World Trade Center (WTC)
October 21-22, 2002
Peer Review Meeting Notes

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Prepared for:
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Executive Summary

An expert panel was assembled on October 21 and 22, 2002 to conduct a scientific peer review of the U.S. Environmental Protection Agency (EPA) draft document titled, "World Trade Center Indoor Air Assessment: Selecting Contaminants of Potential Concern and Setting Health-Based Benchmarks." The panel held in-depth discussions regarding key aspects of the document as highlighted in the charge to the panel. The deliberations of the panel were supported by input from the document authors and meeting observers. Key comments and suggestions made by the panel are summarized below.

The panel noted that the overall method of selection of contaminants of potential concern (COPC) was reasonable, but greater effort is needed to include more potential contaminants. In particular, several individual panel members noted specific contaminants that might need further consideration; these were arsenic, beryllium, mercury, phthalates, and polybrominated diphenyl ethers. They also noted that greater transparency in the selection process needed to be provided. Based on the available data for review, none of the panel members suggested removing any of the currently identified COPC from the list, although the weakest case for inclusion was presented in the document for fiberglass. Panel members as well as observers noted the availability of additional sources of data relevant to the identification of COPC. The panel noted that these additional data might justify adding some new COPC or removing others from the current list. Individual panel members and observers were encouraged to provide these relevant data to the full panel (by submitting them to Toxicology Excellence for Risk Assessment) for consideration of whether these additional data might lead the document authors to select alternative COPC.

In evaluating the screening methodologies used to identify the COPC, the panel suggested that a risk-based approach, with some allowance for professional judgment based on other information, should be maintained. However, such a risk screening approach should include not only an inhalation pathway, but also a pathway that accounts for the ingestion of dust. Further, a number of panelists suggested modifying the process for selecting COPC to include the use of parameters for children's exposure and to select available toxicity benchmarks that reflect toxicity endpoints relevant to children's health. One approach to accomplish these suggestions is to adapt existing appendix D of the document for at least two exposure scenarios, a child at home (residential) and an adult at work (commercial scenario), since the risk criteria (e.g., target values) may be different for these scenarios. The panel noted that a key issue in applying a risk-based approach is to provide for a transparent methodology for selecting COPC. The panel also suggested that the approach used to consider the health effects of mixtures of COPC, such as in applying EPA Chemical Mixtures Risk Assessment Guidelines, be described more clearly in the document. It was recommended that the authors further evaluate possible interactions among potential COPC by using information available in EPA's MixTox database.

The panel discussed at length the authors' proposed strategy for health-based benchmarks, and the potential utility of the proposed three tier system in light of its understanding of the way the document was being used in the overall World Trade Center (WTC) clean-up response. Although the document described the intended and potential uses of the Tier III criteria for cleaning residences, and Tier I and Tier II criteria for possible future uses, several panel members commented that that the purpose of the Tier II levels, and the relationship among the tiers with regards to underlying risk management implications was unclear and should be described further. The panel also suggested that the rationale and purpose of each tier be more fully described in the document. For example, the intended use or potential uses of each tier criterion should be described to help the user interpret the acceptability of each criterion. The panel also noted that a two tier, rather than three tier, approach might be adequate and easier to implement.

The panel was in general agreement that the hierarchical approach used to set benchmarks was reasonable. For criteria based on existing standards, it was noted that underlying risk-based assumptions for existing standards should be considered in selecting the final benchmarks. The panel generally agreed with the selection of the specific standards (e.g., Housing and Urban Development lead standards) or published risk values (e.g., U.S. EPA's reference doses) used in determining the health benchmarks. However, several panel members disagreed with the rationale provided in the document (limitations in the sampling methods) for using an upper limit excess lifetime cancer risk level of $1x10^{-4}$ in calculating the criterion for each tier. In addition, it was suggested that the risk value for indoor air for lead incorporate local exposure loading data. For setting benchmarks based on occupational exposures, several panel members suggested using duration-based exposure factors that consider chemical-specific issues. For example, when setting occupational exposure limits for chemicals posing a sensory irritation hazard, the objective is to identify limits, which prevent transient effects following short-term exposure. On the other hand, when dealing with more persistent chemicals, which have a long biologic half-life, other approaches are needed (Paustenbach, 2000).

Suggestions for additional criteria for determining the tiers were also made. The panel suggested that criteria for soft surfaces would need to be added for some chemicals, while for others only criteria for air should be used. There was no general agreement among the panel on the applicability of existing K-factors to derive air standards from settled dust concentrations. Based on limitations in the applicability of published K-factors, the panel was unwilling to endorse using K-factors to derive air standards from concentrations of contaminants in settled dust. Furthermore, the panel did not agree on the degree to which aggressive or normal activity patterns should be incorporated into the monitoring protocols for compliance with the air-based criteria. Based on these discussions, the panel recommended a chemical-by-chemical rationale be included for the need for hard-surface, soft-surface, or air criteria for each COPC based on the relevant routes of toxicity and pathways for exposure. As noted in the discussion of the COPC, the panel also suggested that exposure scenarios for residential settings include additional

parameters of child exposure, and that criteria based on exposure assumptions for non-residential (such as schools, day-care and commercial) settings also be considered.

The panel noted that identifying a background level for each COPC would be essential in applying the Tier III criteria, and specifically noted the importance of applying a statistical methodology in determining background concentrations, as well as assuring that background samples are from similar structures. It was noted that there are several publications on EPA methods that should be consulted in identifying background levels. Panel members and observers also noted the existence of several additional studies that might be useful for this purpose.

The panel discussed the likely future need to characterize WTC dust as distinct from other dusts via a "fingerprint" by using either a unique pattern of substances or one or several indicator COPC that are characteristic of the WTC, but not otherwise generally present in buildings in New York City. Some suggestions were provided on types of chemical fingerprints that may be considered, but the panel noted that defining this is beyond the charge of this effort, would require an unknown amount of effort, and that in any case a specific recommendation could not be given absent a review of other data that were not made available. It was noted that use of marker or indicator chemicals, once validated, might also serve as surrogates in measuring cleaning efficiency for other groups of compounds that would be removed similarly by the same cleaning technique.

In summary, the following overall suggestions were made:

- Include more potential contaminants in the screening process as appropriate based on the availability of additional sources of relevant data as noted by the panel and observers.
- Employ greater transparency in the selection of COPC.
- Include a dust pathway for risk-based screening for COPC selection.
- Include parameters for children's exposure and toxicity endpoints into the residential exposure scenario for a child at home, as well as applying a residential scenario for adults. Also consider adding an exposure scenario for adults at work (commercial scenario).
- Describe more fully the approach used to consider the health effects of mixtures of COPC.
- Describe more fully the rationale and purpose of each tier.
- Reconsider some of the specific benchmarks. For carcinogens, some panel members disagreed with the rationale (limitations in air sampling methodology) for using an upper limit excess lifetime cancer risk level of $1x10^{-4}$ in calculating the criteria for each tier, although they noted that this risk value falls within the range of $1x10^{-4}$ to $1x10^{-6}$ used by EPA. For the lead benchmark, local exposure loading data should be incorporated. When setting benchmarks based on occupational standards, duration-based adjustment factors should be used that weigh chemical-specific issues such as the type of effect (local irritation versus systemic toxicity) and the toxicokinetics of the chemical under consideration.

- Describe the rationale, for setting hard-surface, soft-surface, or air criteria on a chemical by chemical basis.
- Consult additional published studies, as well as EPA methods documents, that have been identified by members of the panel as having direct bearing on determining background levels.

Many additional technical comments were made by the panel regarding the array of issues covered within the scope of the charge questions. The panel also received and considered a number of verbal and written comments and these are reflected in the full summary of the technical meeting notes.

Introduction

An independent panel of scientists with diverse expertise met in New York City on October 21-22, 2002, to review the document entitled, "WTC Indoor Air Assessment: Selecting Contaminants of Potential Concern and Setting Health-Based Benchmarks." The Contaminants of Potential Concern (COPC) Committee of the World Trade Center Indoor Air Taskforce Working Group developed this document, which identifies pollutants of concern in indoor environments in lower Manhattan and determines health-based benchmarks or clearance levels for these contaminants. This document is part of a larger effort by health and environmental agencies to clean indoor environments in lower Manhattan. To insure that the document is based on the best scientific information and judgments, the U.S. Environmental Protection Agency (EPA) requested that the non-profit research organization, Toxicology Excellence for Risk Assessment (*TERA*), conduct an independent scientific peer review.

The objective of this peer review meeting was for the panel to evaluate the scientific basis and appropriateness of the document, its conclusions and recommendations. Expert peer reviewers donated their time and talents to serve on the panel and provide an independent evaluation of the document. Appendix A provides additional information on the background and structure for the conduct of the meeting. Briefly, document authors provided initial presentations summarizing key points from the document being reviewed, and provided clarifications as solicited from the panel. The peer review was open to public observers, who were given periodic opportunities to make technical comments for consideration by the panel in their review of the EPA's document. Meeting observers were also encouraged to provide written technical comments and additional data to the panel (by submitting these materials to *TERA*).

Listed below are the sponsors of this meeting and the list of panel members:

Sponsors:

- U.S. EPA, on behalf of the Contaminants of Potential Concern (COPC) Committee of the World Trade Center Indoor Air Taskforce Working Group (includes members from U.S. EPA, New York City Department of Health, Agency for Toxic Substances and Disease Registry, New York State Department of Health, and Occupational Safety and Health Administration)
- Federal Emergency Management Agency
- Mickey Leland National Urban Air Toxics Research Center

Panel Chairperson: Dr. Michael L. Dourson, *TERA*

Review Panel:

- Dr. Jerrold Abraham, SUNY Upstate Medical University

- Dr. John Christopher, California Environmental Protection Agency
- Dr. Annette Guiseppi-Elie, Dupont Engineering
- Dr. Lynn Goldman, The Johns Hopkins University School of Public Health
- Dr. Hugh Granger, HP Environmental, Inc.
- Mr. John Kominsky, Environmental Quality Management, Inc.
- Dr. Dennis Paustenbach, Exponent, Inc.
- Dr. Bertram Price, Price Associates, Inc.
- Dr. Charles Salocks, California Environmental Protection Agency
- Dr. Susan Youngren, Bergeson & Campbell, P.C.

Process Overview and Conflict of Interest Statements

The technical meeting opened with a brief overview of the peer review process and the ground rules for the meeting. Each panel member was asked to introduce themselves and was asked to make a statement about any potential conflicts of interests, or elaborate on items noted in the conflict of interest statements (provided in Appendix A) that were submitted to *TERA* as part of the panel selection process. Most of the panel members stated that they had no prior work activity related to the WTC disaster or any known conflicts and felt they could participate fully in the meeting. Additions to the written conflict of interest statements are noted here.

Mr. Kominsky stated that he had done previous work in characterizing the impact of the WTC collapse on residential structures. He also stated that he had done a small project for a nonprofit organization for which he provided data interpretation for samples collected by others.

Dr. Granger stated that he had prior involvement in the acute toxicity investigation surrounding the terrorist attack on the WTC in 1993. In regards to the current incident, he was retained by an on-site construction company to conduct an exposure assessment in the days following the attack. He has published a manuscript on issues related to measurement of asbestos fibers related to the WTC incident. He also noted that he has provided consultation to the Securities and Exchange Commission, which currently occupies a building close to the WTC site, and to the Smithsonian Institute regarding cleaning of artifacts, and that he has had a fair amount of ongoing correspondence with residents in the area of the WTC.

Dr. Abraham noted that his only prior involvement in WTC-related work had been preliminary screening of samples collected on September 12, 2001.

Dr. Paustenbach stated that although he is not personally involved, his employer is involved in consultation on structural engineering issues on the collapse of the WTC buildings. He also stated that he had personally been involved in providing advice on clean-up criteria for polychlorinated biphenyls (PCBs) and dioxins for a private client in the surrounding area, but that he had no current work activity related to the WTC collapse.

Mr. Kominsky, and Drs. Granger, Abraham, and Paustenbach were all of the opinion that these prior experiences would not represent a conflict of interest or inhibit their ability to participate fully in the deliberations of the panel. The panel members were given the opportunity to ask other panel members clarifying questions about individual conflict of interest statements that had been made or submitted in writing. Dr. Granger was asked whether he felt that the conclusions presented in his recent manuscript on WTC-related asbestos fiber sampling would represent an advocacy position. Dr. Granger stated that he would not consider this work as advocacy since the work was presented to educate others about pitfalls in traditional ways of making asbestos measurements for the unique characteristics of the material at the WTC site, and further that the manuscript took no position on the medical or toxicological relevance of the unique size distribution of the material. Based on this response the panel concluded that this prior work would not interfere with Dr. Granger's full participation on the panel. The panel chairperson solicited additional comments on the conflict of interest statements. The panel raised none, and therefore, the discussion of conflict of interest was closed with all panel members participating fully in the following deliberations.

The panel then discussed two major issues regarding the document: selecting the appropriate contaminants of potential concern (COPC) and setting benchmarks for the COPC. The first issues encompassed the first three charge questions and the second issue encompassed the remaining charge questions. For each major issue, the general format of the meeting consisted of an overview presentation by the document authors, clarifying questions from panel, short presentations by panel members on specific charge questions, and finally, open discussion. This meeting report is generally organized following this format. The main body of the text is intended to highlight the flow of the discussions that took place during the meeting, including initial suggestions, clarifying questions and commentary from panel members. The conclusions and recommendations to the document authors arising from these discussions are highlighted at the end of each section.

Selecting COPC

Discussion of this issue included the topics listed in charge questions 1 thru 3. These charge questions addressed the methods and underlying data used to select COPC. The questions were also geared towards identifying additional contaminants for inclusion or exclusion from the selected list of COPC. The full text of the charge questions is listed in Appendix A.

Presentation by Document Authors

The technical portion of the meeting began with a presentation by a document author (presentation slides are presented in Appendix B). The presentation provided an overview of the WTC clean-up process highlighting how the document being reviewed is related to the ongoing clean-up, cleaning validation studies, and the studies to determine background levels. The author noted that the current effort to review the document on a parallel track with clean-up efforts was a risk management decision made to expedite the start of the clean-up process. The presentation also provided an overview of the considerations and types of data used in the COPC selection process. The author noted that asbestos fibers less than 5 micrometers in length were considered, but were not included on the final COPC list because the toxicity data are not sufficiently robust to demonstrate that fibers of this length pose a health hazard (except pneumoconiosis at high doses). The document author also commented that several areas of the written public observer comments regarding the COPC selection process covered important issues, but addressed risk management issues outside the scope of the current document being peer reviewed. Examples of these risk management issues included the regulatory mechanism being used to support the clean-ups, the geographical boundaries established for clean-up, and comments on the scope of the clean-up regarding types and use of buildings.

Clarifying Questions

The presentation by the document authors was followed by clarifying questions from the panel. Some panel members commented on the intended scope of the review. One panel member asked whether a similar type of guidance document would be provided for buildings types other than residential. This panel member suggested that the panel note specifically whether any recommendations made regarding the current document would also apply to other building uses. Other panel questions addressed whether the document authors saw a need to consider issues outside the designated geographical zone of the current clean-up effort. However, one panel member commented on the lack of sampling data for these areas.

Several panel members commented that the list of COPC seemed to have been narrowed fairly rapidly, and asked for clarification from the document authors on this process. For example, one panel member asked if technical soundness of the assessment was lost by setting benchmarks, while at the same time engaging in clean-up activities, rather than the more standard risk assessment approach applied to Superfund sites where COPC are identified and benchmarks are set prior to making clean-up decisions. The document author noted that the Superfund type of approach would be more comprehensive, but that the required representative sampling, sampling analysis plans, and data interpretation can take years to complete, and therefore, a decision was made by the Agency to follow a parallel track. A panel member noted that the incremental costs of analyzing a sample for additional compounds such as additional metals is often not that great. Based on this consideration, the panelist asked whether it was necessary to pare down the list of COPC so early in the process. A document author responded that the a standard protocol is to

pare down the list of COPC to a manageable size based on the toxicology and exposure screening process, but noted that in the clean-up sampling a full battery of metals are being tested. One panel member asked about the availability of data on PCB levels in settled dust, since the document's Appendix A did not indicate that this type of data had been used for screening out PCBs. A document author responded that for each potential COPC multiple data sources were used. For metals, both air and dust samples were often available, but the evaluation of semivolatiles relied more heavily on air sampling data. Another panel member asked whether the document authors felt that the clean-up process would address health risks from chemicals other than those that were selected as a COPC. A document author responded that by addressing asbestos the semi-volatiles and metals could also be addressed (since similar cleaning methods would be employed in either case).

One panel member clarified that the document's Appendix A included dust concentration data for some COPC and that tier criteria have been set for settled dust, but that a dust exposure pathway did not seem to have been included in the COPC selection process. A document author commented that the preponderance of data was for air sampling results, and that the available bulk dust sample results were reported in terms of a mass/mass basis, rather than a mass/surface area basis, which limited relying on existing bulk dust data for quantitative screening of COPC.

Another panel member noted that the process described in the current document gives a sense of circular logic since the background study has not been completed, but decisions presented in the document rely on a judgment of background levels. This panel member asked for clarification on the definition of background used in the current document. A document author summarized that existing historical background data were used to identify and select COPC. The authors wanted to have more contemporary background data for the impacted area, and this is the reason for initiating the background study.

Panel Discussion

Several panel members gave presentations on issues related to selecting COPC (presentation slides are provided in Appendix B). The major areas where the panel made suggestions on the document includes transparency in the presentation, appropriateness of the sampling data used, methods used for COPC screening, and the appropriate chemicals to include on the COPC list. The panel discussion is summarized for each of these major areas.

Transparency in the Process

One panel member commented that the intended use of the document is an important consideration in judging the adequacy of the approach used to develop the list of COPC. Other panel members agreed with this comment and further noted that the intended use of the document in relationship to ongoing activities related to the WTC-site clean up was unclear. The

panel agreed that the document should more clearly state its intended use. In response to questions from the panel, the document authors provided some clarifying comments on the purpose of the document, indicating that it was developed to inform the effectiveness of the clean-up, provide a link to the background study, and to provide guidance on the need for clean ups initiated by other users of the presented criteria.

Several panel members commented on the presentation of the underlying process used in the COPC selection process. It was noted that the logical progression of the methods that were used to identify and exclude potential COPC needed to be presented more clearly in the document. For example, starting with a description of the event, relevant sources of potential COPC (e.g. from the explosion, implosion, and fire), then a description of pathways into homes, and results of sampling for potential COPC would have been helpful. Another panelist agreed that the current document lacks a clear presentation of the flow of logic in the way the potential COPC were identified, although it does appear that the COPC selection process included the key requirements of looking at toxicity potential and concentration data. A general framework for identifying COPC was suggested as an alternative presentation of the order of the process that begins with an accounting for types of materials in the WTC buildings, plus likely thermal or chemical degradation products, followed by a chemical characterization of residue samples to develop the initial list of potential COPC.

Appropriateness of Sampling Data

The review panel discussed issues regarding the underlying data used to identify and screen potential COPC. One panel member noted that the document was not transparent as to the method used to compare the toxicity and concentration data and what specific criteria were used in screening the list of potential COPC. For example, it was noted that the document does not clearly indicate the source and type of sampling data being used (e.g., if the screening data were for indoor versus outdoor samples, type of dust samples, etc.). Regarding the use of ambient data, a panelist suggested that a statement about limitations in this approach should be made in the document, since exposure conditions inside a building may be quite different than outside, particularly given the apparently unique nature of the particulate size distributions associated with the WTC collapse.

The panel discussed the importance of the particle size distributions associated with WTC dust. A document author noted that the dust from the WTC collapse was very heterogeneous in nature, and further noted that the definition of the smaller size fraction in reported studies on WTC-related dust still includes particles that are much larger than those particles that are deposited in the pulmonary regions of the lung. A panel member clarified that the particle size issue could be important for two reasons; 1) to point out that reliance on ambient data should be used with caution, since the COPC contaminants indoors may be different, 2) in evaluating screening criteria for specific chemicals there is a need to consider whether the particle size distribution

used to set the criteria represent the exposures to which the criteria are being applied. Another panel member concurred that the ambient air monitoring data have limited meaning for evaluating the indoor environments.

A panel member noted that not all available data appeared to have been considered in evaluating the COPC. Several panel members suggested additional data for assessing background levels. Suggested sources of information included recent study of background exposures in New York City children, data from the Department of Housing and Urban Development (HUD) on background levels of lead, and a study conducted by the National Institute for Occupational Safety and Health (NIOSH) of background concentrations of polychlorinated-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), and polychlorinated biphenyls (PCBs) in commercial office buildings (Kominsky and Kwoka, 1989; Kominsky et al. 1989). One panel member noted that a key finding from the NIOSH investigation was that undisturbed surfaces were found to be an important consideration, and therefore, not adequately accounting for these surfaces in the current background study will generate a lower level as the background.

Another panel member further commented that settled dust was the critical consideration, and that the air sampling data that was used for COPC screening would not be indicative of exposure potential to COPC. This conclusion was based on independent findings for beryllium shared by the panelist, as well as the panel member's prior experience in sampling for asbestos. This panelist further reported on a study that had been done to look at surface dusts associated with the WTC collapse that included both wipe samples and bulk dust samples (Chatfield and Kominsky, 2001). The study results showed that settled dust on surfaces was the critical pathway for exposure, particularly through resuspension of the settled dust, and that the results showed that wipe sampling and bulk dust samples were qualitatively similar in terms of the array of chemicals found, although individual chemical concentrations varied. Regarding the issue of using ambient air sampling data, a panel member noted that in some cases ambient air sampling for asbestos shows very low levels where asbestos surface loading measurements are high. In response to these opening comments a document author noted that settled dust was considered in selecting COPC, but this evaluation was limited by the fact that there was much less existing data for this as compared to air sampling results.

Methods for Screening COPC

Many panel members expressed concern with the rapid process that was used to narrow the potential COPC to the final six that were selected. One panelist noted that the current six identified COPC might be acceptable, although a larger list would probably have been better. Given adequate resources it would be beneficial to have run each potential chemical through several different criteria in deciding to narrow down the potential COPC list, although the panelist recognized that the COPC list had to be generated in a short amount of time with limited resources. A panel member suggested that increased transparency in laying out the basis for the

toxicity values, the exposure assumptions and the resulting risk levels used for screening the COPC list would be useful. For example, several panelists commented that the limitations of the methods that were used to screen COPC needed to be more clearly documented, even though as a general comment it was noted that the screening criteria were not necessarily incorrect values to use. Panelists commented that the rationale for the selected screening methodology was not clear, and the appropriateness of the resulting screening criteria was not well explained. Examples of choices that were made by the authors that needed further discussion included reliance on the percentage of asbestos in bulk samples and use of ambient data and National Ambient Air Quality Standards (NAAQS). Another panel member commented on the reliance on the limited dust sampling data available, and questioned the merit of including frequency of detection as a primary criterion for selecting COPC. Other panel members agreed that frequency of detection is not an appropriate screening consideration, since the goal of the screening process was to be inclusive and the available data reviewed were limited.

Another panel member commented on transparency in the underlying method used to calculate screening criteria. This panelist stated that when he attempted to independently calculate values, he could not reproduce the values calculated using the approach selected by the document authors: EPA's HEH guidelines (EPA Region 3 Hazard Evaluation Handbook: A Guide to Removal Actions; 1997). Therefore, the panelist suggested that a spreadsheet should be developed to increase the transparency in these calculations. Another panel member was able to duplicate some of the calculations as presented in the document. A panelist further suggested screening criteria could be based on values from EPA's Integrated Risk Information System (IRIS) when available, supplemented by regional EPA and occupational values. This panelist suggested Region 9 guidance as an example of a more transparent process for calculating risk-based screening criteria than the current methodology as presented in the document. A document author made a few clarifying remarks in response to these comments. The author noted that the HEH criteria were used as a guide in selecting COPC, and that while the HEH guidance document needs to be updated, the methodology does use current IRIS values as inputs.

One panel member questioned whether the same list of COPC would be selected if a risk-based approach for dust had been used, although this panelist was not aware of a list of published values for a settled dust pathway for indoor dust contamination. A second panelist suggested that the dust pathway could be considered using the approach presented in Appendix D with some parameters modified to consider indoor environments. In response to a question from a panel member, one panelist provided several examples of childhood specific parameters that should be addressed in adapting the approach in Appendix D such as values for palmar surface area, frequency of contacts per day, and transfer fractions (e.g. skin to mouth, hand to mouth, body weight, etc.). One source of information for childhood exposure parameters is those used by EPA in the evaluation of pesticides. This panelist agreed with earlier comments that probably the most important pathway is dust and the most important receptor is children.

One panel member raised a question about the selection of a hazard quotient of 10 for use in the screening process. This panelist cautioned that this approach should take into account whether the chemical of interest has a current risk value based on a short-term effect (since the rationale for using a hazard quotient of 10 is to account for the application of a chronic risk value for less-than-lifetime exposure). A specific example noted from the list of chemicals in Appendix B was for ethylbenzene for which the IRIS value is based on a developmental toxicity endpoint. Another panelist agreed that it was appropriate to use a shorter-term focus in developing the screening criteria, and that greater emphasis on acute exposures that cause developmental toxicity should be considered. The panelist also noted that the process needs to consider the critical periods for different endpoints that makes use of relevant toxicity data and relevant exposure information that consider children's health. This panelist noted that if cancer were the most sensitive endpoint for COPC screening criteria then considerations for determining if the hazard would be the same for children as for adults would need to be weighed. Another panel member asked whether the screening criterion for asbestos takes into account the greater cancer risk early in life for this COPC, since this was not noted explicitly in the document. It was noted that ideally one would have different slope factors by age groups. However, a panel member commented that this is a broader issue of EPA methodology, and probably goes beyond what can be dealt within the scope of the current meeting.

Another panel member suggested that basing the COPC screening criteria on the chronic reference dose (RfD) or reference concentration (RfC) coupled with childhood exposure parameters would be a conservative approach. In response, another panelist suggested that the exposure parameters should be selected as appropriate to match the effect of concern. For example, use of subchronic effects criteria would better reflect childhood assumptions. One of the panel members questioned the degree to which children's exposure parameters were considered in the one-year and 30-year exposure duration assumptions. A document author noted that for the 30-year duration adult parameters were used and that this would have a more profound effect on the calculation for noncarcinogens than for carcinogens. The panel Chairperson summarized that the panel's suggestion for developing risked based criteria for the COPC selection was to include: 1) childhood parameters for one-year criteria, 2) 6 years of childhood exposure and 24 years as adult exposure in deriving the 30-year criteria, 3) for commercial settings 25 years as an adult would be recommended.

To make the COPC screening approach more defensible, panel members suggested that the document should use a risk-based approach such as presented in Appendix D that considers both dust and air pathways. The risk-based approach should be modified to include more recent childhood exposure parameters. The approach would include scenarios for children and adults, including domestic service workers (residential) and could be enhanced by adding scenarios for commercial uses. As an extension of this idea one panel member also suggested consideration of day-care centers. One panelist noted that risk criteria are usually developed based on the intended end-use of the facility, and that risk criteria based on residential criteria would not

necessarily apply to commercial uses. For example, the criteria can vary by building type, where the exit criteria based on children's risk are not appropriate for a commercial structure. This panelist commented that it would be hard to imagine a more conservative approach than applying Appendix D with childhood parameters as a COPC screening process. In support of this comment another panelist suggested that using multiple scenarios in addition to children would not likely add more COPC. Several panel members agreed with the suggestion to develop one set of COPC that would cover both residential and commercial.

Appropriateness of Chemicals on COPC List

The panel discussed whether the appropriate potential COPC were identified, and whether any contaminants should be added or removed from the current COPC list. Some panel members noted that phthalates, arsenic, as well as some additional metals could be found in WTC dust and should be considered as COPC. A panelist also noted that public observers had suggested adding several potential COPC to the list, and that these would also warrant further investigation using the suggested risk-based criteria (i.e., modification of Appendix D to including a settled dust pathway), since these chemicals were initially eliminated based on ambient air sampling data. The panel discussed several other potential contaminants in more detail as described below.

One panelist commented that the most recent toxic equivalency (TEQ) scheme includes coplanar PCBs, and therefore if PCBs were eliminated as a COPC, then the full dioxin equivalent would not be accounted for. A document author commented that the current protocol may not be capturing all the dioxin equivalents, but that when the COPC were identified there was concern about double counting the risk of PCBs. One panelist suggested that a detection method like chemically-activated luciferase gene expression bioassay (CALUX) would account for all the dioxin equivalents, although panel members did not agree on the degree to which this *in vitro* assay has been validated.

Another panel member noted that the document authors had considered dust resuspension in setting criteria, but based on this panelist's prior work, beryllium was consistently identified in settled dust. The panelist noted that this finding is supported by the concentrations of beryllium reported by Lioy et al. (2002) in bulk dust samples. The panelist further noted that if normalized on the basis of mass per unit surface area, then levels observed in the independent studies are slightly greater than the lower limit established in Department of Energy Guidelines (DOE, 1999). The panelist suggested that based on the concentrations observed and the inherent toxicity of beryllium; this metal should be included as a COPC. The panelist noted that beryllium might have been screened out due to the low frequency of detection. The panelist noted, however, that if additional apartments were being screened with analysis of a full suite of metals, then whether beryllium is a consistent problem would become apparent. Another panel member agreed that if beryllium were present it would warrant a closer look, although he noted

some concerns about the specific calculation of risk values using the DOE methodology regarding transfer, but noted that other methods could be employed. Lastly, one panel member noted that because there was no clear reason to expect that there was a significant source of beryllium and because most sampling had found little if any beryllium (above background concentrations), that it was probably appropriate that it not be a COPC. In response to this discussion, the document authors noted that beryllium had been considered, but may have been excluded by the screening process, since the critical sensitization endpoint is not the basis for the current RfD.

One panelist commented that based on the available data there was no compelling argument to include any of the potential COPC that were excluded. Phthalates as well as polybrominated diphenyl ethers (PBDE), however, might warrant further consideration. One panel member agreed with the suggestion to look further at PBDE, noting that upholstery contains fairly high levels of these materials. Based on the presence of these compounds, this panelist suggested that the polybrominated dibenzofurans (PBDF) also be considered. One panel member commented that the available data did not show PBDE or phthalates. Another panelist commented that it is doubtful that phthalates, PBDEs, or PBDFs would be found in appreciable amounts, but that their consideration would be worth noting in the document. Panelists agreed that additional data on these classes of compounds would be helpful in determining whether the phthalates, PBDFs, or PBDEs should be included in the list of COPC.

With regard to the decision to exclude mercury as a COPC, one panel member noted that no background levels for mercury in Manhattan were referenced, even though measured level for Brooklyn were reported in the document. A second panelist noted that since mercury is released as a vapor, residual mercury levels measured today would not have been the result of WTC-residue.

The panelist also commented that it might be that some of the COPC could be excluded, but this is
difficult to determine based on the provided information. The panelist noted that of the selected COPC, fiberglass presents the weaker case for inclusion, but it is difficult to make this determination based on the limited data. The remaining panel members agreed with the conclusion that based on the available data none of the current COPC could be removed, but that with more information, elimination of some of the COPC might be warranted.

Selecting COPC: Conclusions and Recommendations

The panel discussed a variety of key areas for improving the document regarding the transparency of the COPC selection process, the inclusion of appropriate sampling data, the scientific basis for the underlying methods that were used, and the rationale for considering individual contaminants.

Specific recommendations regarding the selection of COPC included the following:

- Improve the document's transparency in the selection of COPC. Specifically the panel suggested that the document should:

  - more clearly state its intended use
  - include a clear presentation of the logic used to select COPC
  - more clearly describe the basis for the choice of toxicity values and exposure assumptions used to estimate COPC screening criteria
  - more clearly describe the limitations of the methods used to screen COPC
  - include a spreadsheet or sample calculations to document how the screening values were calculated

- COPC selection should primarily be based on a risk-based screening approach for settled dust and air pathways that uses exposure parameters appropriate for children and reflects toxicity endpoints relevant to children's health. The panel suggested three exposure scenarios: including a child at home for a 1-year exposure duration, an adult at home for a 30-year exposure duration (time-weighted average 6 years of child exposure parameters and 24 years of adult exposure parameters), and an adult at work for a 25-year exposure duration.

The panel recognized that once risk-based screening criteria based on dust have been developed, the list of COPC could potentially change. In addition, the panel observed that additional sources of relevant data discussed during the meeting suggest that contaminants which should be further evaluated to determine whether they should be listed as COPC include phthalates, arsenic, beryllium, polybrominated diphenyl ethers, and polybrominated dibenzofurans, as well as other potential COPC identified in the public observer comments.

Setting Benchmarks

Discussion of this issue included the topics listed in charge questions 4 thru 8. These charge questions addressed the methods used in setting benchmarks. Discussions were held regarding selected criteria for settled dust and indoor air for each COPC. Considerations for deriving criteria using risk-based approaches, existing standards, and occupational exposure limits were included in the scope of these charge questions. The full text of the charge questions is listed in Appendix A.

Presentation by Document Authors

The discussion of benchmarks began with a presentation by the document authors on the development of tiers to set benchmarks for each COPC (presentation slides are presented in

Appendix B), including a brief presentation of the basis of chemical-specific benchmarks for both settled dust and indoor air. To address some of the public comments that had been submitted in writing prior to the meeting, a document author commented on several additional points. It was noted that the $1x10^{-4}$ criterion was based on limitations in the available sampling methods as described in the document's Appendix C. The document author also noted that there are issues outside the scope of the review regarding the implications of using aggressive sampling methods (i.e., aggressive disturbance of surface contamination though means such as blowers prior to conducting air sampling), and that complications in using a phase contrast microscopy equivalents (PCME) approach have been considered. The document author also noted that for fiberglass no settled dust criterion was developed since the data on the applicability of the K-factor approach was not judged sufficient to estimate air levels from settled dust data.

The document authors also noted that for the current clean up there is a need to ensure that the correct COPC were identified and that the Tier III criteria were scientifically defensible. Although the current screening approach for selection of residences to be cleaned does not rely on the use of the Tier I and Tier II criteria, this does not preclude the need for these values if other users of the document (e.g., under voluntary clean ups, use by building owners, etc.) For this reason, technical comments on the scientific defensibility of the Tier I and Tier II criteria were also needed.

Clarifying Questions

Several panel members asked specific questions regarding the sampling protocols used as the basis for evaluating the air (asbestos) and surface criteria (dioxin). Two panel members asked about the rationale for applying a factor of 10 (for Tier I) or 100 (for Tier II) to occupational exposure limits. Another panel member clarified that Millette and Hays (1994) had not derived a specific K-factor for fiberglass, and that K-factors are empirically derived under specific conditions that might not apply in the field. The document author confirmed this comment. These issues were discussed in more detail in the panel discussions as summarized below.

Panel Discussion

Several panel members gave presentations on issues related to setting benchmarks for the selected COPC (presentation slides are provided in Appendix B). The panel discussed numerous general considerations in the methodology that was applied for setting benchmarks. In addition, the panel discussed contaminant-specific issues for each COPC. The panel discussion is summarized for these major areas.

Definition of the Tiers

A panel member commented that the risk assessment document being reviewed should not be separated from the applications document that considers risk management issues, since it is difficult to evaluate the adequacy of the underlying science without understanding the applications for which it will be used. Other panel members also commented on this issue noting that the current program for deciding when to conduct clean-ups is not what they expected based on their review of the document. In particular, panel members were surprised that pre-cleaning evaluations according to the Tier I and II criteria were not being done. That is, a member of the public only needs to ask for clean-up to occur and then action is taken without the need for a comparison of pre-cleaning sampling results against the proposed tier criteria. Several panel members commented that, in light of the ongoing clean-up program, there is confusion in the applicability of the Tier I and Tier II definitions. The panel was concerned about the specific use of the tiers because, while the implementation of the tiers in the ongoing clean ups is a risk management decision, the intended use of the tiers could drive risk assessment decisions on how to construct them, and therefore, an important aspect of the technical review of the document.

Some panelists considered whether the Tier I and Tier II criteria should be removed from the existing document, leaving just a single criterion for each COPC equivalent to the respective Tier III criteria. One panel member noted that this single criterion could still be used as a benchmark to determine if cleaning is necessary (apartments with exposures above the criterion should be cleaned). Another panel member noted, however, that Tier I criteria would be needed to implement a program to decide what action was needed after pre-cleaning samples were evaluated.

Panel members noted that the intended use of Tier II was not at all clear to them. Panelists commented on foreseeable uses of the Tier I versus Tier II criteria. One panelist noted that Tier II criteria could be used in prioritizing clean ups. Another panel member noted that in prior work, particularly in site-specific clean-ups, the use of criteria similar to Tier II had been used to set zones for assigning lower priority for action, which allowed for a range of clean-up options. A panelist suggested that the document authors review the Agency for Toxic Substances and Disease Registry (ATSDR) soil clean-up levels for dioxin as an example of the communication of Tier II type of criteria (DeRosa et al., 1998). One document author agreed that these suggestions were a good characterization of the intent of the Tier II criteria.

The panel also discussed the fact that the tiers are, in part, defined by the cleaning method, for example Tier I requires “aggressive cleaning”, but Tier II requires “diligent cleaning”. One panel member asked if there were any data to confirm the relative effectiveness of the alternative cleaning methods identified in the definitions of Tier I versus Tier II. This information should be developed (if not already available) to show that a difference in risk would result from using Tier I versus Tier II cleaning protocols. Another panelist noted that the document does not address the critical consideration of defining compliance with the criteria, which would be based on statistical considerations.

The panel also discussed the question of whether the risk-based criteria recommended earlier by the panel for identifying COPC are the same as the Tier III criteria being proposed. A panel member noted that these would likely be different, since the COPC criteria are based on one-year child exposure, while Tier III criteria are based on a 30-year exposure scenario. Additionally, the criteria for the COPC screening are compared against existing data, while the tier criteria will be compared against newly collected data. One of the panel members suggested, however, that the risk-based criteria for selection of COPC would be the same as the Tier I criteria. Another panelist noted that it would be a concern to use different criteria to pick a COPC than is used to determine whether a residence should be cleaned. This panelist suggested that in using a single method to identify COPC, the Tier III criteria would be more appropriate than the Tier I criteria since the Tier III criteria include all relevant pathways, while the Tier I criteria do not. Several panel members agreed that they were not clear on the logic of using the one-year exposure criteria for screening, questioning why criteria for one-year would be used to estimate lifetime risk. Another panel member noted however, that using the Tier I criteria for COPC would identify immediate concerns, while using a Tier III approach would identify chemicals for which there is time to address issues, but for which there is no immediate risk.

In summary, the panel agreed that the document did not clearly describe the rationale or intended applications of the three tiers, with many panel members specifically mentioning that the intent of Tier II was sufficiently unclear that it could possibly be dropped (and only two tiers be used

Developing Criteria - General Considerations

The panel Chairperson asked the panel to discuss the hierarchical approach used to set tier criteria (existing standards, risk-based approaches, then occupational standards). One panelist noted that risk-based methods are preferred, followed by occupational standards and then existing standards. On the other hand, this panelist noted that a practical approach is to rely on existing standards with a proven track record. Several panel members agreed with these statements. Other panelists noted that existing regulations are based on an underlying risk assessment, and that the scientific basis for that assessment should be examined before adopting the existing standard. Another panelist commented that this would apply to both the use of HUD and Asbestos Hazard Emergency Response Act (AHERA) standards. The AHERA was not used as the basis for a clean-up criteria.

It was also noted that in some cases it can be difficult to choose an appropriate basis for setting a benchmark. It was suggested that describing the confidence level of each criterion would help communicate the level of uncertainty. For example, confidence in the fibrous glass benchmark would be relatively low. Regarding the selection of benchmarks, one panelist suggested considering the use of international values where appropriate. The chair summarized that as a group the panel was comfortable with the overall hierarchical approach used for selecting tier

criteria, but when standards (e.g., HUD standards for lead or the AHERA standard for asbestos) are used, the underlying risk assessment should be scrutinized.

The panel discussed the decision to use a $1x10^{-4}$ risk level for developing the risk-based criteria, noting that the rationale for this choice was apparently a limitation with air sampling approaches for asbestos. The panel suggested that this limitation would not preclude using a different risk level for the asbestos dust pathway or for other COPC. In addition, several panel members commented that the rationale provided in the document for the choice of a $1x10^{-4}$ risk level was not convincing. On the other hand, one panelist could not cite any occupational or environmental clean-up level or regulatory limit for the airborne concentration of asbestos, which attempted to meet lower cancer risks (e.g. $1x10^{-5}$ or $1x10^{-6}$).

Several panel members suggested that it would be appropriate to use updated childhood exposure parameters when developing the benchmarks for the tier criteria for the settled dust pathway (EPA Children's Exposure Factors Handbook, 2000; Hubel et al., 2001). One panelist suggested using information on settled dust exposure pathway assumptions in publications based on pesticide exposures (Berteau et al., 1989). Based on these sources of data it was suggested that gaps in dust exposure assumptions could be addressed with the approaches used for pesticides. Panel members noted alternative assumptions to account for children's parameters using newer data for developing risk-based criteria. For example, body weight, palmar skin surface, contact frequency data, and transfer factor data from lead studies were noted. Another panelist noted two additional references that could be consulted in updating the assumption used for the settled dust pathway, including the recent release of the draft EPA Children's Exposure Factors Handbook (USEPA, 2000; Hubel et al, 2001).

One panel member noted that for asbestos the differential cancer risk to children may already be considered in EPA's slope factor, because the criteria used in developing the benchmarks takes into account life table analysis. Another panel member noted that it is not clear from the document that the asbestos criteria consider differential risk to children, and that the document should discuss this consideration. Another panelist commented that the age-dependent differences in susceptibility for asbestos cannot be explicitly addressed in the different scenarios (i.e., one-year versus 30-year), but that exposure parameters could be changed. For example, this panelist noted that the exposure criteria for Tier II would change for residential (assuming 30 years) to include childhood parameters for a portion of this period as compared to commercial scenarios (where 25 years of exposure is typically assumed). One panelist noted that because virtually all information upon which our understanding of asbestos is based is from occupational studies, there is no way to attempt to account for potential increased risks due to exposure during childhood.

Another panel member commented on the appropriateness of assuming exposure for 30-years as the basis for the Tier III benchmarks. An analysis of recent census data revealed that

approximately 10% of New York City residents live in the same residence for more than 30 years, a similar result for surrounding counties. The panelist suggested that these data generally support the use of the 30-year exposure duration assumption in developing the risk criteria. Another panel member noted however that these data do not account for individuals moving to another residence within the same area. However, another panelist noted that the alternative of using a 70-year basis only lowers the risk value by a factor of approximately two, which is within the level of precision of the method, and furthermore, use of a 70-year assumption decreases the weight of childhood consideration which would tend to have the opposite effect (i.e., increases the risk value). Another panelist commented that accounting for residence time of 90% of the population would be appropriate. Another panelist recommended against using a 70-year residency scenario, as not reasonable based on residence patterns of most individuals. This panelist suggested that applying assumptions consistent with a reasonable maximum exposure scenario is a better approach. Based on a comment from an observer, that many people live and work in the area and could have continuous exposure, one panel member believed that this might be a reason not to develop separate criteria for residential and commercial scenarios. Another panelist noted that since this factor represented only a minor contribution to the overall uncertainty in the calculations, that additional study was simply not worth the effort.

The panel also considered the need to consider worker and commercial considerations. One panel member noted that from a public health point of view it would be of concern not to comment on property uses other than residential. A panelist added that the risk-based scenarios being considered to set the tier criteria rely on assumptions about the use pattern for the life-span of the property. Another panel member agreed, but noted that one cannot predict the future use of the property, but that setting residential and commercial criteria would provide the resources needed to calculate risk levels for various future uses.

The panel Chairperson summarized the discussion of the panel members citing the suggestion that information on both residential and commercial situations should be included. The panel also suggested that for the Tier I criteria (which are based on a one-year scenario) child-specific toxicology and exposure parameters should be used.
The panel Chairperson further summarized that the panel agreed that an adequate approach for the Tier III criteria was to include consideration of both children's and adult exposure parameters for partial periods of exposure. The panel chair summarized that the suggestions made regarding updating the exposure parameters for children for the modification of risk-based criteria for COPC screening could also apply to the tier criteria benchmarks.

Developing Criteria - Criteria for Hard Surfaces, Soft Surfaces, and Air

One topic discussed at length by the panel was the need to develop criteria for various types of surfaces. Technical considerations in developing surface criteria were reviewed by one of the panelists, who noted that sampling of surfaces is complex and that sampling techniques often

need to be tailored to the contaminant. The panelist also commented on the problem of getting a representative surface sample due to recontamination. The issue of setting criteria on a mass/mass basis rather than a mass/area basis was also described. The panelist noted that either approach could be used, but that mass/mass can be more useful for surfaces that act as reservoirs for contaminants. The panel member noted that additional references regarding settled dust methodology that should have been cited in the document as the basis for assumptions used in developing the risk-based criteria for this pathway (e.g., USEPA, 1997; Ness, 1994).

Much of the discussion centered on the need to develop separate criteria for soft-surfaces. Several panel members commented that in practical situations, clean up is usually driven by soft surfaces such as carpets or sofas, and that from a cleaning perspective source removal is often recommended. While soft surfaces can be an important exposure pathway, a panelist commented that surface criteria based on hard surfaces cannot be applied to soft surfaces, suggesting the need to consider soft-surface criteria. Another panel member noted that the absence of soft-surface criteria is an important data gap in the document that the document authors could address in the future.

The panel discussed technical difficulties that can be encountered in developing soft-surface criteria. One panel member noted that if soft-surfaces were to be included in the document then there will be a need for a sampling method to show that the criteria have been met, and that background data have been developed. Another panelist noted that for surface cleaning criteria natural attenuation is often considered, although the degree of attenuation varies by source. A further technical complication raised by the panel was the estimation of transfer rates from soft surfaces. One panel member noted that although it would not be easy to do, the data are available to develop criteria for soft surfaces, particularly by adapting methods used to address this issue for pesticides. This panelist suggested additional references (such as Berteau et al., 1989) that should be considered by the document authors. Another panel member mentioned that a general approach used for pesticides to get around the difficulties of exposure to soft surfaces is the use of biological markers of exposure.

Another important issue discussed by the panel was whether both surface criteria and air criteria are needed for each COPC. Several panel members remarked that air criteria might not be necessary for non-volatile COPC, such as asbestos that have hard and soft-surface criteria. Another panel member disagreed with this idea and stated that only air criteria were appropriate for asbestos, since the only relevant exposure pathway for asbestos is inhalation and EPA standards are based on air monitoring. Another panel member commented that even if aggressive air sampling was done and measured air samples were below the current standard, the results might still not be acceptable for assessing exposure from surface contamination. Another panelist noted, however, that aggressive sampling of air provides a surrogate for surface sampling. A panelist responded that if air sampling for agitated soft surface were included, then the idea of using only air sampling criteria might be appropriate. Several panel members agreed

that the key issue is to provide a chemical-specific evaluation of relevant exposure pathways and the chemical's physical properties, then develop appropriate criteria.

Determining Background Levels

Panel members also noted that the background level will need to be determined to assess whether the currently listed quantitative Tier III criteria or the background level will be used for cleaning validation. Several panel members noted that for Tier III criteria, there is an absolutely critical need to appropriately determine background concentrations of the various possible COPC and that this should be done using a robust statistical sampling protocol. One panelist noted that in prior remediation work the clean-up goal or criteria had been to return a residence to pre-incident conditions, and therefore, knowledge of background levels is essential. The panel Chairperson summarized that there was agreement with the idea of using the risk-based benchmark unless the background is higher than the benchmark. It was also noted that understanding background in the apartments and homes in the New York area which were not affected by the WTC event is essential for defining the geographical area which will be eligible for clean-up activities as well as inclusion in future epidemiological studies or personal injury liability litigation. The panel was in general agreement that this was a significant shortcoming in the current approach.
The panel discussed how to define the background. One panelist noted that without having reviewed the protocol for the current EPA background study as described by the document authors, the panel cannot comment on the appropriateness of the current approach. However, this panelist noted that the main point is that a sufficient number of samples be collected from a set of locations that are representative of the buildings in the WTC target area. Issues to consider include the number of samples taken at each residence and the distribution of samples from many locations, as well as the location of collection. Another panel member noted that background should be defined for each COPC. One panel member commented specifically that some data are available on background levels of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) Equivalents, noting that an earlier study reported a 95th percentile background concentration of TCDD equivalents across the United States of 0.08 ng/m^2 (Kominsky and Kwoka, 1989; New York State Department of Health, 1999; Kominsky et al., 1987) as compared to the current Tier III criterion of less than 4 ng/m^2.

Another panel member noted the availability of several EPA guidance documents on methods for establishing background level, but was unable to make a recommendation on the technical merit of those papers. One panel member asked the document authors if soft-surfaces are being sampled in the background study. The document authors reported that this was being considered to a limited extent for lead and asbestos, but other (air and hard surface) criteria being considered for all the COPC. In response to another panel member, the document authors noted that the current protocol does not include HVAC systems in the background study.

Consideration of Mixtures

The panel also discussed the issue of mixtures. One panelist commented that based on the spectrum of effects and target organs involved with the list of COPC, as well as the very low concentrations, mixture effects are almost certainly not an issue for this exposure scenario (e.g., inhabitants of homes or offices). However, the consideration of mixtures and the rationale for concluding that the hazard posed by mixtures is *de minimus* needs further discussion in the document. Another panel member noted, however, that several of the COPC were lung toxicants. Another panelist noted that EPA Guidelines for Mixtures Risk Assessment provide an approach to use for addressing these issues, and also that EPA's MIXTOX database could be used as a source of data on assessing the potential for interactions among the COPC. The panel agreed that the document should more clearly describe how mixture toxicology was considered.

Applications of Indicator or Surrogate COPC

A panel member raised the issue of the appropriateness of selecting a one or two chemicals to drive the clean up (i.e., the idea of using indicator or surrogate chemicals), and noted that although it might be considered appropriate to develop cleaning strategies based on indicator chemicals, that there is a need to document this consideration. Several panel members agreed that the use of indicator chemicals could inform the clean up if cleaning protocols for a COPC such as asbestos would address contamination by other COPC. This panelist noted that if a single COPC were chosen, then asbestos would be most appropriate. Another panelist noted that a reason to use a surrogate is that if you adequately clean for this single COPC, then you will likely clean the other COPC. However, another panel member noted that using an indicator COPC for determining the need for clean up does not preclude the need for a more comprehensive post-cleaning validation.

Several panel members commented on possible indicator or surrogate chemicals for WTC-related dust. One panelist noted that regarding the use of indicator chemicals, a chemical such as asbestos that is prevalent in the background would not really be a good indicator. This panel member noted hesitation in recommending any single chemical of the current COPC as a surrogate or fingerprint for WTC-related contaminants, but could consider the group of COPC as a reasonable indicator. One panel member noted that mathematical approaches for using a family of chemicals as a fingerprint for identifying whether an area was impacted by WTC dust are available and could well be invaluable. The document authors noted their efforts to select an appropriate indicator(s) COPC, but had not identified a suitable choice. One panel member noted that if the original EPA deliberations were available, a future peer review panel could review these and comment on whether the issue was adequately considered. Another panel member noted that based on the data available for this review meeting, suggestions on the suitable indicator COPC could not be adequately provided, rather a rigorous review of the ratio of various COPC might yield an adequate fingerprint. Another panel member noted that some

specific ideas to consider would be patterns of dioxin congeners, or perhaps calcined asbestos (assuming temperatures were high enough), or a suite of several building materials.

PAH Benchmarks

The panel discussion on risk-based benchmarks included several comments on PAHs. One panelist noted that the selected value for PAHs is the correct value from IRIS and the calculated extrapolation to an inhalation value was done using the standard approach for adults. The panel member also noted that an extrapolation using childhood values would have resulted in a slightly different value. The panelist agreed with the use of the relative potency approach. The panelist noted the larger issue of whether the seven PAHs listed in the equivalency approach represents all of the other potentially carcinogenic PAHs that could be present in WTC-related dust, but further noted that this is a larger issue relevant to risk assessment for PAHs in general and is probably outside the scope of the current review.

Dioxin Benchmarks

A panelist noted that the document authors had been health protective in using the cancer potency factor from the 2001 dioxin reassessment, and by adapting the new TEQ approach, which includes coplanar PCBs. Another panel member agreed that for dioxin the document authors had made a health protective choice of using the risk value from the more recent draft dioxin assessment, rather than the traditional value on IRIS. In response to an observer comment regarding the need to consider the combined impact of dioxin from the diet and WTC-related exposure, one panel member noted that for dioxin the diet represents 95% of the dose, so to the extent that one is worried about the remaining 5%, the suggested criteria are protective. The panelist further noted that the primary dietary source of dioxin is meat and dairy products, which presumably are not raised in close proximity to residences where a direct contribution of WTC-related dioxins would occur via these pathways. Another panelist commented that some recommendations in the dioxin risk assessment community are to use a total body-burden approach, but the more traditional method being applied here is acceptable. Another panel member commented that with regard to the level of public health protection afforded by the selected benchmarks that the chosen values are probably protective, but this is hard to decide for at least two of the COPC (dioxin and asbestos). There is ongoing scientific debate among learned bodies regarding the appropriate risk criteria for dioxin (Paustenbach, 2002), and issues of fiber size and mineral type for asbestos (Berman and Crump, 2000).

Asbestos Benchmarks

The panel discussed at length numerous issues in evaluating the recommended criteria for asbestos. Key issues included the consideration of short fibers, the use of a K-factor approach

for settled dust, and the impact of sampling methods on selecting the appropriate criteria. Panel discussions on these topics are summarized below.

One panel member noted that embedded in the evaluation of the asbestos criteria is the issue of how fiber length relates to risk. Another panel member commented that the panel would not find a scientific basis for including short asbestos fibers as part of the criteria, noting that this is an area of ongoing scientific controversy. This panelist commented that the data show a gradient of increased potency with longer fiber length greater than 5 to 8 micrometers. Another panelist also confirmed that all the current data suggest that longer fibers are more potent. This panelist also mentioned that there have been recent and upcoming scientific meetings and studies that are looking specifically at this issue. The panel discussed the relationship between the underlying epidemiology data that served as the basis for existing asbestos standards and the recommended approach in the document under review. One panel member noted that the current risk-based value is based on occupational epidemiology using phase contrast microscopy (PCM) so it is difficult to translate directly to the risks related to the characteristic fiber distribution for WTC-related dust (i.e., having a high proportion of fibers less than 5 micrometers in length as compared to fiber size distributions in occupational settings. Several panel members clarified differences in fiber counting characteristics of PCM versus transmission electron microscopy (TEM), and how these relate to the PCM equivalents (PCME) approach applied in the criteria used in the document being reviewed.

With regard to the issue of applying the risk-based criteria that were developed from occupational PCM data, one of the panel members made a brief clarifying presentation on this issue. A wider size range of asbestos particles can be counted using current technology than could be counted with the older technology available when the risk values for asbestos were developed. However, these new sampling data cannot be directly applied against the original risk criteria developed because the underlying exposure patterns may not have changed. In other words, the older data likely also included exposures to fibers less than 5 micrometers in length, even though the fibers longer than this were used as the quantitative basis for the risk value. Furthermore, the frequency of disease does not change just because we alter the sensitivity of the sampling method.

The panel members discussed that with additional research it could be possible to relate quantitatively the risk criteria using the older measurements with newer measurements, and that this type of research might allow one to look at risk when the distribution of fibers changes is known for a unique exposure situation. This panelist noted that mostly fibers less than 5 micrometers in length are found in people's lungs at autopsy, but it is not known if the ratio of fibers less than 5 micrometers in length to those longer than 5 micrometers from modern studies is consistent with the ratio of fiber lengths from the earlier studies. Another panelist noted that these shorter fibers may be observed more frequently in human lungs, but that fibers longer than 5 micrometers are retained much more so than short (i.e., less than 5 micrometers) fibers. The

prevalence of shorter fibers could reflect the possibility that inhaled fibers are changed while in the lungs. Due to this uncertainty about ratios of fiber lengths among different studies, these types of lung sample data cannot be used directly in the risk assessment. Another panel member noted that as a risk assessor, since we may be trying to apply risk-based criteria that were derived from a different exposure situation (i.e., different distribution of fiber lengths) that this can be addressed as an uncertainty in the risk assessment, and that even if we do not have information on the magnitude of the uncertainty, perhaps one can at least think about the direction of uncertainty. Overall, the panel members agreed that sufficient research has not yet been done in this area to make a definitive statement about use of short fiber data in setting the criteria.

One panelist added several comments regarding the selected settled dust criteria for asbestos. This panel member suggested that the Tier III criterion for asbestos should be compared against air sampling by PCME during normal living activities, rather than during or following aggressive distribution of surface dust (e.g., by conducting air sampling after disturbance of settled dust with a blower). A panelist further suggested conducting measurements for comparison to criteria against typical activities for the space, commenting that aggressive methods such as leaf blowers are not needed, and noting that the AHERA approach was developed to assess cleaning efficiency. Another panelist noted that aggressive sampling methods (such as ultrasonication of carpet samples) extract fibers more efficiently than normal life activities, and that these aggressive approaches can increase the fiber count by breaking apart fiber bundles, which is an additional confounder in using these approaches for applying risk-based criteria. One panel member commented on the issue of comparing the criteria against modified versus aggressive sampling and noted that not applying kinetic energy to the surfaces will not get air sampling results that reflect potential risk, and therefore, aggressive sampling is needed for asbestos and other contaminants. This panelist concluded that the normal living activities such as walking over a carpet would not be sufficient. The panel members did not agree on the appropriateness of comparing the criteria to aggressive sampling methods.

A document author noted that the criteria in the document for settled dust was intended for hard surfaces, and was not intended to apply for ultrasonication of soft surfaces. A panelist commented that if the panel recommended setting criteria for both hard and soft surfaces for asbestos, then a sampling approach should also be recommended. Another panelist noted that the reported high number of structures reported from some sampling of surfaces using techniques like ultrasonication should be put in perspective to the number of fibers one inhales over the course of a lifetime. This panelist noted that an individual's non-occupational background exposure will result in inhaling millions of fibers over their life-time, yet we have not seen a major epidemic of asbestos-related disease in the general population. Another panel member added that it is well accepted that background air concentrations have not increased the mesothelioma or lung cancer rate in the United States. One panelist commented that the use of the IRIS value in the current document is extremely health protective. One reason that this is the

case is that for asbestos related cancer there is evidence for a cumulative exposure threshold and the cumulative exposure at the level of the criteria based on the IRIS value is well below this threshold. The threshold value is more or less established by the concentrations reported in studies of brake mechanics because eleven or more epidemiology studies have shown no increased cancer risk for these workers. The recent work of Berman and Crump (2000) can also be used to help identify a "practical threshold" for asbestos in air.

The relevance of using the K-factor approach for asbestos settled dust was discussed. One panelist remarked that the K-factor used for setting the criteria for settled asbestos dust is experimentally derived and that data are not available to suggest that the value used for setting the asbestos criteria is an appropriate one. A second panelist commented that in applying K-factors a different value would be needed in each home due to the many variables that impact this factor. Another suggested that the K-factor approach was too uncertain to use for risk assessment. Another panelist noted that in the current document the K-factor was used for asbestos for the Tier I criterion, but was not used for the Tier III clearance criterion due to the degree of uncertainty. Another commenter suggested that the approach might be useful as a worst-case estimate. One panel member offered a suggestion that a K-factor approach could also apply to transfer from soft surfaces. This panelist noted that although one could use a settled dust measure and apply a K-factor approach, when looking at the distribution of fiber sizes, sampling of soft surfaces would not find as many fibers in the size range (i.e., fibers greater than 5 micrometers in length) more closely linked to carcinogenic outcomes than traditional sampling.
One panel member recommended that the document authors ask for an opinion for the authors of the K-factor methodology (Millette and Hays, 1994) in judging whether the current K-factor is appropriate for this use. Another panelist noted that ASTM has formed a subcommittee to investigate the development of a protocol for estimating K-factors for asbestos, but at this time no standard protocol exists. Overall, the panel did not endorse the use of K-factors based on the rationale provided in the document.

One panel member suggested that many of these technical difficulties of assessing fiber release from surfaces and estimating K-factors would be eliminated if the asbestos benchmark was set for only air, rather than for surfaces. One panelist commented that this suggestion would seem appropriate if it could be confirmed that aggressive sampling techniques would release asbestos from soft surfaces. One of the panel members noted that these types of data have been generated in other projects, but noted that predicting kinetic energy requirements for fiber release would be difficult. Other panel members agreed with the suggestion for asbestos that only air benchmarks would be needed, but added that the document should clearly evaluate the potential pathways for exposure and the chemical properties for each COPC in determining the need for air versus surface benchmarks.

The panel also discussed issues surrounding the microscopy approaches being used to measure

asbestos fibers for evaluating compliance with the criteria. One panel member opened this discussion noting that part of the issue is the use of risk-based data, which were based on PCM (i.e., counts of fibers at least 5 micrometers in length and having a length to width aspect ratio of at least 3:1). However, this PCM data counts more fibers (since not limited to counting asbestos) as compared to a transmission electron microscopy (TEM) analysis of the same sample. This leads to questions about the applicability of the asbestos criteria when compared against samples measured by TEM. A document author noted that since the samples are being analyzed by TEM short (i.e., less than 5 micrometers) and long fibers (greater than or equal to 5 micrometers) are identified, but for comparison to the tier criteria PCME is used, which addressed the longer fibers.

The panel also discussed sampling methods for surfaces. A document author noted that in a pilot program the microvac technique was being used, which looks at both short and long fibers, but this measure is not being compared against the cleaning criteria. A panel member commented that microvac technique might not be the most appropriate approach; rather the ASTM method for surfaces may be better. The document authors noted that for post-clean up activities AHERA counting was also being done, and that the apartments are being cleared on risk-based standard where samples are not to be exceeded which is a health protective approach. Another panelist had assumed that for final clearance of residences aggressive sampling was performed and the results were being compared against the AHERA standard. A document author noted that this approach is being used, but the primary criterion being used is the risk-based air value discussed in the document. One panelist added several comments regarding the different types of asbestos criteria that could be used, describing in particular issues in using the AHERA standard. This panelist commented that the 70 structures/mm^2 AHERA standard is compared against aggressive sampling methods, and that this value is performance-based, not risk based. The panelist noted that the AHERA standard was intended to evaluate the efficiency of cleaning, that this is a rigorous test, and that it is hard to achieve this level. In terms of the historical rationale for the AHERA criterion, it was noted that this standard was based on the limit of detection above the background level of contamination of filters used for asbestos sampling at the time. The panelist did note that, although the AHERA standard is performance-based, it has been used elsewhere to set clearance criteria. The panelist further noted that, when using the AHERA criterion this level is close to the range of normal background, so the results of the background study would be needed to evaluate sampling results using these approaches.

Lead Benchmarks

A panel member opened the discussion of the benchmarks for lead with a few summary comments. This panelist noted that for lead two alternative approaches were used: for settled dust the existing HUD standard was employed, while for lead in air a risk-based approach using the output from the integrated exposure uptake biokinetic (IEUBK) model was used. The panelist noted that the document does not provide a discussion of the consistency in the degree

of risk provided by these two alternative approaches, even in the same tier. The panel member suggested that the document describe the rationale for using these alternative approaches. Another panel member agreed that the degree of risk provided in the appropriate and relevant applicable regulations (ARAR) such as the HUD standard is critical. A panelist also noted that some recent publications suggest that the health risk limit should be less than 40 ug/ft^2 (e.g., Lamphear et al., 1998), and noted that these studies had not been discussed in the document. With regard to relating the IEUBK modeling approach to the settled dust criteria, the panel discussed a difficulty in the use of load data (mass/mass basis) as the model input. This value is difficult to relate to the surface criteria (mass/area) presented in the HUD standard.

It was noted that in running the IEUBK model that national default values were used as model inputs, where local data should be used. An example given by a panel member was the use of national averages for drinking water concentrations of lead. The panel also discussed that basis for using lead dust loading value of 240 ug/g in running the model. One panel member cited the Lioy et al. (2002) bulk data, which showed a range of 100 to 600 ug/g, a value that would be consistent with the load data entered into the IUEBK model. Another panelist noted sampling results from apartments around the WTC in September, 2001 (Chatfield and Kominsky, 2001) showed surface levels of lead of 14-30 ug/ft^2 and surface loads of 96-220 ug/g in bulk samples, which are consistent with the value entered in the IEUBK model.

In summarizing the usefulness of the IEUBK Model, it was suggested by one panel member that the model could be used for air, but the use of this approach needed to be better justified in the document. Another panelist also noted that the IEUBK model has been validated and reviewed extensively; the problem of using load data has resulted from the inability of current studies to correlate mass/mass data with mass/area data. This panelist agreed that it was appropriate to use the existing HUD standard for settled dust. One panel member noted that if it is anticipated that the acceptable blood level in upcoming standards will be lowered in the near future, one way to address this is to use the 99% risk rather than 95% risk as the cutoff.

Fiberglass and Silica Benchmarks

One of the panel members opened the discussion of the fiberglass and silica benchmarks by summarizing some background information on these chemicals. The panel member began by noting that the carcinogenic potential of fibrous glass is unclear, since the underlying data are insufficient to categorize it. For example, the panel noted that IARC currently lists glass wool as *not classifiable as to human carcinogenicity*. In light of this uncertainty the panel member suggested that it is appropriate to make health protective assumptions in the current document. The panel member commented that the decisions made in developing the criteria for fiberglass appear reasonable. The panel noted the absence of a current cancer slope factor for silica for use as a basis for the tier criteria. One panel member commented that California EPA has a value, but it is based on an assumption of linearity, while the current data suggest that silica-induced

tumors only occur at concentrations that also induce fibrotic disease.

The panel Chairperson also asked for comment on the notion that in the absence of an RfC, using occupational values seems reasonable for these two substances. The panel noted that occupational values could be used. Several panel members commented on the appropriate adjustment factors to use for extrapolating from occupational limits. One panel member suggested that a duration-based adjustment of 4.2 would be more typical for extrapolating from occupational exposure limits. Another panelist noted that values of 42 or even 420 have also been used, depending on the type of effect that served as the basis for the exposure limit. One panelist noted that some occupational values are based on lowest-observed-adverse-effect-levels (LOAELs), rather than no-observed-adverse effect levels (NOAELs), and therefore, there is a need to look at the basis for each value in deciding the appropriate factor. Another panel member noted that in some cases for an occupational standard that the value is based on the protection of only 80% of a healthy adult population, so adapting these standards to residences is not always that straight forward. This panelist suggested that standard methodology papers (e.g., Paustenbach, 2000) be reviewed and cited as the rationale for the adjustment that is used in the document.

One panel member noted that for fiberglass a settled dust number for Tier I was developed. Another panelist suggested that for the same reasons discussed regarding asbestos, only air sampling criteria should be used for fiberglass. A document author noted that the K-factor for asbestos had been applied to fiberglass as a conservative approach (due to the greater density of fiberglass and therefore the expected higher gravimetric settling rate), but the value was considered too uncertain to use in setting a Tier III criterion.

Key recommendations regarding the Tier Criteria and Benchmarks included the following:

- The rationale and purpose of each tier should be more fully described in the document. Specifically, the document should describe the application for each tier and indicate how the benchmarks for that tier are constructed to fulfill the intended application. This recommendation particularly applies to the Tier II criteria. In addition, the document needs to more clearly describe the “aggressive cleaning” versus “diligent cleaning” that are used to define Tier I compared with Tier II benchmarks and show how a difference in risk would result from using these two different cleaning approaches.
- In general, the panel recommended using a risk-based approach to develop benchmarks for the COPC, but indicated that when a benchmark is based on occupational or existing environmental standards, the document should clearly describe the underlying risk assessment for the standard, and discuss how the scientific basis of the standard is relevant to the WTC situation. Also, it was suggested that the document specify a confidence level in each benchmark developed.
- For defining the different tiers, the panel recommended that Tier I benchmarks be based on a

1-year exposure, child exposure parameters, and where available, child-specific toxicological endpoints. The panel recommended that Tier III benchmarks be based on a 30-year exposure, where 6 years are based on child exposure parameters and 24 years are based on adult exposure parameters.

- Panel members disagreed with the rationale provided in the document for using an upper level excess lifetime cancer risk level of $1x10^{-4}$ in calculating the benchmarks for each tier. The panel noted that the sampling and analysis limitations described in the document for asbestos that limit the risk evaluation to a $1x10^{-4}$ risk level could be easily overcome and lower risk levels could be achieved for other COPC. The panel did not address specifically the risk management decision of whether using a risk level of $1x10^{-4}$ versus a risk level of $1x10^{-5}$ or $1x10^{-6}$ would be most appropriate.
- The panel recommended that for some COPC, the authors should develop benchmarks for contaminants on hard surfaces and benchmarks for contaminants on soft surfaces, instead of just developing a single benchmark for contaminants in settled dust. The panel noted that, although there are limited data available in order to recommend soft-surface benchmarks, some methods for this have been developed to address exposure to pesticides. These methods could be applied to the WTC situation. The panel recommended that for each COPC, the document clearly analyze the chemical properties and the potential exposure pathways to that contaminant before determining whether an air, hard-surface, or soft-surface benchmark is needed.
- The panel suggested that the document more clearly describe how mixture toxicology is being considered in developing benchmarks.
- For the air benchmark for lead, the panel recommended incorporating local exposure loading data into the IUBEK model.
- The panel did not endorse the asbestos settled dust benchmark because the only relevant exposure pathway for asbestos is inhalation and K-factor methodology is, at this time, inadequate for predicting inhalation exposure from asbestos surface loading measurement. However, the panel did note that settled asbestos is a potential source of airborne asbestos if disturbed or not remediated.
- For setting benchmarks based on occupational standards, duration-based adjustment factors should be used that weigh chemical-specific issues. Specifically, the panel suggested that a duration adjustment of 4.2 is typical to extrapolate from occupational to environmental exposure, and that additional adjustments of 10 or 100 (for a total factor of 42 or 420) may be needed to address the underlying, chemical-specific biological factors (toxicokinetics and toxicodynamics).

Closing Statements by the Panel

Panel members generally commented that the document was a good start for tackling this difficult issue. The document authors were applauded by the panel for taking on the issues involved, many of which are cutting edge, with no easy answers. The panel members noted that

they hoped that the peer review comments are found to be helpful for improving the document. The panel also acknowledged that it was unfortunate that the document had not undergone this level of scrutiny prior to its release, but understood why this was not possible given the pressures on EPA and others to move forward with cleanup.

In addition to comments on the process, several panel members reiterated a number of points. One panelist stressed the importance of developing an approach to identify WTC-related dust in identifying background levels. Another panelist highlighted that a primary suggestion was to use a risk-based approach for identifying COPC, and to set criteria for the tiers that include an evaluation of the chemical-specific nature of how they should be measured. Another panel member noted the hope that the comments made on this document will be considered in the broader scope of the cleanup. Following that idea, another panel member noted a concern that the peer review of the document will be looked at as a platform for risk communication. As such, this panel member noted that technical comments on this document should not be viewed as an endorsement of the entire clean up process.

The panel members commented that the document could benefit from a second review.

List of Abbreviations

AHERA - Asbestos Hazard Emergency Response Act
ARAR - Appropriate and relevant applicable regulations
CALUX - Chemically-activated luciferase gene expression bioassay
COPC - Contaminants of Potential Concern
DOE - U.S. Department of Energy
EPA - Environmental Protection Agency
HEH - EPA Region 3 Hazard Evaluation Handbook: A Guide to Removal Actions
HUD - U.S. Department of Housing and Urban Development
IARC - International Agency for Research on Cancer
IEUBK - Integrated exposure uptake biokinetic model for lead
IRIS - Integrated Risk Information System
NAAQS - National Ambient Air Quality Standards
NIOSH - National Institute for Occupational Safety and Health
PAH - Polycyclic aromatic hydrocarbon
PBDE - Polybrominated diphenyl ethers
PBDF - Polybrominated dibenzofurans
PCB - Polychlorinated biphenyl
PCDD - Polychlorinated-p-dioxins
PCDF - Polychlorinated dibenzofurans
PCM - Phase contrast microscopy
PCME - Phase contrast microscopy equivalents

RfC - Reference Concentration
RfD - Reference Dose
TCDD - 2,3,7,8-tetrachlorodibenzo-p-dioxin
TEM - Transmission electron microscopy
TERA - Toxicology Excellence for Risk Assessment
TEQ - Toxic equivalency factor
WTC - World Trade Center

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