA, 1994). The Technical Panel encourages the Agency to develop its own guidance for chemical-specific adjustment factors (CSAFs) on the basis of some of the available methodologies (e.g., the International Programme on Chemical Safety [IPCS]).

Several other issues discussed by the Technical Panel were considered more appropriate for deliberation by other panels/committees, e.g., further consideration of the use of BMD modeling approaches for deriving reference values; harmonization of the approaches for HEC and HED derivation for all types of health effects; further evaluation of approaches such as probabilistic analysis for characterizing variability and uncertainty in toxicity reference values; further evaluation of appropriate adjustment of doses for duration of exposure for acute toxicity data; and further evaluation of duration adjustment for short-term and longer-term reference values analogous to the subchronic to chronic duration UF for chronic reference values.

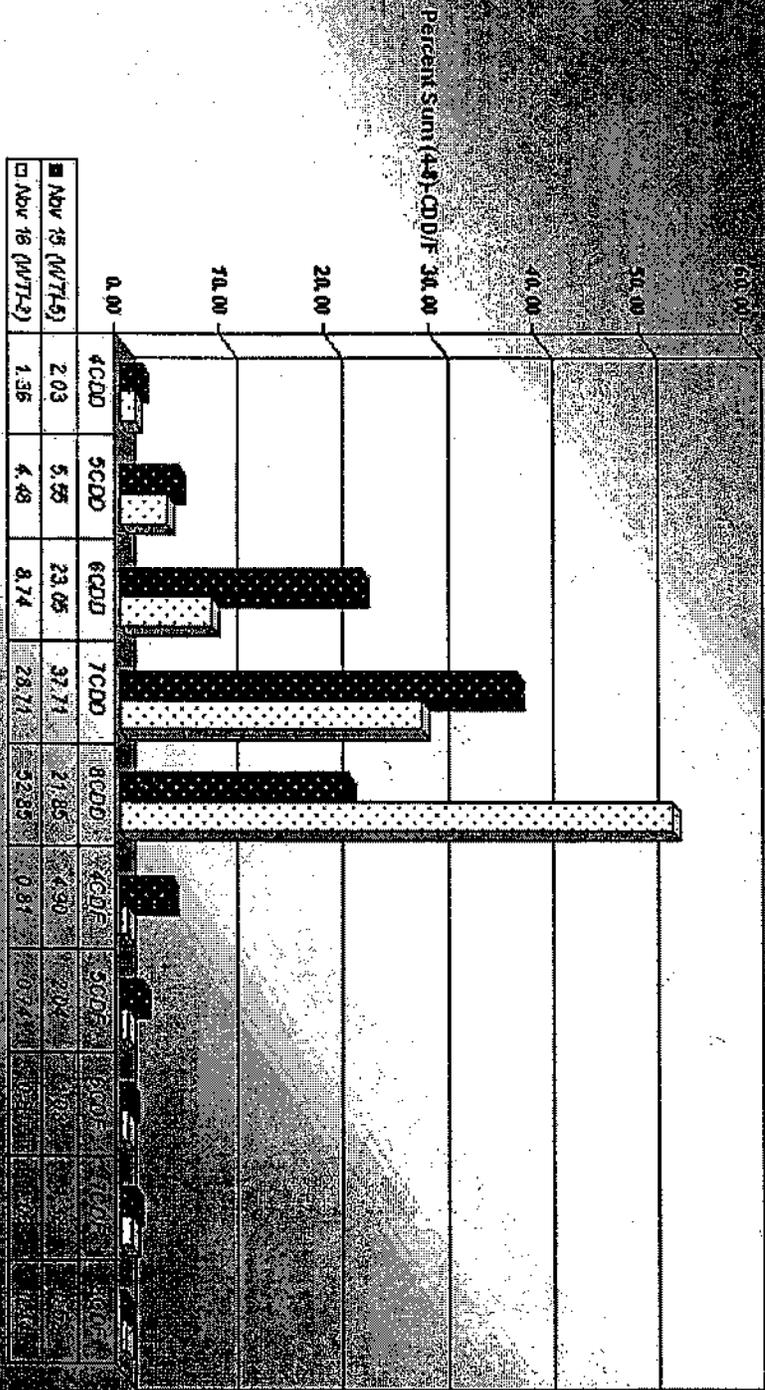
Chapter 5 summarizes the recommendations of the Technical Panel.



Attachment F

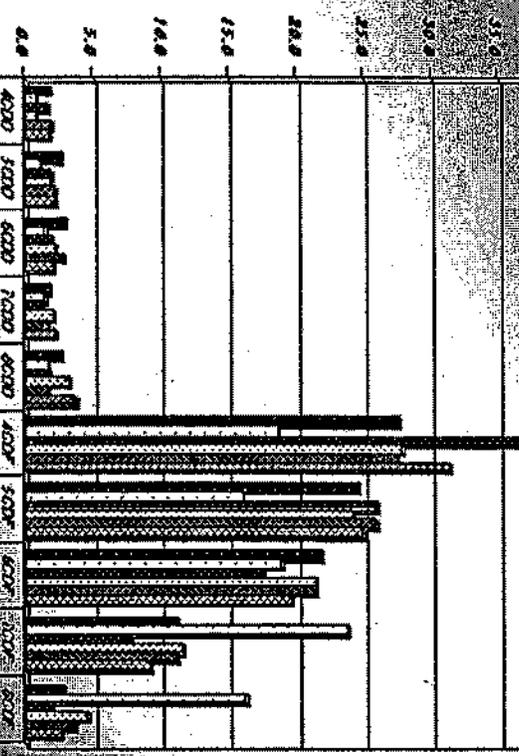
**Document entitled PCDD/F Signatures for November 2000 Air Concentrations and Stack Emissions containing two charts, undated
(As referenced in the Response to Comment 16D.4)**

Ambient Air PCDD/F (High Values) Nov 2000



Conquest Group

7.9
 VIII
 Sessions of PCDD/F: November 2000



	4DD	5DD	6DD	7DD	8DD	1,2,3,4,6,7,8	1,2,3,4,6,7,8,9	1,2,3,4,6,7,8,9,10
■ 11/18/00	1.8	2.6	3.0	1.8	2.6	2.1	2.1	2.1
□ 11/19/00	0.9	4.1	4.5	1.5	1.6	1.6	1.6	1.6
■ 11/20/00	1.7	1.9	2.0	1.5	1.6	2.3	2.3	2.3
□ 11/21/00	0.9	1.8	2.3	2.2	2.2	2.2	2.2	2.2
■ 11/22/00	2.0	2.4	2.7	1.8	1.7	2.3	2.3	2.3
□ 11/23/00	1.8	2.2	2.7	2.5	2.7	2.3	2.3	2.3

Concentration (ppt)

Attachment G

**Letter from Valdas V. Adamkus, Regional Administrator of
U.S. EPA Region 5 to Terri Swearingen, President of the Tri-State
Environmental Council, dated August 17, 1995
(As referenced in the Response to Comments 15A and 15D)**



Central File

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
 REGION 5
 77 WEST JACKSON BOULEVARD
 CHICAGO, IL 60604-3590
 AUG 17 1995

FILE - FROM NEWSPRZ

*Copy - PIC
Judith*

1995 AUG 25 AM 4:20

REPLY TO THE ATTENTION OF:

R-193

Ms. Terri Swearingen, Coordinator
 Tri-State Environmental Council
 P.O. Box 76
 Chester, West Virginia 26034

Dear Ms. Swearingen:

Thank you for your document entitled Petition Requesting Denial of Permit Renewal, Termination or Revocation of the WTI Permit, which I received on April 5, 1995. That petition raised your objection to the potential reissuance of a permit under the Resource Conservation and Recovery Act ("RCRA") for the Waste Technologies Industries ("WTI") facility in East Liverpool, Ohio, and requested termination or revocation of that permit.

We will consider the arguments and information presented in your submission during the process of developing for comment a draft permit renewal decision for WTI. With respect to your request for termination or revocation and reissuance of the permit, we do not believe at this time that the points raised in your submission warrant these responses. As further explained below, many of the points are presently undergoing rigorous examination by the United States Environmental Protection Agency ("U.S. EPA") and/or the appropriate Ohio authorities. We will follow closely the results of these examinations, and determine, based on the results, what if any permit actions are warranted. For now, I would like to respond to the most significant issues you raise.

Since a primary focus of your petition is on permit renewal and the procedures for citizen participation in that process, I believe it is important to clarify that it is the State of Ohio, not the U.S. EPA, which has primary authority over whether or not the RCRA permit will be renewed. Because of this, I am providing a copy of this petition to the Director of the Ohio Environmental Protection Agency ("Ohio EPA"), so that he and his staff can analyze and consider all the issues you have presented. The Ohio EPA can provide you with any additional information you may need about the proper procedures for public participation in the Ohio EPA permit process.

If the Ohio EPA tentatively decides to renew the State-authorized portion of the RCRA permit, the U.S. EPA will have the responsibility for making a permit decision concerning any RCRA regulations promulgated under the Hazardous and Solid Waste Amendments of 1984 for which the State of Ohio has not yet been authorized at that point in time. For example, at this time, the State of Ohio has not been authorized for the corrective action provisions of Section 264.101 of Title 40 of the Code of Federal Regulations ("40 CFR 264.101"), and the U.S. EPA would have to make any decisions regarding permit conditions to implement those regulations. WTI would need both the State and Federal portions of the permit to have a complete renewed RCRA permit.

MS: Perry Swearingen
August 17, 1995
Page 2

Whenever a tentative decision is made regarding the renewal, the U.S. EPA will publish a public notice, open a 45-day public comment period, and hold a public hearing regarding any portion of the RCRA permit over which it retains authority. In response to a question in Attachment A of your petition, the deadline for intervention in the Federal renewal process would be the close of that public comment period. The U.S. EPA will make its final decision regarding the Federal portion of the RCRA permit after the close of that comment period, based on the ability of the facility to meet all applicable regulatory standards.

To ensure that any outstanding concerns are considered whenever final decisions are made regarding both portions of the RCRA permit renewal decision, you should submit any concerns you have during the public comment period(s) on the draft permit decisions to both the U.S. EPA and the Ohio EPA.

Your submission deals extensively with changes in the WTI partnership. The U.S. EPA does not believe these changes warrant termination or revocation and reissuance of the permit (please see the fact sheet accompanying the August 24, 1993, WTI permit modification, enclosed). It is our understanding that the Ohio Hazardous Waste Facility Board ("HWFB") has an extensive, on-going proceeding to consider, among other things, the partnership changes to which you refer. We are confident that the Ohio EPA and the HWFB will give appropriate consideration to these matters in future permit decisions, including any decisions regarding permit renewal.

I would like to briefly address several specific points you make with respect to WTI's ownership. You criticize several of the bases for our conclusions in the August 24, 1993 fact sheet, cited above. I continue to believe the bases are sound. First, Von Roll America, Inc. ("VRA") was an original WTI partner. This is true regardless of whether or not VRA had offices or employees within the State of Ohio, or had actively conducted business there. Second, the changes to the WTI partnership did not involve the addition of outside companies into the partnership. Rather, the two partners (Von Roll (Ohio), Inc. ("VRO") and Waste Technologies Incorporated ("Wastetech")) that replaced two of the original partners were closely related to the original partner companies. The corporate changes you refer to relating to Environmental Elements Ohio (Inc.) did not involve the insertion of a new partner, but, rather, changes of the stockholders of the original partner¹. Such changes are not changes in ownership under RCRA (and, in any event, they occurred before the permit was issued). Third, the substitution of VRO and Wastetech for two original partners resulted from corporate reorganizations, not the addition of outside entities. We fully recognize that these two corporations are legally distinct from the corporations they replaced. The point we tried to make in the August 1993 fact sheet is that they are closely related to the

¹Environmental Elements Ohio (Inc.) was not new, as you suggest. The original partner, Koppers Environmental Corporation, changed its name to Environmental Elements Ohio (Inc.), but remained the same legal entity. See the Ohio Attorney General's Report, p. 52.

Ms. Terri Swearingen
August 17, 1995
Page 3

original partners, rather than outside companies, and that this fact supports the conclusion that the changes to the WTI partnership have been technical in nature².

In addition we do not believe that the financial situation of Von Roll AG or the 1986 WTI tax return to which you refer are significant factors in WTI permitting decisions. WTI and VRA have satisfied applicable regulatory financial responsibility requirements without reliance on the finances of Von Roll AG. The 1986 tax return simply acknowledges that changes in the WTI partnership resulted in a technical dissolution under Section 708(b)(1)(B) of the Internal Revenue Code. That section defines "termination" of a partnership, for federal taxation purposes, as occurring if 50 percent or more of the interest in the partnership is transferred within a 12-month period. Under this provision, all partnerships are treated uniformly for taxation purposes, so that federal taxation determinations are not dependent on the application of varying state laws. This provision is not relevant to the question of the status of a partnership under state law; indeed, Section 708(a) expressly limits the applicability of the definition to the subchapter of the Internal Revenue Code governing taxation of partnerships.

You also discuss, in relation to WTI's ownership and operational control, the ties between a company partly owned by VRA (New Jersey Steel ("NJS")) and an alleged mafia figure, NJS's compliance history, and VRA's candor relating to these ties during the Ohio Attorney General's ("OAG") background investigation. It is our understanding that these issues are being evaluated in the present HWFB proceeding, and that Ohio EPA and HWFB will give them appropriate weight in future permit decisions³. In addition, HWFB's conclusions will provide a basis for the U.S. EPA to evaluate whether action is warranted with respect to WTI's RCRA permit.

In your letter, you suggest that the U.S. EPA does not know who owns the WTI facility. This is misleading. Questions have been raised, and extensively analyzed, regarding the legal effect of changes in the WTI partnership; we continue to believe there is no clear right answer under Ohio law as to the

²Our conclusions relating to WTI have been fully consistent with the conclusions you discuss relating to the Lafarge facility in Alpena, MI. Our position regarding WTI has been that the permittee is the legal entity identified on the permit, and that changes in the stockholders or corporate parents of the entity are not changes in facility ownership so long as the permittee remains legally the same "person." Of course, we acknowledge the Ohio Attorney General's conclusions with respect to the WTI partnership, and have expressed our views as to those conclusions in the August 1993 fact sheet and the accompanying "Legal Analysis of Validity of WTI Permit."

³As you know, the OAG considered many of the points you raise with respect to these issues, and concluded that the relationship between the WTI incinerator and the alleged mafia figure is remote.

Ms. Terri Swearingen
August 17, 1995
Page 4

effect of these changes. However, we know the identities and relationships of the people and companies operating the incinerator. The ownership issues that have been raised do not affect our ability, or the ability of citizens, to enforce compliance with the RCRA permit and other applicable requirements.

Another point in your petition deals with the change in WTI's operational control. We agree that the change was effected unlawfully, and we have penalized WTI for that violation. However, we do not believe WTI's violation required or warranted permit revocation. The reasons for this conclusion are detailed in the Region's decision of August 24, 1993, adding Von Roll (Ohio), Inc., to the RCRA permit, and are included in the January 23, 1995, decision of the U.S. EPA Environmental Appeals Board (enclosed), upholding that permit modification.

Regarding WTI's compliance history, we agree that this has not been perfect, but we do not believe that the severity or number of violations recorded to date warrants such a severe response as permit termination. It is our assessment that the WTI facility has generally been returned to compliance quickly and that the facility management has responded to incidents and violation notices with improved procedures to reduce the likelihood of repeat problems. The State of Ohio will consider compliance history in its permit renewal decision.

I would also like to address your concern over the WTI facility endangering public health. In your petition, you mention the findings of Judge Ann Aldrich from the United States District Court for the Northern District of Ohio. Judge Aldrich's March 5, 1993, Memorandum and Order in that case (later dismissed for lack of subject matter jurisdiction⁴) was, for the most part, based on the results of a U.S. EPA screening⁵ analysis of cancer risks from stack emissions of dioxin and furan compounds. That analysis was not intended to be an in-depth exposure assessment using site-specific information regarding locations of key exposed individuals. It covered the first year of operation of the facility and assumed continuous operation. Since the

⁴The U.S. EPA believes that the Court of Appeals would have overturned Judge Aldrich's findings regarding the risk from the facility had it reached the issue. In particular, Judge Aldrich mistakenly determined that the risk from one year of post trial burn operation was "...likely to result in an increased cancer risk of at least 4×10^{-5} ." It is important to keep in mind that the conservative, hypothetical exposure scenarios in any screening analysis refer to plausible but unlikely conditions. The actual risks are likely to be less than the upper bound risk predicted by a screening.

⁵A screening analysis of risk is a simplified exercise which, due to its conservative assumptions, tends to overstate potential risks. It is only meant to be used as a first step to determine whether a more detailed risk assessment is called for.

Ms. Terri Swearingen
August 17, 1995
Page 5

facility had not yet started operations, estimated air concentrations of dioxin and furan compounds from the Phase I risk assessment were utilized. Further, a number of aspects of the fate, transport, and food chain modeling were intentionally very conservative.

Lifetime cancer risks resulting from the one-year uninterrupted operation, followed by residual risks from soil impacts, were estimated for four different exposure scenarios: a subsistence farmer who ate only beef raised on his farm, a "high-end" farmer who ate beef both from his farm and from other sources, a resident with a home garden, and a child with schoolyard exposures. Since the analysis was for screening purposes, it was also conservatively assumed that the subsistence farmer lived at the point of maximum impact of the stack emissions.

For the residential and schoolyard exposures, no risks exceeded 10^{-7} . For both farm scenarios, the only risk which exceeded the 10^{-7} level was the beef ingestion risk, which was in the 10^{-5} range. From this highly conservative screening analysis, the Agency concluded that a one-year period of uninterrupted operation of the incinerator would not result in unreasonable risk to the population in the environs of the facility.

This analysis was updated in the Fall of 1994 based upon site-specific data which became available after the completion of the initial analysis. Such data included one-year meteorological data from the site, actual emissions data from the performance tests and trial burn conducted subsequent to the installation of the enhanced carbon injection system, and actual percentages of time that the facility had been operating since the start of the period of limited commercial operations. Further, it utilized updated dioxin fate and transport parameters, consistent with the Agency's dioxin exposure reassessment document. All of the exposure scenarios and assumptions were unchanged from the initial screening analysis.

For the residential and schoolyard exposures, no risks exceeded 10^{-8} . For both farm scenarios, the only risk which exceeded the 10^{-8} level was the beef ingestion risk, which was 1×10^{-6} for the subsistence farmer and 5×10^{-7} for the high-end farmer.

The U.S. EPA has concluded from the results of the updated screening analysis that the potential risks posed by this facility are not sufficient to terminate operating the facility until the more detailed, site-specific Phase II risk assessment is completed. As you know from previous correspondence with the U.S. EPA, the Phase II risk assessment will go beyond a consideration of the impacts of dioxins and furans, and will address the following routine emissions:

Ms. Terri Swearingen
August 17, 1995
Page 6

- 1) Dioxin/furan emissions;
- 2) Emissions of nondioxin products of incomplete combustion;
- 3) Emissions of toxic and carcinogenic metals;
- 4) Potential for emissions from process upsets;
- 5) Routine fugitive organic emissions, such as leaks from valves, flanges, and pumps; and
- 6) Routine fugitive particulate matter emissions.

It will evaluate both direct and indirect routes of exposure, potential ecological impacts of major emissions, and the impacts of potential accidental release events such as fires and major spills.

The draft project plan for this risk assessment was the subject of an independent scientific peer review, and the resulting risk assessment has been modified based upon the recommendations of those peer reviewers. The draft Phase II risk assessment will also be peer-reviewed by an external panel later this year. The Agency is committed to performing an objective risk assessment for this facility based on sound science and the best information available. The final Phase II risk assessment will be considered by the U.S. EPA and the Ohio EPA in making permitting decisions for the facility.

Your letter also mentions recently discovered noncancer health effects associated with dioxins/furans that are discussed in the U.S. EPA's draft Dioxin Reassessment document. That draft document is currently undergoing scientific peer review by the U.S. EPA Science Advisory Board. When that document becomes final, the Agency will consider whether additional dioxin impacts need to be evaluated in Agency risk assessments.

In footnote 7 on page 23 of your petition document, you make reference to the availability of written legal analyses by your various listed legal experts. I would be very interested in receiving copies of those written analyses.

You assert in your petition that the WTI permit should be terminated because it was issued in violation of Executive Order 11988, regarding floodplains. However, the U.S. EPA did consider that Executive Order in promulgating its location standards in 1980 (see 40 CFR 264.18), and the WTI permit was issued in compliance with those standards.

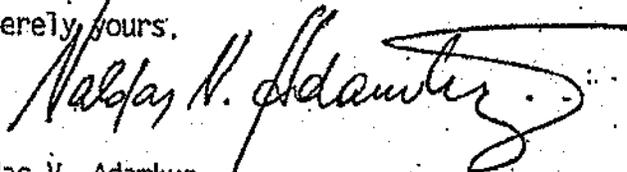
In response to your question about how a responsible government official could approve Von Roll's operating a hazardous waste incinerator in East Liverpool, I believe that responsibility in government involves a number of factors, the first of which is the protection of the public against unreasonable risks. Based on the Agency's best scientific analyses to date, we have no basis to conclude that the facility presents an unreasonable risk to human health or the environment. The U.S. EPA is continuing to study potential risks associated with this facility and when finalized, the Phase II risk assessment will be used in the permitting decision-making process. I believe that responsibility in government also includes an understanding of the relevant statutes; respect for due process; consistent adherence to the requirements of duly promulgated regulations; reasonableness in the enforcement and

Ms. Terri Swearingen
August 17, 1995
Page 7

implementation of regulations and statutes; and proper allowance for the roles of the States in implementing and enforcing environmental programs. WTI has complied with the applicable Federal location standards, financial responsibility requirements, and other regulatory obligations. Under these circumstances, I believe we have acted responsibly and prudently in regulating WTI.

Thank you for your interest in this matter. If you have any questions regarding this response, please contact Mr. Gary Victorine of my staff at 312-886-1479

Sincerely yours,



Valdas V. Adamkus
Regional Administrator

Enclosures

cc: D. Schregardus



Attachment H

**Letter from David A. Ullrich, Acting Regional Administrator,
U.S. EPA Region 5, to Donald Schregardus, Director, Ohio Environmental
Protection Agency, dated April 22, 1998
(As referenced in the Response to Comment 16A.7)**



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

APR 22 1998

REPLY TO THE ATTENTION OF:

R-19J

Donald Schregardus, Director
Ohio Environmental Protection Agency
1800 Watermark Drive
Columbus, Ohio 43226

Dear Mr. Schregardus:

The purpose of this letter is to transmit the results of the detailed risk assessment Region 5 conducted relative to the Waste Technologies Industries ("WTI") facility in East Liverpool. In addition, I have enclosed a summary document which (1) summarizes the findings of the risk assessment; (2) highlights those areas that this risk assessment, and the risk assessment process in general, does not address; (3) discusses additional information relative to the overall health of the East Liverpool community; and (4) discusses the findings of the Ohio Department of Health regarding an apparent overall higher cancer rate in East Liverpool compared to the average rate in Ohio.

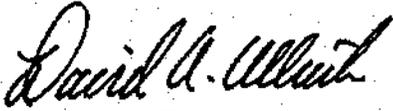
I understand that the Ohio EPA will in the near future decide whether or not to renew WTI's hazardous waste installation and operation permit. Because Ohio is now authorized for almost all elements of the RCRA program, this renewal action will result in the Ohio EPA taking over the primary responsibility for administering the RCRA permit. The information transmitted along with this letter is intended as additional information that you might want to consider as you approach that decision.

The risk assessment underwent three rounds of scientific peer review and comment. The final assessment and subsequent addendum together address the peer comments in detail. As an extra step, my staff is preparing a detailed response document for those who attended the U.S. EPA's August 1997 availability session, and I will send that document to you when it is complete.

Our respective staffs have worked closely over the years to ensure effective coordination between the Ohio EPA and the U.S. EPA regarding the regulation of WTI, and I want to assure

you that my staff and I continue to stand ready to assist you as you take the lead in this matter. If there is any additional information or assistance we can provide, please do not hesitate to let me know.

Sincerely,



David A. Ullrich
Acting Regional Administrator

Enclosures:

- Summary Document: U.S. EPA Risk Assessment
- U.S. EPA Risk Assessment for the WTI Hazardous Waste Incineration Facility

Enclosure
April 1998 Letter to
Mr. Schregardus

SUMMARY DOCUMENT:

U.S. EPA RISK ASSESSMENT REGARDING THE WTI FACILITY

U.S. EPA Risk Assessment Document:

The U.S. EPA risk assessment, developed over a four-year period, consists of three basic parts: a human health risk assessment, a screening ecological risk assessment, and an accident analysis or "hazard assessment."

Both the initial project plan and the draft report of this risk assessment were reviewed by external panels of independent scientists, selected from stakeholder nominees. The panels included experts in the fields of toxicology, combustion engineering, atmospheric dispersion and deposition modeling, exposure assessment, accident consequence analysis, and ecological risk analysis. The U.S. EPA made changes at both stages to reflect the recommendations of these independent experts. In addition, we had a group of the reviewers perform a supplemental peer review on a portion of the accident analysis that was added in response to the second peer review. An addendum to the original eight-volume risk assessment was recently developed in response to that supplemental peer review, and your copy of the risk assessment includes that addendum.

In summary, we believe the risk assessment did not show significant or unusual risks associated with the activities at the WTI plant. A brief summary of the conclusions of the three main portions of the document follows:

Human Health Risk Assessment

The report concluded that for most of the population, including students who attend the nearby elementary school, the potential increased lifetime cancer risk would be less than 1 in 1 million from stack emissions, and less than 2 in 1 million from fugitive emissions (Note that the average lifetime cancer risk in the U.S. from all causes is roughly 0.25, or 250,000 in 1 million).

In addition to potential cancer effects, the HHRA also evaluated potential toxic effects and concluded that because emission exposures were all found to be well below the relevant toxic thresholds, no toxic health effects are expected.

Enclosure
April 1998 Letter to
Mr. Schregardus

Screening Ecological Risk Assessment

The Screening Ecological Risk Assessment ("SERA") concluded that, for the expected stack emissions of organic compounds and metals from WTI, there would be very low or negligible long-term ecological risks.

For fugitive emissions, the SERA predicted very low to negligible ecological risks except possibly for the chemical formaldehyde. For formaldehyde, potential effects were indicated in one small area immediately adjacent to the site, where wildlife exposures are expected to be quite limited and, therefore, adverse effects are expected to be unlikely.

Both the HHRA and the SERA also evaluated a second scenario, which considers the hypothetical situation of WTI emitting toxic and carcinogenic metals at its maximum permitted hourly rates, 24 hours a day, 365 days a year. This condition is not expected, but such an analysis can be important from a regulatory point of view. This exercise showed that additional permit restrictions were warranted to ensure that the facility will not operate continuously at these levels. Those additional restrictions have now been put in place in the federal RCRA permit.

Accident Analysis

The accident analysis is not really a risk assessment, but rather, is a study of the likelihood and potential magnitude of off-site consequences of general categories of accidents. The specific categories studied include accidents that might occur at the WTI plant site, and those that might result during off-site transportation of waste. We believe that the results of this type of an analysis can help identify where additional preventive measures and protective measures might be warranted. The study concluded that, for both on-site and transportation accidents:

-events predicted to have major off-site consequences (i.e., unacceptable concentrations potentially extending 300 - 3000 feet from the plant) are unlikely (i.e., predicted to occur between once every 100 years and once every 1,000 years) or "very unlikely" (i.e., predicted to occur less than once in 1,000 years).

-accidents predicted to have catastrophic off-site consequences (i.e., unacceptable concentrations extending out 3000 feet or more) were determined to be very unlikely.

Enclosure
April 1998 Letter to
Mr. Schregardus

-at least two categories of accidents which could have moderate impacts (i.e., having potentially unacceptable impacts out to 650 feet), were found to be reasonably likely (i.e., predicted to occur between once in 10 years and once in 100 years).

Areas Not Addressed by Risk Assessments

One concern that certain members of the East Liverpool community have is whether the final risk assessment provides reasonable assurances of safety, and whether the risks associated with WTI's operation might go beyond current knowledge and understanding.

The U.S. EPA believes that the most objective means of assuring that a hazardous waste combustion permit is protective is to conduct a thorough risk assessment based on sound science. However, it is probable that there are risks which cannot be identified or characterized in such assessments. The present science of risk assessment cannot completely address all potential risks. However, it is important to emphasize that due to the conservative nature of this risk assessment, the U.S. EPA believes that the findings do demonstrate that controls at the WTI facility are protective of human health and the environment.

A list of the major issues which the present science of risk assessment is not able to completely consider is as follows:

- 1) The potential endocrine disruptor effects of dioxins/furans have not been evaluated due to the lack of essential dose/response information. The risk assessment evaluates only the carcinogenic effects of PCDDs/PCDFs, and not potential endocrine disruption effects. The U.S. EPA is aware of the growing body of scientific research that indicates a number of synthetic chemicals may interfere with the normal functioning of human and wildlife endocrine systems. The U.S. EPA is very concerned about these findings and is investing significant resources into learning how and to what extent these chemicals may be adversely affecting human health and wildlife. However, no substantiated dose-response profiles have yet been established. Without this type of information, a quantitative risk assessment cannot be performed for these effects at this point in time.
- 2) There is currently no established method to evaluate potential synergistic or antagonistic effects of the many trace chemicals known or suspected in the emissions. Synergistic effects could potentially increase toxic responses above those predicted in a current risk assessment, and antagonistic effects could reduce the toxic responses. The risk assessment did consider the potential additivity of chemical impacts.

Enclosure
April 1998 Letter to
Mr. Schregardus

- 3) Current risk assessments do not completely address the possible existence and potential effects of "dioxin-like" compounds which, due to insufficient test methods or toxicological standards, cannot be evaluated further. Such compounds could possibly result in the risks being greater than predicted. The risk assessment did conservatively take into account the potential for brominated dioxins/furans, which we believe is a major category of such "dioxin-like" compounds.
- 4) In some cases, risk assessments use national statistics in lieu of site-specific demographic information. For example, the WTI risk assessment uses many of the same assumptions that other U.S. EPA assessments have used, including an assumption that people generally only live in an area for nine years. Some members of the community have objected to this as being unrealistically short, given the specific situations of the residents of East Liverpool.

There are additional areas where the community has pointed out what they believe to be potential weaknesses in the risk assessment, and these are being addressed in the upcoming Response To Comments document. One concern expressed has been that all the recurring fires, fugitive releases, waste feed cutoffs, etc., at WTI, indicate negligent management of operations. There clearly have been compliance problems at this plant. Violations are not acceptable, nor are situations which might expose the public to toxic chemicals, even if those situations are not strictly violations. It is important that both the U.S. EPA and the Ohio EPA continue to enforce the regulations and permit requirements, and work to ensure that problems involving releases are investigated and solved.

Background Health of the Community

This risk assessment, like any other predictive risk assessment, calculates and predicts possible increased risk based on what is known about the chemicals being emitted, air dispersion, toxicology, plant uptake, human consumption patterns, etc. It does not fully consider background pollution or cancer rates, because U.S. EPA's rules currently regulate based on each facility's individual potential to increase risk. An individual source of pollution should generally not be allowed to have a significant impact, whether the area in which it is located is industrial, rural, or pristine. However, background health information is one issue that the decision makers can consider along with the results of a risk assessment.

One of the peer reviewers suggested that one gross indicator of the overall health of the East Liverpool community would be the rate of emergency room admissions for asthma. The local rate could be compared to similar figures for the State and for the United States (which are

Enclosure
April 1998 Letter to
Mr. Schregardus

generally understood to be increasing). We asked the Commissioner of the East Liverpool Board of Health for his suggestions and his assessment as to whether such a study could be performed and whether it might give credible information. While he indicated an interest and provided general comments, he did not offer concrete suggestions as to how one might proceed with such a study.

Ozone and particulate matter are the two major air pollutants which appear to be associated with acute respiratory health effects in the general population. These health effects include inflammatory responses in the lungs, reduced lung function, and exacerbation of asthma symptoms. Recent epidemiological and public health studies have shown a positive correlation between hospitalization rates and elevated levels of ozone and particulate matter. The most sensitive population groups are the elderly, asthmatics, and persons with pre-existing respiratory illness. To address these public health concerns, the U.S. EPA has promulgated new national ambient air quality standards for these two pollutants. The purpose of these standards is 1) to provide additional protection for the most sensitive population subgroups by lowering the allowable concentrations of these two pollutants; and 2) to present specific target levels and time frames which the states must achieve in order to be in compliance with the new standards.

Because undesirable health impacts can result from elevated levels of ozone and particulate matter, the most proactive urban areas issue advanced warnings (e.g., "ozone alert days") to reduce the potential health consequences. The U.S. EPA suggests that a preventive approach should be taken by all communities. Consequently, instead of relying on "after the fact" measures such as the collection of hospital admission data to serve as an index of air quality, regular local air monitoring for ozone and particulate matter might be considered. It would also be desirable to establish a reporting system that would provide rapid notification to the local health department and/or the local emergency response group that elevated levels of these two pollutants have occurred. This would allow the appropriate public health responses to be activated in a timely fashion.

Department of Health Report

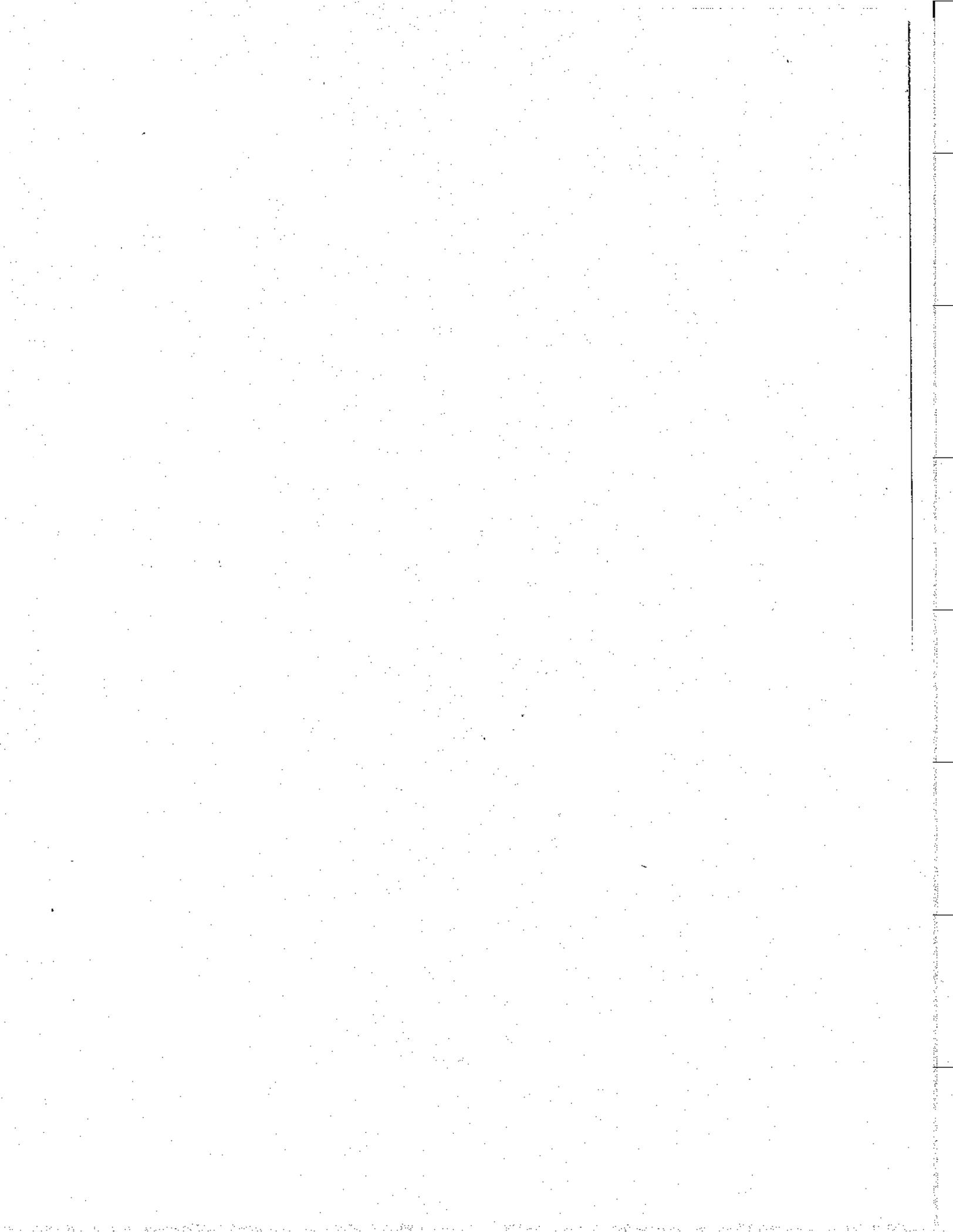
At a public meeting held on May 8, 1997, Mr. Alonzo Spencer presented information which indicated a higher-than-normal rate of cancer in the ELO area, based on a draft report from Ohio Department of Health (ODH). The final version of this document, issued in August of 1997, appears to confirm this higher cancer rate.

Enclosure
April 1998 Letter to
Mr. Schregardus

The ODH report, (as summarized in an August 14, 1997, letter from Robert W. Indian of the ODH to Gary Ryan of the East Liverpool Board of Health) found that for the years 1992 to 1995, in general, the average annual direct age-adjusted mortality rate for East Liverpool residents was higher than the rates for the State of Ohio and for the United States. The report stated that the overall cancer rate was 235 per 100,000, which Mr. Indian characterized as being strikingly higher than the Ohio rate of 182.6 and the U.S. rate of 172. While Mr. Indian's summary letter makes it clear that this observed higher cancer rate is not thought to be caused by WTI, it is quite possible that these higher rates are related to the area's industrial legacy.

Attachment I

**Information Regarding Potential Non-Cancer Effects of Dioxin.
A summary of information and conclusions presented in the
Draft Dioxin Reassessment for the three human organ systems
(As referenced in the Response to Comment 16B.14)**



Attachment I

Information Regarding Possible Non-Cancer Effects of Dioxin

The following is a summary of the information and conclusions presented in the Draft Dioxin Reassessment (Part II, Chapter 7, Part B) for the three human organ systems mentioned in the response to Comment 16.B.14. The full review may be read or downloaded from the EPA Internet at:
<http://cfpub.epa.gov/ncea/cfm/part1and2.cfm?ActType=default>

REPRODUCTIVE SYSTEM

Effects on Hormones

Conclusion: The human data offer some evidence of alterations in male reproductive hormone levels associated with substantial occupational exposure to 2,3,7,8-TCDD. The results support the animal literature, in which dioxin-related effects have been observed on testosterone synthesis and on the hypothalamic-pituitary-Leydig-cell axis.

Evidence:

In laboratory rats, high doses of 2,3,7,8-TCDD have been related to decreased testosterone levels, with evidence that dioxin decreases testosterone synthesis.

A reported symptom of men who were exposed to 2,3,7,8-TCDD-contaminated materials as a result of daily exposure or industrial accidents is reduced libido. Two independently conducted studies of West Virginia trichlorophenol workers noted that exposed study subjects also reported this condition approximately 50% more often than either the unexposed controls or individuals without chloracne. Endocrine studies or evaluations of conditions or situations that may lead to a reduction in libido were not conducted.

In a NIOSH study of trichlorophenol workers, questions regarding libido were not addressed. However, reproductive hormone levels were measured and related to serum 2,3,7,8-TCDD levels. In linear regression analyses, serum 2,3,7,8-TCDD was positively and significantly related to serum levels of luteinizing hormone (LH) and follicle-stimulating hormone (FSH) and inversely related to total testosterone after adjustment for potential confounders ($p < 0.05$). The prevalence of abnormally low testosterone was 2 to 4 times greater among workers with serum 2,3,7,8-TCDD levels of 20-75 pg/g (OR = 3.9, 95% CI = 1.3, 11.3), 76-243 pg/g (OR = 2.7, 95% CI = 0.9, 8.2), or 244 pg/g (OR = 2.1, 95% CI = 0.8, 5.8) than among unexposed reference subjects (4.8%) (mean serum 2,3,7,8-TCDD = 7 pg/g). Workers in these same serum 2,3,7,8-TCDD quartiles had a greater prevalence of abnormally high LH than workers with serum 2,3,7,8-TCDD levels of 244 pg/g to 3400 pg/g, but the differences between each serum 2,3,7,8-TCDD category and the reference subjects were not significant.

The Vietnam War veterans "Ranch Hand" study provides the only other human data available that evaluate the relationship between serum 2,3,7,8-TCDD and testosterone. (The study population consisted of U.S. Air Force personnel who served in Operation Ranch Hand units in Vietnam from 1962 to 1971 and were employed in the dissemination of Agent Orange defoliant through aerial spraying. A comparison group included Air Force personnel who flew or maintained C-130 aircraft in Southeast Asia during the same time period.) Ranch Hand veterans with serum dioxin levels exceeding 33.3 pg/g were reported to have a lower mean total serum testosterone level (515.0 ng/dL) than the non-exposed comparison group (525.2 ng/dL), but the difference was statistically insignificant. No association was observed between serum 2,3,7,8-TCDD levels and FSH or LH levels.

Testosterone, FSH, and LH were also measured in U.S. Army veterans and non-Vietnam War veterans ("Centers for Disease Control Vietnam Experience Study", 1988). No significant differences in hormone mean levels were noted between the two veteran groups. Additionally, the proportions of values outside the reference range were also similar.

Endometriosis

Conclusion: Two studies of infertility patients (Mayani study, 1997; Pauwels study, 1999) raised the potential for an association between endometriosis and TCDD exposure. These studies were small and of limited statistical power. A third study compared women who were breast-fed as infants to women who were bottle-fed. But the study contained little documented data on dioxin exposure and, most likely, an incomplete and potentially biased selection of cases. As a group, these studies are of limited use for examining the relationship of dioxin to endometriosis.

Evidence:

In 1993, a report was published on the prevalence and severity of endometriosis in rhesus monkeys chronically exposed to 2,3,7,8-TCDD. Following this, investigators started looking at a possible association between TCDD and endometriosis in humans.

The first report was a case-control study (Mayani study, 1997) comparing 79 women, all treated in an infertility clinic during 1991-1995, some with endometriosis (N = 44), and the comparisons with tubal infertility (N = 35). All women underwent laproscopic examination for diagnosis and scoring of endometriosis. Altogether, 9 women had detectable levels of TCDD: 2.9% of the controls (N = 1 of 35), 12.5% of those women with Stage I-II endometriosis (N = 3 of 24), and 25% of those with Stage III-IV endometriosis (N = 5 of 20). Logistic regression was used to control for potential effects of the different racial/ethnic compositions of the cases and controls. The results of this analysis, compared to other unadjusted analyses, were not explicitly identified, but are probably Odds Ratio = 7.6 (95% Confidence Interval = 0.87-169.7). The investigators did not present sufficient information on their data analyses to evaluate them (for example, whether actual levels of TCDD were entered, or whether detectable levels were observed), but they did note the limited power of this study. An exposure dose-severity relationship was not observed. The frequency of exposure appeared to increase with increasing severity, but the relationship was not statistically tested.

The second study (Pauwels study, 1999) examined 101 infertile women treated at the Center for Reproductive Medicine in Belgium between 1995 and 1998. Women were defined as infertile after attempting pregnancy for at least 1 year without success. Using laproscopic examination, 42 women were diagnosed with endometriosis; 25 women had mechanical infertility (e.g., tubal disease), and 8 husbands of 20 without diagnosis were found to be infertile. Fourteen women were excluded from analysis because of ovulatory dysfunction. Dioxin-like TEQs levels based on measurement of major PCB congeners and chlorinated pesticides were generated using serum (N = 101), adipose tissue (N = 46) and follicular fluid (N = 8). In preliminary analyses and using a cut point of 100 pg dioxin-TEQ/gram serum lipid weight, the investigators observed that proportionately more women with endometriosis exhibited elevated dioxin-TEQs (17%) compared to the controls (4%) (OR = 4.0; statistically non-significant).

The third study of endometriosis was based on an examination of the history of breast milk consumption (Ikezuki study, 1999). The investigators hypothesized that women who were breast fed as infants would have higher dioxin levels and subsequently higher rates of endometriosis than would those who had been formula fed. A total of 2,848 women were queried: 2,281 women from 8 Japanese companies participating in the project, and 567 women in the Japanese Endometriosis Association or who had surgery at Tokyo University Hospital. The results indicated that the proportions observed were the reverse of what was hypothesized: namely, more women in the control group had been breast fed (68%) than had women diagnosed with endometriosis (51%). These data are considered of questionable use because of limited ascertainment of dioxin exposure, lack of knowledge about potential cases missed by the recruitment methods, and lack of detail about the comparability of the case and control groups.

RESPIRATORY SYSTEM (PULMONARY SYSTEM)

Conclusion: Case reports indicate that intense acute exposure to 2,3,7,8-TCDD can produce respiratory irritation. However, the findings from controlled epidemiologic studies do not support an association between 2,3,7,8-TCDD exposure and chronic noncancer effects on the respiratory system.

Evidence:

Studies of long-term exposure to 2,3,7,8-TCDD in Sprague-Dawley rats, B6C3F1 mice, Swiss-Webster mice, and rhesus monkeys have reported changes in bronchiolar or alveolar tissue ranging from epithelial hyperplasia and

metaplasia to squamous cell carcinomas. The hyperplastic and metaplastic changes observed in exposed animals are similar to the pathologic picture of chronic bronchitis in humans.

Case reports have described temporary respiratory irritation and tracheobronchitis among chemical workers exposed to 2,3,7,8-TCDD-contaminated herbicides following industrial accidents. In addition, chronic bronchitis was reported in seven workers involved in pentachlorophenol production, which resolved in all but two workers within 2 weeks after production was discontinued.

There is conflicting evidence from controlled epidemiologic studies regarding an association between chronic respiratory system effects and human exposure to substances contaminated with 2,3,7,8-TCDD. One study of workers involved in the production of trichlorophenol and 2,4,5-T suggested that 2,3,7,8-TCDD exposure increases the risk for abnormal ventilatory function. This study found a statistically significantly increased risk for an abnormal forced expiratory volume at 1 second (FEV1) ($p < 0.01$), an abnormal forced vital capacity (FVC) ($p < 0.001$), and an abnormal FEV1/FVC ratio ($p < 0.05$) among workers who were smoking at the time of the study. For workers, the percent predicted spirometric parameters for FEV1, FVC, and FEV1/FVC were: 99.4%, 92.7%, and 76.5%; and for the reference subjects, the percent predicted spirometric parameters for FEV1, FVC, and FEV1/FVC were: 104.4%, 97.6%, and 79.9%, respectively.

The only other study of trichlorophenol and 2,4,5-T production workers that reported on ventilatory function found no association between serum 2,3,7,8-TCDD levels and declines in ventilatory function. The disparity in results between the two studies may be related to the age of the exposed population and the unexposed reference population. In the Suskind and Hertzberg study, the exposed workers were, on average, 10 years older than the unexposed workers. Although the investigators indirectly adjusted for age by analyzing age-adjusted ventilatory measures, it is not clear if these adjustments can completely control for a 10-year difference in age. In the study by Calvert, the difference in mean age between the exposed and unexposed groups was only 0.6 years. The second significant difference between the two studies involves the potential for exposure to 2,4,5-T acid dust. The 2,4,5-T acid that was produced at the pesticide plant studied by Suskind and Hertzberg was finished as a powder. At the plants studied by Calvert, the 2,4,5-T acid was finished as a liquid. Therefore, the potential for exposure to 2,4,5-T acid dust was greater at the plant studied by Suskind and Hertzberg. Although U.S. EPA is not aware of any published reports supporting an association between ventilatory function and 2,4,5-T acid exposure, the respiratory burden of particles, in the absence of a specific toxic agent, can be a probable cause of ventilatory function declines.

The U.S. Veterans Ranch Hand study also examined the association between serum 2,3,7,8-TCDD level and respiratory system effects. This study found measurable declines in the mean FEV1 and the mean forced expiratory volume (FVC) for Ranch Hands with serum 2,3,7,8-TCDD levels above 33.3 pg/g (adjusted mean FEV1 = 91.3%; mean FVC = 87.4%) compared to a non-exposed comparison group (adjusted mean FEV1 = 93.5%; mean FVC = 91.7%). However, these 2,3,7,8-TCDD-related declines were small and were interpreted by the investigators to be "subtle" and "not clinically significant." As expected, smoking appeared to have the greater influence on lung function although this has not been considered by the Air Force in their interpretation. In the followup examination conducted in 1992, no consistent relationship was found between serum 2,3,7,8-TCDD concentrations and respiratory parameters.

Reports of mortality from respiratory diseases among the various TCDD exposed populations is mixed. In chemical production workers, no excess mortality was observed from all respiratory diseases among a subgroup of workers in the IARC study who were exposed to phenoxy herbicides or chlorophenols (SMR = 86, 95% CI = 73-101, N = 151), or among German workers exposed through an accidental release. Overall mortality from respiratory diseases among the Seveso, Italy population was less than expected for all exposure zones except males in zone A. However, chronic obstructive lung disease was twofold higher than expected in females in zone B (N = 7) and threefold higher in males of zone A (N = 4).

IMMUNOLOGIC SYSTEM

Conclusion: At the present time, there appears to be too little information to suggest definitively that 2,3,7,8-TCDD is an immunotoxin in humans. Additional studies of highly exposed adults are needed to

shed light on the effects of long-term chronic exposures.

Evidence:

The information on immunologic function in children or adults and exposure to 2,3,7,8-TCDD is scarce. All but one of the epidemiologic studies are restricted to adults and do not describe a consistent pattern of effects among the studies. Natural killer cells (NK) were increased among one population of chemical workers exposed to 2,3,7,8-TCDD and examined 17 years after exposure ended. (NK cells comprise a small fraction of the circulating white blood cells which are called "natural" because they attack without first having to recognize specific antigens. They specialize in attacking certain types of target cells, mainly cells that have become infected with virus or have become cancerous.) But these findings were not corroborated by the veterans Ranch Hand study, the BASF chemical accident cohort (German pesticide factory), the NIOSH cohort (U.S. pesticide workers), the Hamburg cohort (German workers), or a study of workers exposed to 2,3,7,8-Tetrabromodibenzodioxin and Tetrabromodibenzofuran.

Dose-related elevations in Immunoglobulin A (IgA) were observed in the Ranch Hand study in relation to current serum TCDD levels and in the BASF chemical accident cohort with respect to both current and half-life extrapolated 2,3,7,8-TCDD levels. But, IgA was not higher in adult Missouri residents who had adipose tissue 2,3,7,8-TCDD levels above background. Immunoglobulin G (IgG) was also significantly related to 2,3,7,8-TCDD in the BASF accident cohort but not in Ranch Hand veterans.

The effect of acute, high exposure to 2,3,7,8-TCDD among children from Seveso, Italy was reportedly negative within 2 years after exposure. Although no data have been published illustrating the values obtained from the tests of immunologic function in these children, the investigator reported that the measured parameters were no different in the exposed and unexposed children after two series of tests.

More advanced functional analyses have been conducted relating to the ability of T-cells to respond to intercellular stimulators such as the interleukins and interferon. These studies are suggestive of a decreased ability of T-cells to respond in individuals more heavily exposed to PentaCDDs and PentaCDFs. More work needs to be done in similarly exposed populations to confirm these findings and to determine the mechanism of action.

More comprehensive evaluations of immunologic function with respect to 2,3,7,8-TCDD exposure are necessary to assess more definitively the relationships observed in nonhuman species. Longitudinal studies of the maturing human immunologic system may provide the greatest insight. This expectation is based on the finding that many of the significant results in animal studies were observed in immature animals, and because breast milk can be a source of 2,3,7,8-TCDD and other dioxin-like compounds.

Attachment J

**Letter from Randy Ohlemacher, OhioEPA,
to Alfred Sigg, VRAWTI, dated July 20, 2004
(As referenced in the Response to Comment 8L)**



State of Ohio Environmental Protection Agency

STREET ADDRESS:

Lazarus Government Center
122 S. Front Street
Columbus, Ohio 43215

TELE: (614) 644-3020 FAX: (614) 644-3184

MAILING ADDRESS:

P.O. Box 1049
Columbus, OH 43216-1049

July 20, 2004

Final

Re: Von Roll America, Inc.
EPA ID No: OHD 980 613 541
Ohio ID No: 02-15-0589
Complaint Investigation

Mr. Alfred Sigg
Vice President & General Manager
Von Roll America, Inc.
1250 St. George Street
East Liverpool, Ohio 43920-3400

Dear Mr Sigg:

Thank you for yourself and David Cuppett accompanying Michelle Tarka, Patricia Natali and me of Ohio EPA, and Paul Little and Allan Batka of U. S. EPA during a joint investigation conducted February 25-27, 2002, of the Von Roll America, Inc. (VRA) facility in East Liverpool, Ohio. The investigation was in response to a complaint filed with U. S. EPA in January, 2002. We investigated VRA to determine the validity of the allegations and its compliance with Ohio's hazardous waste laws as found in Chapter 3734. of the Ohio Revised Code (ORC) and Chapter 3745. of the Ohio Administrative Code (OAC) and VRA's federal and state Part B permits.

The following is a summary of allegations levied against Von Roll America, Inc. and the findings of Ohio EPA. The findings are based upon interviews and documents reviewed during the February, 2002 investigation, subsequent documents provided by VRA, and the September 9, 2002 VRA response to a U. S. EPA request for information. U. S. EPA is finalizing their own findings because of some variations between state and federal permits and regulations.

Allegation 1: The "carbon feed to the neutralization system (to tank N-1) was suspended by VRA somewhere between fall of 1998 and summer of 1999, when the tank was replaced." The complainant states that the facility discontinued feeding carbon at least three years prior to the spring of 2001.

Background:

The "N" tanks (three) perform a neutralization process for the incineration system. The neutralization system receives acidic blowdown from the scrubber into N-1. This acidic

Bob Taft, Governor
Jennette Bradley, Lieutenant Governor
Christopher Jones, Director

process water is neutralized by adding lime and then used as make up water for the spray dryer. Carbon feed into N-1 was part of the original design and permit of the plant and was intended to reduce stack emissions of mercury. Carbon feed into N-1 continued until 2003 when the facility requested a permit modification to terminate carbon feed to N-1. Ohio EPA and US EPA approved the permit modification since mercury emissions were being restricted via an alternate technique of waste feed limitations. Carbon has not been fed to tank N-1 since the permit modification was approved.

Findings:

The N-1 tank was replaced during the summer of 1999, and the facility reported the work took approximately a month to complete. During that time, carbon was manually fed to the system through the feed chute on top of the N-2 tank. VRA stated that at no time was the feeding of carbon to tank N-1 ceased between January 1, 1998, and September, 2002.

According to Jeff McLaughlin of VRA, this practice has always been followed except during the time when N1 was being replaced and carbon was fed to N2. VRA states carbon has been fed to N1 continuously since the system was installed.

In conclusion, evidence was not found to substantiate this allegation.

Allegation 2: The complainant stated that "a problem lied in that the ARTS database would assign a new profile number to the hazardous waste but neglect to change the constituents for that particular profile."

Findings:

When the waste arrives at VRA, a sample is pulled to fingerprint the waste for comparison to the profile. The issue revolved around the potential for a new profile number to be assigned to a particular waste stream if there was a change in general information (e.g., generator name or address) or in the characteristics of the waste (e.g. acidic instead of neutral). If a new waste profile number was generated, it would be connected to the previous profile number by a lab-assigned number which is directly associated with the waste analyses. The lab-assigned number (called an L-number) can be connected to the container number, the analyses, the waste profile and the manifest. A Container History report can be generated to show all the movements within the facility of each container accepted for treatment at VRA. At the time of the complaint, analytical data was entered into the Laboratory Information Management System (LIMS) and then changes were made manually in the Container History report to make the connection to the old profile number. Also, any necessary notations are made in Box 19 on the manifest associated with the waste, before manifests are released from the lab. VRA explained that in May 2001, an audit program was put in place to automatically link the various programs and allow the

Container History report to reflect both the previous and current profile numbers. To further evaluate this allegation, several randomly selected Container History reports with new profile numbers were compared to manifests, LIMS reports, and ARTS reports.

In conclusion, evidence was not found to substantiate this allegation.

Allegation 3: The complainant stated that in early fall 2000, VRA inserted a blank between the secondary recirculated flue gas (SRFG) fan and the secondary combustion chamber (SCC) and that VRA intended to permanently remove the SRFG. Additionally, VRA had a process management change (PCM) form for the removal of the SRFG during early 2001.

Background:

A section of the permit describes the flue gas recirculation system. The flue gas is recirculated from the outlet of the Electrostatic Precipitator (ESP) to the secondary and tertiary air nozzles of the SCC. The flue gas recirculation affected turbulence and mixing in the SCC and nitrogen oxide formation in the incineration system.

Over the course of several years, modifications to the incineration system (e.g., steam nozzles and ambient air flow to the SCC), were approved and installed to produce turbulence in the SCC. Consequently, a permit modification request from VRA to remove the SRFG system was approved by both Ohio EPA and US EPA.

Findings:

Interviews with Mr. Bob Buchheitt of VRA revealed that a blank was temporarily inserted in the duct work of the SRFG system when maintenance work was conducted on the duct work or the fan. If the blank were not in place, flue gas from the SCC would by-pass the boiler and spray dryer and pass directly into the ESP. In addition, when work was performed on the system, safety procedures required the fan to be locked out/tagged out to prevent accidental start-up. Mr. Buchheitt stated that work orders would describe the repairs to be performed, e.g., repair SRFG fan, but would not include a step by step description of the work completed (e.g., it would not state "blank inserted/blank removed").

Interviews with Mr. Ty Geanangel of VRA revealed that his reservations regarding this modification were in reference to the process change management (PCM) form requesting the Bailey Distributed Control System (Bailey DSC) be modified so that when the SRFG fan was turned off, it would not result in an automatic waste feed cut-off and consequently a shut down of the entire system. He hesitated making the change until Ohio EPA was consulted. According to Mr. Geanangel, he did not have reservations about operating the incinerator with the SRFG system off.

According to your September 9, 2002 response to US EPA, the lockout/tagout records are only maintained for one year in accordance with OSHA regulations. A review of the work orders from June of 2000 through December of 2001 indicate that a blank was inserted during routine maintenance. The SFRG system was taken out of service on August 20, 2001, after receiving a Class 1A permit modification from Ohio EPA and a temporary authorization from US EPA. Subsequently, US EPA required a Class 2 permit modification to remove the SFRG system.

In conclusion, evidence was not found to substantiate this allegation.

Allegation 4: The packed beds of the scrubber were inspected by VRA personnel in late Winter 2000 to early Spring 2001, during a mini-outage. The complainant contends "at that time it was apparent that the packed bed of Stage Two needed to be replaced because the bed had literally melted together." The removal efficiency for sulfur dioxide and hydrogen halides may have been hindered. As of July 2001, the packed bed of Stage Two had not been replaced to the complainant's knowledge.

Background:

The 4 stage scrubber removes acid gas pollutants (chlorine and sulfur) and fine particulates (metals and salts). The first stage is the quench, a vertical duct with nozzles to spray recirculated water to cool the hot flue gases. The second stage is the first packed bed, which removes HCL in the form of an acid gas into the water.

Findings:

The scrubber is visually inspected during most outages by entry into the unit by a VRA employee. The scrubber was inspected in April 2001 during a mini-outage for refractory repair and no damage to the media was observed at that time. In May 2001, VRA employees began noticing pieces of media from the first packed bed (the second stage) in the recirculation pumps for the second stage of the scrubber. It was determined the plastic media had become brittle due to age and needed replaced. Data from HCl and SO₂ monitors were evaluated at that time and it was determined that no impact to the environment was occurring, nor were permit limits exceeded. The situation was discussed with Ohio EPA on-site inspectors on May 30th, 2001 and it was determined the system was functioning adequately and the media would be replaced during the upcoming outage. VRA and Ohio EPA personnel also discussed installing a strainer prior to each second stage recirculation pump to remove debris. A class 1A permit modification was submitted on June 11, 2001 to Ohio EPA for the installation of strainers. This modification was approved by Ohio EPA in a letter dated June 22, 2001. Strainers were installed on the second stage recirculation pumps and media was replaced in the first packed bed (second stage) during the August 2001 outage (see the August outage schedule dated 7/31/01).

The second packed bed (third stage) was inspected at that time and no media replacement was deemed necessary.

VRA stated that there was no evidence that the media "melted together". It was stated that the only way the packing media could have melted would have been in the presence of extreme temperatures in excess of the media design. You stated that several other components are made of similar material and therefore they would have melted also if such extreme temperatures had actually been experienced. This did not occur. Additionally, you stated that if the media were to have melted together to become one large mass, a decrease in pressure would have occurred. Therefore, the system could not have been operated under the alleged condition of having the packed bed media melted together. Most importantly, data from the HCl and SO₂ monitors indicated the system was operating properly and acid gases were not being emitted into the atmosphere.

In conclusion, evidence indicates that this allegation was unfounded and there are no violations associated with this allegation.

Allegation 5: This allegation dealt with the vapor recovery system. The complainant stated, "When the External Truck Wash vapor recovery unit is in the operating position, the trunk of the vapor recovery system located in the lab pack building begins pushing harmful vapors into the air instead of pulling them from the air. This is one of the reasons why the environmental department had a separate vapor recovery unit designed into the External Truck Wash/processing permit (ETW) modification."

Findings:

There is no separate vapor recovery system in the External Truck Wash building. There is an extra fan in the vapor recovery line from the External Truck Wash, but this fan is part of the original design of the vapor recovery system for the entire facility. According to VRA employees, this extra fan is almost never used because the induced draft fan maintains an adequate draft on the vapor recovery system.

The entire vapor recovery system at VRA was evaluated in 1999 by an outside company and vapor recovery locations were found to meet or exceed requirements at that time. After that evaluation, a number of unused or unnecessary vapor collection points were closed off. The vapor recovery system was then re-evaluated and it was determined that closing the unused collection points had further improved the system.

VRA stated in their September 9, 2002 letter to U. S. EPA that they had no records of vapors being discharged from the vapor recovery system into the lab pack building and that there have been no complaints to the Safety Department. Additionally you stated that

periodic reviews of the vapor recovery system are performed by the Safety Department. The reviews were conducted after construction of the lab pack building after was complete and VRA had begun processing activities inside the building.

However, VRA did indicate that during construction of the lab pack building, there was one incident in 1999 when vapors were released into the lab pack building. During construction, the flexible hoses used during processing activities were not yet attached to the main vapor recovery line in the lab pack building. To keep ambient air out of the vapor recovery system, covers were placed in front of the openings and the draw from the primary air fan held the covers in place. At the time of the incident, the extra fan was turned on resulting in a change of pressure which released the covers. This incident occurred prior to completion of construction activities in the lab pack building. According to VRA, this was quickly resolved with minor adjustments to valve controls on the vapor recovery system. This incident occurred prior to completion of construction activities in the lab pack building and facility personnel were not aware of any other incidents or complaints in relation to the lab pack building.

In conclusion, evidence indicates that this allegation was unfounded and there are no hazardous waste violations associated with this allegation.

Allegation 6: The complainant states "on more than one occasion, the operators in the control room must wear full-face respirators during their shifts because the vapors from the incineration building are so bad." A change to the ventilation system was proposed by Mr. Mike Salisbury, formerly with VRA. The complainant states "This ventilation change would guarantee that the operators within the control room would be free of an unhealthy and unsafe workplace."

Findings:

The control room is located in the facility's feed building. The first complaints of odors were reported in 1993. The make-up air for the control room at that time was collected on the fourth floor of the feed building which is where the feed hopper for the incinerator is located. The system was inspected and leaks were observed and repaired. In 2000, the make-up air fan was moved onto the roof of the feed building. The control room, drum pulpit and connecting hallway on the third floor of the feed building are all under positive pressure to prevent the accumulation of vapors from processes in the feed building. This system is only effective when the door leading outside is kept closed which is often not the case according to Ohio EPA on-site inspectors. VRA should work to insure that these doors are indeed kept closed.

The VRA Safety Department received complaints of odors in the control room on August 3 and 5, 2000. A photo-ionization detector (PID) was placed in the control room for approximately one hour after each complaint. VRA stated that "the concentration of ionizing compounds was less than 5 ppm which is below any standard which triggers the need to sample for specific constituents". While a PID is a good screening device for volatile organic compounds (VOCs), it does not detect all VOCs nor inhalation hazards. Therefore, it should not be the sole means of determining hazards from vapors which may occasionally migrate into the control room.

In the event that vapors do enter the control room, it is supplied with self-contained breathing apparatus (SCBA) equipment. Also, approximately two years ago supplied air was installed in the control room for incidents which may have a longer duration than what can be provided with SCBA air tanks.

No hazardous waste violations were identified.

Allegation 7: U. S. EPA Region 5 inspected VRA sometime during the spring/summer of 2000 for compliance with Subpart BB and CC regulations. The complainant began asking questions regarding the change-out of the carbon boxes and how the carbon in the boxes was handled. The complainant states that "in the time I had been at the facility none of the carbon boxes had been changed out." The complainant states that "not changing any of the boxes could be an immediate cost savings of \$20,00 per year." Two samples of carbon were collected on February 23, 2001 for analysis. One sample was analyzed by the VRA lab and the other was sent to Calgon Carbon for analysis. The complainant further states "VRA had not completed any new paperwork on the carbon or thought it necessary to re-analyze the carbon even though waste streams received by the facility had changed substantially since the operation began processing waste."

Findings:

Ohio EPA has not adopted the Subpart BB and CC regulations. Therefore, U. S. EPA will address this allegation of the complaint.

Allegation 8: The carbon that is fed through the Enhanced Carbon Injection System (ECIS) must be Calgon carbon or equivalent, as stated in the permit. In the spring of 2000, the complainant states that Mr. Jim Smith asked Mr. Bill Bailey whether the carbon for the system could be changed to something less expensive. Mr. Smith was informed that the alternative would have to be tested in a lab. In addition, Mr. Smith was informed that "if the carbon and/or coke met and/or exceeded the characteristic of Calgon carbon, additional testing would be required to ensure that dioxin and furan compounds were being removed from the flue-gas cleaning system." Testing of 4 different types of carbon was conducted

by Alternative Testing Laboratory. The complainant alleges that VRA "switched from the Calgon carbon to Lignite coke, which is a by-product of a process in Germany."

Findings:

Ohio EPA is going to defer to U. S. EPA regarding any potential violations because of specific permit requirements in the federal permit that are not in the state permit.

Allegation 9: The complainant questioned whether "the data from the facility continuous monitoring system (CEMS) was accurate." The complainant says the daily waste feed cut-off and exceedance data would be printed, then transferred into a database." From this database, the complainant would "create charts and graphs that would display the number and type of exceedances that facility had." When it was time to do the quarterly exceedance emissions reports (EER), the daily sheets would be matched up to the information forwarded by Mr. Gary Jones, independent computer programmer. The data "very seldom matched each other exceedance for exceedance." The complainant would contact Mr. Jones to "confirm missing data and/or forward him information that was missing." The complainant states that Mr. Jones would always say "it was because the information was recorded on two different computers and when he combined the data some of the exceedances would be tossed out."

Findings:

Exceedance report data is obtained from the Continuous Emissions Monitoring System (CEMS) and subsequent Bailey DCS. VRA explained the certified data, which is part of the operating record, is used to generate quarterly EER. There may be differences between the real time data (data in the database) and data that has been certified. There are redundant computer systems used to make up the CEMS, mainly CEM_1 and CEM_2. The primary computer is CEM_1 and CEM_2 is the backup to provide any missing information or errors. Missing data can be a result of the PC shutting down. This may not be discovered until the alarm goes off. A quarterly Excess Emissions Report (EER) is generated the Bailey DCS using CEM data.

Ohio EPA reviewed several quarterly EERs and daily data from the database. It appeared that were generally in agreement. Additionally, quarterly EERs are the reports used to determine compliance with regulatory and permit requirements for the Ohio EPA Division of Air Pollution Control (DAPC). Ohio EPA's DAPC reviews the EERs for compliance regarding the number and type of exceedances. Ohio EPA reviewed the first three quarters of 2001 for the total hydrocarbon exceedance counts to the real time data. The first two quarters matched exactly and the third was in 96% agreement. Since there are multiple computers recording minute by minute data, it appears that some discrepancies can occur.

In conclusion, evidence was not found to substantiate this allegation. No violation of hazardous waste regulations was identified.

Allegation 9.A: The complainant alleges "During air monitoring testing at the facility, VRA burns what is referred to as "candy." The complainant did not give a definition of "candy" to further explain the allegation.

Findings:

While "candy" is not a term that is commonly used at the facility, you indicated that the term "candy" might be used to describe waste which would not be expected to cause CO spikes during incineration. CO spikes could result in a waste feed cut-off, where VRA must discontinue feeding waste to the incineration system for a period of time. VRA purposefully designs the burn menus to combine wastes in the kiln in such a way as to minimize the possibility of waste feed cut-offs. The burn plan is developed from all the different processes (lances, skip hoist, bulk feed and container feed) to stagger wastes or to maximize certain processes. Waste fed during testing is comparable to waste fed at other times, and may include higher levels of metal-bearing waste, and does not emphasize the incineration of wastes that would be easy to burn.

This was verified by evaluating types and amounts of waste fed during testing conducted in 2001 against randomly selected dates. Consistent volumes of waste were fed each day during testing as compared to volumes of waste fed each day during the rest of the year. Profiles of waste fed during the 2001 testing included oil-based paints with metals, mixed acids, water reactive siloxane heels, lab packs with metals, lab samples, phenol spill cleanup debris, aqueous waste with metals, high-btu solvent based paints with metals, isocyanates, polyols with silver, and chlorosilane waste. These wastes are comparable to wastes fed during times of non-testing. In addition, there were waste feed cut-offs which occurred during the 2001 testing, which did not affect the outcome of the testing.

In conclusion, evidence indicates that this allegation was unfounded and there are no hazardous waste violations associated with this allegation.

Allegation 10: The complainant alleges that "Heritage and VRA are utilizing this area as additional storage for the facility." The complainant further alleges "When hazardous waste has arrived at the facility and is not approved or in some cases not even manifested, VRA ships material over to the ten-day transfer facility and waits for Ohio EPA approval. Once approval is received, VRA transfers the material back to the facility."

Findings:

By "this area", the complainant is referring to a large parcel of property owned by the Columbiana County Port Authority (CCPA) which is adjacent to the VRA facility. For many years, VRA has leased space from the CCPA specifically for the storage of items such as empty box vans, roll-off boxes, and pneumatic trailers. Some box vans may be also be used for storage of unused containers such as fiber drums. This is acceptable.

The property which VRA leases for storage is separate but adjacent to the space leased from the CCPA by Heritage Environmental Services (HES) in 2001 for the 10-day transfer facility. VRA does not manage the 10-day transfer facility owned and operated by HES. However, a contract is in place for VRA to provide certain services such as VRA technicians to transfer drums and use of the VRA yard truck, as necessary. Additionally, manifests are kept at the VRA guard house for all containers being stored at the 10-day transfer facility.

On occasion, there may be containers destined for both VRA and another facility which are carried in one box van. In those instances, waste might be unloaded and sorted at VRA, and some containers (e.g., those which are destined for another facility) are placed back into the truck. The truck may then be sent to the 10-day transfer facility for up to 10 days, or it may continue to another destination. If VRA is unable to accept a load due to various reasons or if the load is not accompanied by a manifest when required, then the load should be rejected back to the generator. However, VRA may store non-hazardous waste and household hazardous waste at the HES facility since they are not subject to the hazardous waste regulations.

HES personnel were interviewed and records were reviewed in order to evaluate this allegation further. According to internal procedures, HES personnel do not put waste on a truck until the final destination has been determined. When the final destination is the VRA facility, HES personnel must have a profile approval number to assign to each shipment prior to putting the waste on a truck. This was verified by examining HES records, where every truck received at the transfer facility with waste destined for VRA was accompanied by profile numbers for each waste stream.

You stated during interviews that waste containers (destined for VRA) are not brought into VRA and off-loaded and then put back on to a truck for storage at the 10-day transfer facility and we did not find evidence that this had occurred. However, after reviewing the HES 10-day Transfer Facility logs adjacent to your property, it appears that waste destined for your facility frequently arrives prior to the scheduled acceptance date into VRA and is therefore stored at the 10-transfer facility until it can be delivered to VRA. During previous discussions between VRA and Ohio EPA, prior to the installation of the 10-day transfer

facility, it was indicated that the transfer facility would not be used for storing waste destined for VRA. Based upon the review of HES 10-day transfer log, this occurs frequently and causes concern for Ohio EPA on whether this is proper use of a 10-day transfer facility. Ohio EPA will be reviewing all regulations and interpretations regarding 10-day transfer facilities and evaluating the management practices of them throughout the state.

There are no violations associated with this allegation. However, Ohio EPA will be reviewing the proper use of 10-day transfer facilities and anticipates providing guidance on this topic in the future.

The investigative team also conducted a phone interview of a second confidential source, who alleged that containers from a particular generator were unloaded at VRA, labeled with VRA labels, put back on a truck and sent to the HES transfer yard for storage because there was no room in the VRA warehouse. To evaluate this new allegation, members of the investigative team conducted an extensive review of VRA and HES records, documents, manifests, and computer records, including cross-referencing of various independent logs and databases. The investigative team found that the multiple records matched, indicating the containers in question did not leave VRA after acceptance and the allegation was unfounded.

In conclusion, evidence was not found to substantiate this allegation.

Allegation 11: The complainant indicates that VRA is not handling manifest discrepancies appropriately. The complainant alleges that "the facility is not marking anything in box 19, and have trained the receiving staff to not mark anything on the manifest."

Findings:

Manifests are routinely evaluated during inspections by Ohio EPA personnel. Discrepancies are frequently noted in box 19 of the manifests, as necessary. As part of the investigation, manifests from different days were selected randomly and it was verified that discrepancies were noted in box 19. VRA indicated that manifest training was most recently conducted in November 2001 and is part of annual training provided to VRA employees. Training materials clearly indicated discrepancies are to be marked in box 19 of the manifest.

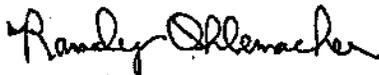
It was noted that manifests are not to be marked until customer service can reach a representative of the generator to gain approval for any notation first. After the approval is received, then the notation is to be made to box 19 of the manifest. In addition, if the discrepancy involves a piece count, then another VRA employee must recount the containers to verify the discrepancy before customer service is even contacted. Ohio EPA

personnel will continue to evaluate the manifests during inspections to verify that discrepancies are being marked on manifests.

In conclusion, evidence indicates that this allegation was unfounded and there are no violations associated with this allegation.

Should you have any questions, please feel free to call me at (614)644-2971. You can find copies of the rules and other information on the division's web page at <http://www.epa.state.oh.us/dhwm>. Ohio EPA also has helpful information about pollution prevention at the following web address: <http://www.epa.state.oh.us/opp>.

Sincerely,



Randy Ohlemacher, CHMM
Compliance Assurance Section
Division of Hazardous Waste Management

Filename: Invest Findings V4.wpd

cc: Michelle Tarka, Ohio EPA, DHWM, NEDO
Patricia Natali, Ohio EPA, DHWM, NEDO
Frank Popotnik, Ohio EPA, DHWM, NEDO
Harry Sarvis, Ohio EPA, DHWM, CO
Paul Little, U.S. EPA
Mike Mikaulka, U.S. EPA