## Miller, Diane M. (CDC/NIOSH/EID)

From:

D Wayne Berman [bermanw@comcast.net]

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### To whom it may concern:

I am pleased to submit the attached comments and suggestions regarding the NIOSH Roadmap for asbestos (Docket No. NIOSH-099). If you have any questions about any of the attached, please do not hesitate to contact me.

### Regards,

D. Wayne Berman, Ph.D. President Aeolus, Inc. 751 Taft St. Albany, CA 94706-1026

Tele: (510)-524-7855 Fax: (510)-524-7854

email: <u>bermanw@comcast.net</u> website: <u>www.aeolusinc.com</u>

# COMMENTS AND SUGGESTIONS ON THE NIOSH ROAD MAP (Docket No. NIOSH-099)

## Prepared by:

D. Wayne Berman, Ph.D.
Aeolus, Inc.
751 Taft St.
Albany, CA 94706

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The following are general comments and suggestions concerning the draft NIOSH Roadmap (Middendorf et al. 2007). These are offered to facilitate focusing of the proposed research effort to better address gaps in knowledge concerning asbestos-related risks, their association with exposure, and the methods employed to characterize such exposures so that existing policies and regulations can be refined to more effectively and efficiently protect worker health. The comments and suggestions are divided into categories that respectively address:

- ! terminology;
- ! the literature review;
- ! potential misconceptions; and
- ! the proposed research.

### Terminology

Adequate conceptualization and resolution of asbestos-related issues are as much a problem of terminology as anything else. So that such issues can be adequately addressed, it is important both: (1) to establish a set of terms that is sufficiently diverse and robust to allow full discussion of all of the important aspects of each issue and (2) to concisely define each term to promote consistency in usage. Based on these criteria, it appears that the glossary of terms presented in the Roadmap (although concise) is too restrictive to support full exploration of the issues at hand. For example, it fails to acknowledge the need to generalize certain terms (such as "fiber") so that it can be used in all of the various senses for which each term is needed (mineralogical, biological, analytical, commercial) and for which each term is actually used in the Roadmap text. Moreover, given the need to define dimensional ranges for fibers that adequately predict biological activity and the fact that the dimensional range defined in the Roadmap may not (for example, Berman et al. 1995 a and b), I suggest adoption of an alternative glossary incorporating definitions along the lines of that provided in Attachment 1. Note that various, concise dimensional ranges for fibers are defined as a series of exposure metrics in the attached glossary, while the term fiber itself is left as general.

## About the Literature Review

I am concerned about the literature review provided in the Roadmap as it may not be sufficient to serve as a departure point for initiating a robust research program. The review in the Roadmap appears to be focused primarily on documenting existing policy positions taken by NIOSH to support their asbestos exposure-limit recommendations. In contrast, what is needed to support design of an efficient research program is a thorough review and reconciliation of the literature that concisely describes the state of knowledge and highlights areas where critical knowledge gaps exist. It is just such knowledge gaps that should be the focus of any proposed research. Thus, I suggest that, before defining future research needs, the literature review itself needs to be refined and expanded.

Moreover, designing a research effort primarily to support existing policy positions may unnecessarily bias the effort. This puts the cart before the horse. Policies should be developed based on the best, current scientific knowledge. Science should not be manipulated to fit existing policies.

To illustrate the above, consider the "thoracic hypothesis." While it may ultimately prove helpful to incorporate this hypothesis as part of the basis of policy, it is certainly premature to do so. As is demonstrated below, when determining exposure, arbitrarily including counts of a greater range of structures than those that are formally shown to contribute to biological activity is not automatically health protective. Yet the thoracic hypothesis may potentially encourage just such an "over count". Thus, it is the scientific merit of the hypothesis that should be explored as part of research, rather than incorporating the hypothesis as a starting assumption that serves only to limit and focus research going forward. Limiting research in this manner, among other things, would hinder the ability to test whether the thoracic hypothesis is indeed health protective.

Similarly, it appears that there is a bias built into the Roadmap toward continued reliance on the PCM metric (as defined by NIOSH 7400, NIOSH 1994a) for assessing exposure and risk without due consideration of the adequacy of the metric for this particular application. I believe that the statement on P. 15 of 47 of the Roadmap that

"The fiber counting rules used in PCM analysis of air samples results in an index of exposure which has been correlated with existing human health data and risk assessments."

may be misleading. Moreover, no studies are cited to support this statement.

It is true that acceptable exposure-response relationships have been established using this metric in *single* environments (such as many of the individual epidemiological studies that have been published). However, it must be remembered that the purpose to which this metric is being applied by NIOSH is to extrapolate *across* exposure

environments (i.e. from research environments including the published epidemiological studies and animal toxicity studies to unstudied environments in which workers are being exposed) so that risks can be predicted.

In single environments, the characteristics of the dusts to which individuals are exposed tend to be highly correlated and exposures among studied cohort members tend to be highly confounded. The former is true because dusts in these environments tend to be generated from reproducible activities involving the handling of selected materials exhibiting highly similar characteristics. Indeed, except for studies of mines and mills, the characteristics of the raw materials used in the various factories studied by epidemiologists generally had to satisfy narrowly defined specifications.

Exposures in these single environments were also confounded because workers in these environments tended to spend at least part of their employment working at each of the work stations around the factory. It is a rare among the published epidemiology studies where a sub-cohort could be identified in which workers spent their employment exclusively in a single room of the factory doing a single job.

Given the above, it is not surprising that almost any metric of dust exposure (including PCM) could be correlated with risk. Indeed, as the attached Table 1 shows, the exposure-response relationships in the vast majority of the epidemiology studies used to establish existing NIOSH policy were first defined using only a very general measure of total particulate concentrations (determined either by midget impinger or by thermal precipitator) and these relationships were only later adapted to PCM through adjustments derived from paired (side-by-side) measurements or cruder procedures (see, for example, Berman and Crump 2003).

In contrast, to reliably apply PCM to link exposure and risk *across* environments requires a demonstration that risks estimated using the PCM metric remain comparable *across* environments. Yet the limited studies available for evaluating this consideration suggest otherwise. For example, in our analysis of the animal inhalation studies (Berman et al. 1995a and b), we found that the PCM metric shows a significant *lack* of fit with tumor incidence. Similarly, our analysis of the human epidemiological data (Berman and Crump 2003) suggests that risk factors based on PCM derived from published epidemiology studies for lung cancer vary by almost two orders of magnitude while those for mesothelioma vary by over three orders of magnitude. Although there may be several explanations for such variation, these findings certainly suggest that the validity of the PCM metric for assessing asbestos exposure needs review. In fact, such concerns have been raised in the literature since at least 1982 (see Walton 1982).

More generally, the set of references cited in the Roadmap suggests only limited review of the rich and varied literature that is currently available to address asbestos-related issues and it is important that the broader literature be fully evaluated and mined before attempting to define goals and objectives for future research. To assist in this regard, a list of a much broader set of potentially relevant citations is provided (Attachment 2).

Even this list may not necessarily be comprehensive (and is especially sparse in the newest studies because it was largely compiled prior to 2003). However, it should provide a solid starting point for completing the kind of literature review that is needed to support the setting of a research agenda in this area.

The reference list in the Roadmap also highlights several potentially serious omissions that need to be rectified before the summary presented in the Roadmap should be used to identify data gaps and the outstanding controversies that remain to be addressed through new research. For example, one such omission involves epidemiology.

The discussion of epidemiological evidence within the Roadmap focuses on studies addressing only three environments (the talc mine in New York, the South Carolina Textile Mill, and the vermiculite mine in Libby, Montana). Yet the literature includes studies of more than 20 relevant environments. To assist with better evaluating and addressing the full range of relevant environments, a more complete list of relevant epidemiology studies is provided (Attachment 3). Importantly, even the attached list is not necessarily comprehensive and should likely be supplemented.

I would also like to suggest that, while adequately reviewing the entire breadth of the existing literature is necessary to provide a basis for efficiently defining future research goals, a simple review is not alone sufficient. What is needed is to reconcile the existing literature. Thus, for example, it is not sufficient simply to acknowledge what may appear to be opposing view points on particular issues within the literature. Rather, science advances when what otherwise appear to be contradicting studies can be reconciled by identifying the underlying source of the apparent discrepancy and then showing agreement once that source is addressed.

Much (but not yet all) of the asbestos literature can in fact be reconciled. To illustrate, many examples of successful reconciliation can be found in the 400+ page review that I completed with my colleague, Dr. Kenny Crump (Berman and Crump 2003). To cite just two: I found that what appeared to be contradictory estimates of solubility and dissolution rates reported for various types of fibers can in fact be reconciled by taking into account the conditions under which studies of these factors are conducted. Thus, solubilities and dissolution rates increase toward their theoretical maxima in those papers in which study designs, respectively, maximize the volume of fluid into which material is dissolving and the rate at which the fluid surrounding the surface of the dissolving fibers is refreshed.

Similarly, I was able to show in our review that the old and new studies of chrysotile fiber accumulation in lung tissue are in fact consistent (despite older studies suggesting that chrysotile reaches a plateau while newer studies do not). The differences in the apparent findings of such studies are due to the differences in the capabilities of the analytical methods employed to track lung tissue concentrations.

It should also be noted (as another example of the sparsity of the literature review included in the Roadmap) that the peer consultation report from the 2003 workshop is cited, but not the original report that was being reviewed or its partial revision in response to suggestions for improving transparency (Berman and Crump 2001, 2003). Web links are provided to obtain copies of both of these versions of our report.

Another important consideration that is critical to the reconciliation of the literature is the need to properly distinguish formal findings from a published study and any opinion or speculation that is also offered by study authors. When reconciling the literature, opinions and speculation should not be treated in the same manner as formal findings. To illustrate, although the opinion by Soderholm (1989) that "....all fibers deemed to be in the thoracic size fraction ... (e.g. capable of depositing in the bronchoalveolar regions) warrant concern" is paraphrased in Section 1.2.1.3 of the Roadmap, this is very different from any formal *demonstration* that all fibers in the indicated range in fact have been shown to contribute to human disease. Moreover, whether all such fibers should be considered to be equally potent is clearly an open question. Given (as illustrated below) that arbitrarily including a greater range of structures in the determination of concentration (than those most strongly associated with biological activity) may not automatically be health protective, simply accepting such opinions as fact (absent more formal analysis) may not be helpful in shaping effective policy or regulation.

As another, and perhaps more obvious, illustration of the need to differentiate between formal findings and speculation is the suggestion that Pan et al. (2005) can in any way inform on the nature of structures that contribute to disease. This paper presents no exposure information whatsoever and the simple presence of a material at a location where disease is observed in no way demonstrates cause and effect. In fact, the Pan et al. paper is at least one step further removed from providing a link between particular hazardous materials and disease, as it does not even demonstrate the presence of any particular material; it only alleges such a presence through inference.

## **Potential Misconceptions**

At least some of the recommendations of the Roadmap appear to be based on common misconceptions that, if not addressed, may hinder the efficient design of future research efforts. These misconceptions potentially include:

- that arbitrarily including a greater range of structure sizes and types in counts to determine exposure concentrations is automatically health protective;
- that efficient evaluation of the effects of structure size and type requires creation of samples of "pure" sizes or types;

- that animal and cell-culture studies will be more informative of human exposureresponse than better characterizing the historical human exposures in existing studies; and
- that one can reasonably evaluate the effects of fiber size and type based on data from a single study environment.

Regarding the last of the above, the ability to distinguish among effects caused by structures of varied sizes and or types in epidemiological studies of single environments is extremely limited. This is because concentrations of structures in the various size and type categories tend to be highly correlated and/or the exposures experienced by cohort members are highly confounded. The reasons for such correlation and confounding were previously described (see above). Thus, the best way to evaluate the effects of size and type is to analyze variations in exposure-response *across* environments. In this regard, it should also be noted that negative studies may be as important as positive studies for investigating the effects size and type.

The first of the above-listed misconceptions can be illustrated by considering the nature of the risk assessment process and the attendant consequences of observing varying concentrations of specific structures in environments of interest. The attached Figure 1 presents a schematic of the risk assessment process.

As can be seen in Figure 1, the risk assessment process can essentially be divided into two complimentary components: toxicological assessment and exposure assessment. Toxicological assessment is portrayed on the left side of the figure and involves research studies in which the incidence of disease in a studied population is observed, recorded, and is mathematically related to the associated exposure, which is also monitored. The result is to derive a mathematical expression relating exposure and response, which usually includes some type of factor indicating the potency of the hazardous material (i.e. the unit response anticipated per unit of exposure).

In an exposure assessment, depicted on the right side of Figure 1, exposure is characterized (typically by some combination of measurement and modeling) in a *study* environment for which the threat of disease needs to be determined. The estimated exposure is then combined with the potency factor derived from the toxicological assessment to predict the risk of future disease in the study environment.

The attached Figure 2 is a modified version of Figure 1 in which effects of using different exposure metrics on risk estimation is illustrated. Suppose that two candidate exposure metrics M1 and M2 are each being considered for assessing risk. In this case, it is further assumed that M1 is a subset of the structures included in the M2 metric so that (in the same environment) the concentration of M2 structures must always be greater than or equal to that of M1.

In Figure 2, for simplicity but with no loss of generality, the toxicological assessment is assumed to include only a single epidemiology study. Further, it is assumed in the one epidemiology study that the concentration of M2 is 15 times the concentration of M1 and that the incidence of the disease of interest is D. Because the incidence of disease observed in a cohort is fixed (at a fixed point of time) and independent of exposure metric, the relative potency factors for the M1 and M2 metrics will necessarily vary inversely with their relative contributions to exposure. Thus:

Potency Factor ( $PF_{M1}$ ) for M1 = D/M1 = 15D/M2; Potency Factor ( $PF_{M2}$ ) for M2 = D/M2

Thus, we see that the effect of counting more structures in a research environment is to make the exposure-response coefficient (the potency factor) *smaller* by dividing the observed incidence of disease over a larger number of structures. Another way to say this is that counting using an exposure metric that includes a greater number of structures will make the slope of the exposure-response curve shallower because one is dividing a fixed incidence of disease among a greater number of structures.

To judge the effect on risk assessment, consider applying each of the two potency factors derived above, respectively, for M1 and M2 to study environments in which one wishes to predict disease. Importantly, because these environments are isolated from the original research environment used to derive the potency factors and exposure conditions in these new study environments are entirely independent, the exposure concentrations of M1 and M2 can vary independently in each environment (both in absolute terms from the concentrations observed in the original research environment and relative to each other). Thus, three example study environments are presented on the right side of Figure 2 (in which the ratio of concentrations of M1 and M2 is assumed to vary from 1 to 100 with M2 always greater). The consequence is that the ratio of the risks estimated in each of these environments derived, respectively, using M1 and M2 varies from 15 to 0.16.

Note that risk in this case is estimated simply as the product of the potency factor for a particular metric and the estimated exposure concentration for that same metric. Thus, for example:

The above clearly illustrates that arbitrarily including a greater number of structures in the determination of exposure concentrations does not assure greater health protectiveness. Although M1 is a subset of the structures counted in M2, if we assume that M1 better represents the set of biologically active structures, than use of M2 underestimates risk in Environment 1 where  $Risk_{M1}/Risk_{M2} = 15$  (see Figure 2).

Table 2 provides data further indicating a real-world comparison of the effect of two exposure metrics for asbestos (although in this case, one is not directly a subset of the

other). Table 2 provides ratios for the risk estimated using the protocol structure metric recommended in Berman and Crump 2001 to the risk estimated using the PCME metric (i.e. concentrations derived using NIOSH Method 7402, NIOSH 1994b). Note that risk is estimated for the PCME metric by applying the EPA slope factor (IRIS Current) to the estimated exposure concentrations of that metric.

In Table 2, ratios are provided for environments studied in a set of government-lead projects in which adequate data were available to support estimation of the risk ratio. These results are consistent with more general observations that indicate the two metrics provide approximately equal estimates of risk in environments in which exposure is composed almost exclusively of chrysotile, but the protocol structure metric provides substantially higher estimates of risk in environments where exposure is to true asbestiform amphibole. In contrast, the sole exception to these observations (for the complete range of studies that I am aware of) is the study in El Dorado County recently completed by the U.S. EPA (Ladd 2006), which is the site listed as "El Dorado" in the table. This is the only site I know of at which the PCM metric provides a substantially greater estimate of risk when the primary exposure is to amphiboles.

It has been postulated that the reason the ratio of risks is reversed for the El Dorado site may be that the vast majority of amphibole structures are cleavage fragments at the locations studied (although this is certainly not true for El Dorado County as a whole). However, the message for this discussion is simpler.

Taken as a whole, the data in Table 2 show that risks estimated using different exposure metrics do not remain proportional from site to site. Thus, if the goal is to minimize the chance that risks will be underestimated in general, it will be important to identify an exposure metric that reasonably tracks biological activity<sup>1</sup>. Moreover, as previously indicated, arbitrarily including larger numbers of structures in the exposure metric does not guarantee that the metric will be health protective.

One additional consequence of these considerations should also be emphasized. That is that, for risk assessment to remain reliable, it is important not to apply exposure-response coefficients established from a defined set of epidemiological studies to sites in which exposures differ radically in characteristics from those included in the epidemiological studies evaluated. Thus, for example, it may not be appropriate to extrapolate findings from the set of epidemiological studies evaluated to support development of EPA's current slope factor for asbestos (IRIS current) to sites in which exposure primarily involves mixed dusts (i.e. dusts containing true asbestiform fibers along with substantial concentrations of cleavage fragments from the breakage of non-asbestiform analogs). This is because the epidemiological studies used to develop the

In fact, it may further prove necessary to devise separate exposure metrics for separate disease end points (e.g. asbestosis, lung cancer, and mesothelioma), as the effects of size and type may not be strictly identical for each.

slope factor in IRIS almost exclusively involve exposures to milled asbestos (see Table 1 of this report) and most milled asbestos is virtually free of cleavage fragments.

Note that Table 1 is derived from an earlier report that addresses this and related issues in much greater detail (see Berman 2006).

Given the above, the most health protective course of action is to identify an exposure metric that closely tracks (or at least remains reliably proportional to) biological activity for each disease end point of interest, to test and optimize these for each type of mineralogically distinct material of interest (including distinctions in both chemical and crystallographic type), and then to derive a matched exposure-response factor for each disease end point paired with each mineralogical and crystallographic type using the optimized metric while incorporating conservative statistical procedures that adequately control for uncertainty.

To illustrate the problem with the second of the above misconceptions, consider an study in which a linear model is assumed for evaluating toxicity in a series of animal experiments. It is further assumed for this model that there is an interest in distinguishing among contributions from four categories of structures. Thus, one way to set up the linear model would be as follows:

$$P_i = 1 - \exp[Q - B\Sigma_i(A_iX_{ii})]$$
 (1)

where:

P<sub>i</sub> is the probability of observing a tumor in an animal in the ith study;

Q is the term representing the background probability of tumors in control animals:

B is the term representing the absolute potency of the particular type of asbestos studied. If multiple types are studied, than different values of B could be employed for each kth type of asbestos;

A<sub>j</sub> is the relative potency of the jth size category of structures; and

 $X_{ij}$  is the concentration of structures in the jth size category in the ith study.

Table 3 provides a set of five equations with data from five experiments, which could be solved to provide unique values for each of the five unknowns of interest (B, and the four A<sub>j</sub>'s). Thus, as long as one has access to samples containing five broadly varying characteristics (i.e. with a broad range of relative concentrations of the four size categories of interest), by conducting an animal study (or epidemiology study) on each such material, it would be possible to obtain sufficient information to uniquely determine the relative potency of each size category.

In contrast, the experiments could also be conducted on samples of "pure" materials. In this case, the same set of equations would apply, except that all but one of the summed terms would drop out of each equation representing each experiment; note

that the remaining term for the equation from each experiment differs. This arrangement is also depicted on the bottom of Table 3.

It should be apparent from Table 3 that, in the absence of error, the experiments conducted on the pure materials provide no additional information than the experiments conducted on the mixed materials. Thus, no advantage to produce such materials is apparent. In fact, there may be a disadvantage in that producing pure materials requires that one guess at the appropriate dimensional constraints for each category in advance of conducting the experiments. Thus, if one guesses wrong, the value of at least some of the experiments would be diminished. In contrast, as long as one spends sufficient effort to adequately characterize the mixed exposures, a database is created from the set of experiments that allows for evaluation of varying sets of categories.

Of course, things are more complicated due to the variation and uncertainty necessarily introduced from various factors in these kinds of experiments. The effects of such variation and uncertainty can typically be addressed by conducting a greater number of experiments over a greater range of conditions than the minimum strictly required to solve the set of simultaneous equations to be employed for analysis. Importantly, both these problems and their solutions apply equally whether the experiments are conducted on pure or mixed materials. Thus, once again, no clear advantage to use of pure materials emerges.

Regarding the third of the above-listed misconceptions, it must be remembered that effects observed in animal studies and cell-cultures need to be correlated against human disease end points of interest before they can be considered to be informative of human disease, even in a qualitative sense. Moreover, if the desire is to use results of such studies to predict the incidence of human disease as a function of exposure, then many complex considerations will need to be validated to address such things as the differences in physiology between the target animals (or cells) and humans and the differences in exposure conditions between the experiments and life situations of interest. This is especially true if there is ultimately an interest in attempting to use animal or cell responses as screening tools for human exposure and risk.

In contrast, human epidemiological studies provide the most direct and expedient information on human exposure-response. Moreover, such studies will be needed in any case to validate the linking of animal and cell studies to human disease end points, especially for any proposed screening procedures. Thus, given the above, the necessarily central role of human epidemiological studies means that greater emphasis needs to be placed on resolving the limitations of these studies (such as to better characterize the historical exposures relevant to these studies) than the emphasis placed on any complimentary animal or cell-culture studies.

# Recommendations for Focusing Future Research

In addition to all of the above, I suggest that the following be considered when designing a research program to fill data gaps and increase our knowledge base for asbestos:

- transmission electron microscopy (TEM) has been shown capable of visualizing and resolving all asbestos structures (including the thinnest structures). Therefore, research on asbestos can move forward using TEM (so that asbestos concentrations can be fully characterized in a manner suitable for evaluating the full range of theories concerning the effects of size and shape). At the same time, it will be important to develop less expensive alternatives, especially if it proves necessary to characterize the longest and/or thinnest structures as part of an exposure metric that tracks biological activity. Less expensive alternatives will ultimately be needed for routine analyses as part of any generalized scheme of monitoring to protect worker health:
- with only rare exceptions (potentially including the latest work on the recharacterization of exposures associated with the South Carolina cohort of textile workers – Kuempel et al. 2006), the existing epidemiology studies do not include data suitable for evaluating the effects of structure size and type. Data suitable for this purpose generally need to be developed from other sources (such as de novo analyses of air filters or bulk material from studied environments);
- once data become available to adequately re-characterize historical exposures from a sufficient number of environments that have been studied by epidemiologists, a meta-analysis of such epidemiological studies will likely prove to be the best approach for evaluating the effects of fiber size and type so that improved exposure metrics for asbestos can be developed. Until such data become available, however, it is unlikely that this approach can substantially improve upon the studies of this type that have already been completed (for example, see Berman and Crump 2003); and
- ! it is important to recognize that the adequacy of the PCM metric and the need to distinguish asbestiform fibers from cleavage fragments are confounded issues (depending on the dimensional constraints ultimately defined for one or more optimized exposure metrics, the need to distinguish asbestiform fibers from cleavage fragments may become unimportant).

With these additional points in mind, I suggest that the plan for research proposed in Roadmap might be refocused to better address needs as follows:

! place greater emphasis on human (epidemiological) studies and, especially, an effort to improve characterization of the associated, historical exposures;

- ! use TEM for research while developing less expensive alternatives to support routine analysis under an improved monitoring regime for health protection. Importantly, the search for alternatives to TEM will ultimately require knowledge of the optimized exposure metrics that are needed to adequately predict asbestos-related risks so that research to identify and optimize appropriate exposure metrics will need to be completed before selection and optimization of analytical alternatives can be finalized;
- ! include studies to automate TEM analysis as a potential means of reducing TEM analytical costs; and
- with regard to supporting our understanding of exposure-response relationships for asbestos, the quest for "pure" samples (containing only a narrow range of structure sizes of specific types) should probably be de-emphasized. Importantly, this is obviously a separate issue from the need for "pure" samples (in terms of the type of a material) to be used as standards for "calibration," quality control, and performance testing.

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# **ACKNOWLEDGMENTS**

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TABLE 1: CHARACTER OF EXPOSURES IN STUDY ENVIRONMENTS USED TO DEVELOP IRIS SLOPE FACTOR

Fiber Type		Exposure	<del></del>	
Operation	Cohort	Metric*	Comments	
			All samples contain asbestiform fiber.	
Chrysotile			The indicated samples contain fiber with:	
Mining and Milling	Quebec mines and mills	MI	serpentinite and trace amphibole cleavage fragments <sup>b</sup>	
		MI	serpentinite and trace amphibole cleavage fragments <sup>b</sup>	
Friction Products	Connecticut plant	MI*	at most, small amounts of serpentinite cleavage fragments <sup>c</sup>	
Textiles	South Carolina plant	PCM	at most, trace serpentinite cleavage fragments	
	•	PCM	at most, trace serpentinite cleavage fragments	
Amosite			·	
Insulation Manufacture	Patterson, NJ factory	PCM**	at most, trace amphibole cleavage fragments <sup>d</sup>	
Mixed				
Friction Products	British factory	PCM	at most, trace amphibole cleavage fragments <sup>c,d</sup>	
Cement Manufacture	Ontario factory	MI*	at most, trace serpentinite and amphibole cleavage fragments	
Oction Managed	New Orleans plants	MI	at most, trace serpentinite and amphibole cleavage fragments <sup>e</sup>	
Factory workers	U.S. retirees	MI*	at most, trace serpentinite and amphibole cleavage fragments	
Insulation Application	U.S. insulation workers	NS	at most, trace serpentinite and amphibole cleavage fragments	
Textiles	Pennsylvania plant	MI*	at most, trace serpentinite and amphibole cleavage fragments	
TOMBOO	Rochedale plant	TP*	at most, trace serpentinite and amphibole cleavage fragments	

#### \* KFY

Symbols in this column indicate the primary metric by which exposure was monitored in the indicated study.

<sup>&</sup>quot;MI" means midget impinger with a study specific factor applied to convert PCM.

<sup>&</sup>quot;MI\*" means midget impinger with a non-study specific conversion factor.

<sup>&</sup>quot;PCM" means phase contrast microscopy. "PCM\*\*" means PCM, but with

<sup>&</sup>quot;PCM\*\*" means PCM, but with measurements determined at a different plant from the one where mortality was monitored.

<sup>&</sup>quot;TP\*" means that the initial measurements were collected by thermal precipitator with a non-study specific conversion factor applied.

<sup>&</sup>quot;NS" means non-specific; exposures were estimated for the Selikoff et al. (1979) simply as the average concentration reported for the overall insulation industry.

# TABLE 1 (cont.) CHARACTER OF EXPOSURES IN STUDY ENVIRONMENTS USED TO DEVELOP IRIS SLOPE FACTOR

#### NOTES:

- <sup>b</sup> Although these are the only environments in which serpentinite or amphibole cleavage fragments might be present at greater than very small amounts (due to the presence of the parent rock in which the asbestos is embedded), these studies were excluded from the EPA analysis used to derive the EPA recommended unit risk factor for asbestos.
- c Although cleavage fragments are potentially present (at most in small amounts) in friction product environments (because the lowest grade asbestos fiber used to manufacture these materials may not have been as well purified as higher grade fiber (Walton 1982), these environments also exhibit among the lowest dose-response factors.
- In these environments, it is possible that particles composed of organic materials or other non-serpentinite and non-amphibole inorganic materials may be present (which are distinct from serpentinite or amphibole cleavage fragments). However, it is not clear whether any of these materials have been shown to cause cancer in other environments where asbestos was not used. Certainly, up to this point, EPA has not applied the asbestos regulations to environments where particles of these other materials might be present without asbestos also being present.
- <sup>e</sup> In these environments, particles composed of the cementitious binders and fillers used in cement manufacture may be present (which are distinct from serpentinite or amphibole cleavage fragments). However, whether any of these materials have been found to be carcinogenic in other environments in the absence of asbestos is not relevant here. Certainly, up to this point, EPA has not applied the asbestos regulations to environments where these types of cementitious binders and fillers are present without asbestos.

## TABLE 1 (cont.)

# CHARACTER OF EXPOSURES IN STUDY ENVIRONMENTS USED TO DEVELOP IRIS SLOPE FACTOR REFERENCES

- (1) McDonald et al., (1980)
- (2) Nicholson et al., (1979)
- (3) McDonald et al., (1984)
- (4) Dement et al., (1983)
- (5) McDonald et al., (1983a)
- (6) Seidman (1984)
- (7) Seidman (1979)
- (8) Berry and Newhouse (1983)
- (9) Finkelstein (1983)
- (10) Weill et al., (1979)
- (11) Henderson and Enterline (1979)
- (12) Selikoff et al., (1979)
- (13) Peto et al. (1982)
- (14) McDonald et al., (1983b)
- (15) Peto (1980)
- (16) Peto et al. (1982)

TABLE 2:
COMPARISON OF APPROACHES FOR ESTIMATING
ASBESTOS-RELATED RISK AT SELECTED
GOVERNMENT-LEAD SITES

Site	Primary Mineral Type	Median Ratio of Estimated Risks: Protocol Strs/PCME	Reference
DiamondXX	Chrysotile	1	ICF Technology 1994
Southdown	Amphbiole Asbestos	50	Berman 2003
Libby	Amphibole Asbestos	7	EPA 2003
El Dorado	Chrysotile and Amphibole	0.04	Ladd 2005

# TABLE 3: SIMULTANEOUS EQUATIONS USED TO SOLVE FOR RELATIVE POTENCY OF DIFFERENT CATEGORIES OF ASBESTOS STRUCTURES IN A SERIES OF ANIMAL EXPERIMENTS

## SIMULTANEOUS EQUATIONS FOR CASE WITH MIXED EXPOSURES

 $P_1 = 1 - \exp[Q - B_i(A_1X_{11} + A_2X_{12} + A_3X_{13} + A_4X_{14})]$ 

 $P_2 = 1 - \exp[Q - B_i(A_1X_{21} + A_2X_{22} + A_3X_{23} + A_4X_{24})]$ 

 $P_3 = 1 - \exp[Q - B_i(A_1X_{31} + A_2X_{32} + A_3X_{33} + A_4X_{34})]$ 

 $P_4 = 1 - \exp[Q - B_i(A_1X_{41} + A_2X_{42} + A_3X_{43} + A_4X_{44})]$ 

 $P_5 = 1 - \exp[Q - B_i(A_1X_{51} + A_2X_{52} + A_3X_{53} + A_4X_{54})]$ 

## INDEPENDENT EQUATIONS FOR CASE WITH "PURE" EXPOSURES

 $P_1 = 1 - \exp[Q - B_i(A_1 X_{11})]$ 

 $P_2 = 1 - \exp[Q - B_i(A_2 X_{22})]$ 

 $P_3 = 1 - \exp[Q - B_i(A_3 X_{33})]$ 

 $P_4 = 1 - \exp[Q-B_i(A_4X_{44})]$ 

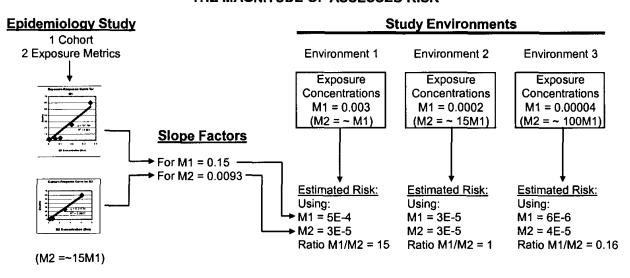
 $P_5 = 1 - \exp[Q - B_i(A_1 X_{51})]$ 

Note that for the latter case, all but one of the concentrations  $(X_{ij})$  are zero in each of the individual equations and, except for one repitition, it is a unique  $X_{ij}$  that is non-zero in each equation.

# FIGURE 1: SCHEMATIC REPRESENTATION OF THE RISK ASSESSMENT PROCESS

#### Research Environment(s) **Study Environment** Exposure Groups **Exposure Environments** Group A Group B Group C Environment 1 Environment 2 Environment 3 Observed Observed Observed Estimated **Estimated** Estimated Disease Disease Disease Exposure Exposure Exposure Exposure/Response Factor/Relationship Estimated Estimated Estimated Estimated Estimated Estimated Exposure Exposure Exposure Risk Risk Risk

FIGURE 2
SCHEMATIC INDICATING THE EFFECT OF EMPLOYING DIFFERENT EXPOSURE METRICS ON
THE MAGNITUDE OF ASSESSED RISK



### **ATTACHMENT 1:**

# PROPOSED GLOSSARY OF TERMS SUITABLE FOR PROMOTING FULL DISCUSSION OF ASBESTOS-RELATED ISSUES

D. Wayne Berman, Ph.D. Aeolus, Inc. April 27, 2007

Note that the following glossary is offered as a starting point, but is not necessarily intended to be comprehensive. Additional terms (some of which are included in the Roadmap glossary) will almost certainly need to be developed to express the full range of important concepts relevant to asbestos.

Asbestiform means the particular crystalline habit of a mineral that exhibits the common characteristics of asbestos (e.g. highly fibrous, polyfilamentous – existing in bundles, flexible, high tensile strength, and good chemical and thermal resistance). Geologically, the dimensions of fibers formed in this habit are defined by the growth of the crystals (in contrast to cleavage fragments).

Asbestos Minerals means the suite of serpentinite and amphibole minerals currently included in the definition of asbestos when they occur in any of their crystalline habits.

**Cleavage Fragment** means a structure that is formed by physical separation from a larger crystal. Thus, the dimensions of such a structure are defined by the orientation of the weakest cleavage planes in the parent crystal, which is in contrast to the manner in which dimensions are determined for asbestiform structures.

**Exposure Metric** means the set of sizes, shapes, and morphological types of structures (e.g. fibers, bundles, clusters, or matrices) that are included in the determination of concentration. Sometimes, a particular exposure metric also includes mineralogical constraints (i.e. only structures identified as specific mineralogical types are included). Therefore, exposure metrics for a particular analysis are defined as a function of both the rules of the specific analytical method applied to determine concentration and the limitations of the particular instrumentation employed during the analysis. To illustrate:

the *PCM Metric* might be defined as: the set of particles that are longer than 5  $\mu$ m with a minimum aspect ratio of 3:1 and largely parallel sides as viewed and counted with a phase contrast microscope using the rules of NIOSH Method 7400 (NIOSH 1994). It should also be emphasized for this metric that, due to the limitations of PCM, the structures included in this metric are typically thicker than a minimum width that varies between 0.2 and 0.4  $\mu$ m, depending on the skill of the microscopist and the condition of his equipment. Note that the metric

should be defined consistently so as either to include or exclude a maximum width. Correspondingly, a "width-limited" version of this metric (perhaps  $PCM-WL\ Metric$ ) might be separately defined to include only those particles thinner than 3  $\mu$ m;

- en attendant PCM equivalent Metric (*PCME Metric*) could then be defined as: the set of particles that are longer than 5 μm and thicker than 0.025 μm with a minimum aspect ratio of 3:1 and largely parallel sides as viewed and counted with a transmission electron microscopy using the rules of NIOSH Method 7402. Using this metric, it would also be simple to indicate whether particles satisfying this metric exhibit the chemical properties of specific minerals;
- other exposure metrics can also be defined to satisfy other discussion needs as they arise.

**Fiber** is a relative term that has come to mean any elongated particle that satisfies specific dimensional constraints. The term is relative because the dimensional constraints placed on the definition of the term fiber are specific to the analytical method/exposure metric by which fiber concentrations are determined for a particular application.

**Fibril** means a single fiber of asbestos (i.e. from an asbestiform population). Single asbestiform fibers cannot be further reduced in width without altering their properties.

**Fibrous** is a relative term that is used to denote a material composed primarily of fibers. The term is relative because the term for fiber is relative (see above). Note, for example, a dust composed primarily of elongated particles that nevertheless satisfy the dimensional definitions for fibers from a particular application could therefore be defined as fibrous.

**Fibrous structure** is a collective term used to mean any fiber, bundle, cluster, or matrix. These latter terms for specific types of structures are concisely defined in ISO (1995).

# ATTACHMENT 2: NEW ASBESTOS REFERENCES January 28, 2001

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## ATTACHMENT 3. REFERENCES FOR ASBESTOS-RELATED EPIDEMIOLOGICAL STUDIES AND A FEW RELATED STUDIES

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