PLAINTIFF'S EXHIBIT
AIA-64

A REPORT

SCIENTIFIC EVALUATION

OF THE

REVIEW OF THE ENVIRONMENTAL EFFECTS

OF ASBESTOS

BY AN

AD HOC STUDY GROUP

TO THE

HAZARDOUS MATERIALS ADVISORY COMMITTEE

SCIENCE ADVISORY BOARD

U. S. ENVIRONMENTAL PROTECTION AGENCY

February 4, 1976

Asbestos Information Association
North America
1660 L Street, N. W.
Washington, D. C. 20036

01-0205588

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 4, 1976

OFFICE OF THE
ADMINISTRATOR

Dr. Martin Alexander, Chairman
Hazardous Materials Advisory
Committee
Science Advisory Board, EPA
Department of Agronomy
Cornell University
Ithaca, New York 14853

Dear Dr. Alexander:

I transmit, herewith, report of the Ad Hoc Study Group to critique the document entitled REVIEW OF THE ENVIRONMENTAL EFFECTS OF ASBESTOS designated ORNL-EPA-17, November 30, 1974.

A memorandum dated May 20, 1975 from Dr. Emil Mrak, then Chairman of the Hazardous Materials Advisory Committee, charged the Ad Hoc Study Group to 1) give its best assessment of the appropriateness and completeness of the information presented; and 2) give its best assessment of the adequacy of the information to serve as a basis for standards under an anticipated legislative mandate. The Ad Hoc Group understood that it was not supposed to rewrite the document, only to critique it. This, it has done, but in so doing it felt obliged to make its comments more or less pointed and it attempted to be helpful and constructive by suggesting ways to correct and improve. The Group also went to considerable effort to provide additional references it thought would be helpful in any rewriting and revision of the document.

The Ad Hoc Group was composed of very knowledgeable persons, truly expert in their fields with respect to asbestos. They put many of their personal hours into the substance of the report and I wish to thank them for their dedicated effort. I should also like to acknowledge the assistance of Dr. J Frances Allen, and the Science Advisory Board Staff.

The Ad Hoc Study Group hopes that the attached report is a satisfactory response to the charges it was created to answer.

Respectfully submitted on behalf of the entire Ad Hoc Study Group.

V. K. Rowe

V. K. Rowe, Sc.D.
Chairman, Ad Hoc Study Group

cc Members Ad Hoc Study Group

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A REPORT

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REVIEW OF THE ENVIRONMENTAL EFFECTS

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TO THE

SCIENCE ADVISORY BOARD - HAZARDOUS MATERIALS ADVISORY COMMITTEE

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Miss Anne M. Wolven
Senior Toxicologist
Shell Chemical Company

February 4, 1976

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I. INTRODUCTION

A letter of May 13, 1975, (APPENDIX A) from Dr. Wilson Talley, Assistant Administrator for Research and Development, to Dr. Emil M. Mrak, Chairman of the Executive Committee of the Science Advisory Board, points out that the Congress has been considering the passage of legislation to address the problem of protection of the public health and welfare against any dangers that might be associated with the disposal of hazardous materials to the soil. In anticipation of the passage of such legislation, the Office of Research and Development is in the process of gathering and organizing information for a series of reports on the transport and effects of critical pollutants, including asbestos and mercury, which are components of materials commonly disposed to the soil. Dr. Talley is seeking through the Science Advisory Board views of the scientific community as to the appropriateness and completeness of the information presented in the reports as well as their adequacy to serve as a basis for setting of standards under the anticipated legislation before the reports are finalized.

At the meeting of the Board's Executive Committee on May 16, 1975, the responsibility for critiquing the draft reports on asbestos and mercury was assigned to the Hazardous Materials Advisory Committee.

In response to this request the Chairman of the Hazardous Materials Advisory Committee established an Ad Hoc Study Group to evaluate the draft report, Review of the Environmental Effects of Asbestos. In a memorandum dated May 20, 1975, (APPENDIX B) Dr. Mrak, at that time also Chairman of the Hazardous Materials Advisory Committee, charged the Ad Hoc Study Group to consider in detail the information contained in the asbestos draft document and to provide a report of its findings to the Committee. This report is to include the following:

1. The Study Group's best assessment of the appropriateness and completeness of the information presented.

2. The Study Group's best assessment of the adequacy of this information to serve as a basis for standards under an anticipated legislative mandate.

The background and purpose of these documents (asbestos and mercury) is stated in the Guidelines and Background for the External Panel Review as follows:

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"The Solid and Hazardous Waste Research Laboratory, at the request of the Office of Solid Waste Management Programs (OSWMP), is developing comprehensive multimedia State of the Knowledge Reports on the Environmental and Health Effects of Substances deemed hazardous and present as components of waste streams destined for land disposal. These reports to be developed from existing literature, are to serve as part (i.e. bioenvironmental aspects) of the total scientific base which must be considered if promulgated guidelines/standards for the disposal of hazardous materials are to be scientifically sound and economically feasible. These reports are being developed under the authority of Section 212 of the Solid Waste Disposal Act, as amended in 1970 and in anticipation of the passage of the proposed Hazardous Waste Management Act or similar legislation."

It is anticipated, as stated in the charge to the Ad Hoc Study Group, that this document on asbestos will:

- Provide an up-to-date compendium of information on toxicities/effects associated with exposures to specific substances contained in the air, water, and land media.
- Provide insight into the effective soil and plant indicators for detecting the presence of substances.
- Provide general data on the complexity, cost, and reliability of state-of-the-art analytical procedures for determining the presence of substances.
- Provide information on predictable reaction products of the substances to aid in the design of criteria relating to mixing of wastes.
- Permit assessment of the need for additional air emission standards because of the operational characteristics of hazardous waste treatment sites.

This report will first discuss briefly the overall Review and then deal in considerable detail with the deficiences of the individual sections. The Ad Hoc Group agreed that pointing out deficiencies in this draft document without offering suggestions as to how they could be remedied would be inappropriate. This report is a collection of comments and suggested changes that will be meaningless by themselves without coordination with the substance of the original document.

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In general, the Review of the Environmental Effects of Asbestos includes a very large part of the knowledge about asbestos that existed before the past two or three years. Since then, a great amount of information on asbestos has become available. When one considers that this document was completed in November 1974, it is obvious that it must have been in preparation for some time before that. The lack of more recent information should not be considered as a deficiency, but the Ad Hoc Group is of the opinion that unless steps are taken to update the document, its usefulness for the stated purpose will be minimal. Furthermore, its adequacy to withstand criticism of validity would be open to serious question.

There are areas in the Review where the data have been inaccurately presented and misinterpreted, and pertinent references overlooked. The commentary will deal specifically with the individual sections.

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II. GENERAL COMMENTS

SECTION 1.0 -- General Summary

1.1 FINDINGS

If the Study Group could assume that the draft Review of the Environmental Effects of Asbestos will be rewritten, this Section would then be expected to reflect essential changes needed in subsequent Sections and Subsections, and little else would need to be said. However, changes in definition of certain disease states are suggested. Other modifications, as well, such as the elimination of irrelevant material, should be given attention.

1.2 CONCLUSIONS

Changes in this Subsection should reflect modifications in subsequent sections. This Subsection includes a considerable amount of irrelevant material that is and would be inappropriate, irrespective of other changes.

SECTION 2.0 -- Physical and Chemical Properties

This Section is badly in need of rewriting chiefly because it is far out of date. New information is available, beginning in 1973, particularly with respect to analytical methodology. Reorganization of the material in 2.0 is required in order to reflect recently developed information. Inclusion of new analytical methods and data is critical to the effectiveness of the Review.

SECTION 3.0 -- Biological Aspects of Asbestos in Plants and Microorganisms

Apparently there is little information available on the biological aspects of asbestos in plants and microorganisms.

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SECTION 4.0 -- Biological Aspects of Asbestos in Animals

As one reviews this whole Section it becomes apparent that there is a huge void in the data base needed to assess the hazard of environmentally encountered asbestos. The experimental data available deal largely with the type of material and the type of exposure encountered in the occupational or occupationally related setting. Toxicological data pertaining to the type of material and the type of exposure encountered in the general environment are lacking for the most part. The greatest need is for information which will permit an assessment of the nonoccupational hazard(s) attending various exposures falling within the jurisdiction of EPA (i.e. drinking water and community air) and also of concern to FDA (i.e. foods and drugs).

Recent developments in analytical procedures as noted in the suggested revisions of Section 2.0 have demonstrated that the asbestos to which the general population is most likely to be exposed on a continuing basis is quite different from that normally encountered in the occupational area. Studies of water and foods have shown that asbestos is ubiquitous in them and that it typically is in the form of very fine fibrils averaging in length about 1 to 2 μm and with an aspect ratio of 30 or more. Even though the numbers of these fibrils is huge, millions, even hundreds of millions/liter of water, one million such fibers is equivalent to only about 0.01 to 0.02 μg in total mass.

If Subsection 4.4.1.3.3 of the Review is revised to include information as suggested by the Ad Hoc Group there will be a body of information showing that asbestos fibers less than 5 μm in length have a minimal, if any, activity when inhaled by, or administered intratracheally to animals. Since this is the type of asbestos widely encountered in nonoccupational settings it would seem that it is the type of material that should be included as a part of any comprehensive study of prime interest to EPA or FDA. Consideration also should be given to the types of asbestos that may be found in homes, offices, public buildings, public water or elsewhere as a result of the use of asbestos. Consideration should be given to that which could be expected from solid waste disposal if different from that occurring in occupationally related areas.

The Ad Hoc Group feels that development of both qualitative and quantitative data through appropriate animal studies on the types of asbestos most commonly encountered in the nonoccupational environment would be most useful.

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The Ad Hoc Group is aware that some ingestion studies on asbestos are already underway. The studies are as follows:

1) A study under the direction of Dr. A. Pelfrene of Eppley Institute in Omaha, funded by NCI

2) A study under the direction of Dr. Will at the University of Iowa, funded by NCI

3) A study by Dr. J. C. Wagner of Wales

4) A study by Dr. W. E. Smith at Fairleigh Dickinson University

5) A study being managed by NIEHS resulting from a specific appropriation from the Congress to assess the effects of oral ingestion of asbestos (APPENDIX C).

Judging from the protocol available it appears that the NIEHS study is designed to more closely simulate occupationally related exposure than general environmental exposure, particularly with respect to particle size of test material and dosage which seems grossly excessive.

Examination by EPA of the protocols for these and other animal studies in progress to determine whether the results will, or will not, provide information useful in assessing the hazard associated with nonoccupational exposure to asbestos is most desirable. Such in-depth consideration before embarking upon any additional animal studies is critical.

SECTION 5.0 -- Physiological and Pathological Aspects of Asbestos in Humans

As with Section 4.0, the commentary on this Section is extensive probably because the Ad Hoc Group is privileged to have as members persons with first hand knowledge on the subject. Generally, the comments reflect the need for precise language and the clinical interpretation of the data presented. Also provided are current data and numerous current references to support this Section.

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Continuation of EPA epidemiologic studies in progress and search for other sites where exposure to naturally occurring asbestos can be documented and a meaningful study conducted would be of great value in producing much needed information. It may well be that the results of epidemiologic studies of local populations will provide reasonable answers to the EPA problem of assessing the risk from exposure related to nature, current uses, and waste.

SECTION 6.0 -- Environmental Distribution and Processes

There appears to be some confusion in this Section with respect to units of measurement. The apparent contradictions are pointed out in the detailed commentary. The Section needs to emphasize the ubiquitousness of asbestos and the fact that it has been with us for a long time.

SECTION 7-0 -- Environmental Interactions and Their Consequences

This Section can be expanded to make it more useful. Further research and data collection are needed in this area and could be of great value in producing much needed information. Actually this Section could easily be combined with Section 6.0.

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III. DETAILED COMMENTS ON INDIVIDUAL SECTIONS

SECTION 1.0 -- General Summary

1.1 Para. 1, line 2: asbestosis, pleural plaques, lung and laryngeal cancer, pleural and peritoneal mesotheliomas, and gastrointestinal cancers. Pleural plaques is not a lung abnormality.

Para. 3, line 7: Concerning the relative fibrogenic potential of various asbestos types (Subsection 4.4.1.3.2) Fibers less than 5 μm in length have not caused fibrosis when inhaled or injected intratracheally. (4.4.1.3.3) Firm conclusions regarding the fibrogenic mechanism are not possible at this time. Delete rest of the sentence.

Para 4, line 1: Conclusions about the carcinogenic mechanism of asbestos are also problematic.

Line 10: After chrysotile, insert and has not been demonstrated with anthophyllite. (Subsection 5.3.4.3).

Line 11: ". . . amosite, crocidolite, and anthophyllite produce . . . ."

Page 2, Para. 1, last line: Change proportionate to related Section 6.0 reference is not pertinent to the statement, use (4.4.2.1).

Para 2, line 3: The signs and symptoms. Delete emphysema.

Line 15: Signs and symptoms include.

Page 3, Table 1.1: Definitions as given do not seem appropriate--suggest the following changes and additions:

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Pleural calcification: Deposition of calcium salts in fibrotically thickened pleura.

Pleural fibrosis: Diffuse, shaggy, fibrotically thickened pleura.

Pleural plaque: A localized, milky-white, glistening patch of fibrotically thickened pleura, usually on the parietal aspect.

Pleural and peritoneal mesothelioma: A rare malignant neoplasm, etc.

Lung cancer: An epithelial malignant neoplasm, most commonly of a bronchus that often invades surrounding tissues and metastasizes to other organs.

Page 4, para 1: Delete last sentence because the conclusion does not relate to the findings.

Para 3, line 9: . . . and the condition results in death.

Para 4, line 1: There is preliminary evidence that asbestos inhalation may enhance. . . .

Line 10: Duluth, Minnesota, over the past 20 years has. . . .

Line 12: The findings are considered inconclusive because cancer induction may require more than 20 years. There is a lack of epidemiological information. . .

Page 5, line 1: Numerical dose-response. . .

Lines 5 to 7 beginning with "An exception . . . delete because inappropriate.

Para 3, line 1: Cigarette smoking is a co-factor in lung cancer.

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Line 5: Add, No such relationship has been demonstrated for mesothelioma.

Para 4, line 4: . . . population to occupationally related asbestos. . . .

Line 8: Add after "United States" but have no significance with regard to health effects.

Delete rest of para 4 unless documentation can be produced. It is not in 5.3.6.2.2

Para 5, line 5: Delete sentence beginning with "Because of." Last line. Delete sentence beginning here and ending on page 6.

Page 6, para 1, lines 3-5: Delete all cities.

Line 6: In addition, asbestos fibers are detectable in beverages. . . .

Para 2, line 2: ". . . and ingestion, but no adverse health effect has been demonstrated. Delete the rest.

1.2 CONCLUSIONS

a. All types of asbestos are pathogenic to humans, causing asbestosis, pleural plaques, and lung cancer. Crocidolite, amosite, and chrysotile also cause mesothelioma. There is also preliminary evidence that they may increase the risk of GI cancers. However, anthophyllite has not been demonstrated to produce mesothelioma in man. In animals all types of industrially used asbestos have produced asbestosis, lung cancer, and mesothelioma.

Page 7 (b) line 2. After "asbestos" insert on humans.

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Line 4, after "significance" insert for humans.

Line 5, put period (.) after "controversial."

Delete rest of paragraph.

d. to predict accurately

g. Page 8, line 6, delete everything beginning with "The recent."

h. Delete "asbestosis and"

i. Available data indicate that the presence of asbestos is widespread in air, water, soil, and food. Methods for quantitatively identifying the concentrations, size distributions, and types of asbestos fibers in the environment are being developed.

j. No human health hazards. . .have been demonstrated. There is paucity of information concerning numerical human. . .

k. A nonoccupational asbestos exposure standard. . . and related hazards. Available environmental and . . . insufficient to enable a scientifically. . . . . . standards. Delete the rest of the paragraph. This material is not relevant to text and should be deleted.

l. This material is not relevant because it deals with occupational exposure and it should be deleted.

m. Page 9, add: Because of the many new publications and reports that are now being generated the data base is being updated continuously.

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SECTION 2.0 -- Physical and Chemical Properties

This section is not up-to-date, particularly with respect to analytical methodology. It is critical that the Section be up-to-date and that the more recent literature, especially since 1973 be included. A number of new and pertinent references are given at the end of this commentary.

2.1 Page 10. Asbestos is defined here as a group of hydrated silicate minerals possessing a fibrous morphology and having commercial worth. The definition generally limits the mineral group to chrysotile, cummingtonite ("amosite"), tremolite-actinolite, anthophyllite, and crocidolite although there are other asbestos minerals such as eckermannite. Would it not be desirable to point out that there are other minerals of the class and also physical forms generally referred to as asbestos bodies? For example, if one uses the common criteria of viewing length/width of ≥ 3 for an asbestiform (= fibrous, = acicular) mineral, the definition can be extended to many tens of commonly occurring minerals, such as plagioclase, other amphiboles (hornblende), wollastonite, ~~pyrite~~ apatite, pectolite, etc. The length/width ratio (aspect ratio) has considerable significance in health considerations, especially for the general environment. In this context, the difficulties of analysis due to the large number of mineral candidates must be considered as highly important.

Page 11. Table 2.1 could well be expanded to include a listing of common impurities, surface properties such as surface area and zero point of charge, solubilities in water, effect of pH, etc. Perhaps new references 3a, 5a, 9a (Tables 2 & 3 especially), and 13a will be helpful here as well in the expansion of the discussion as suggested below.

2.2 & 2.3 Pages 10, 11, 12 and 13. General. Suggest re-organizing the presentation of this information so as to deal more comprehensively with each major item. For example, 2.2 = Uses. This is believed to be of sufficient importance as to merit more attention.

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2.2.1 - Building materials
2.2.2 - Cement pipe
2.2.3 - Floor tile
2.2.4 - Insulation
2.2.5 - Pipe covering
2.2.6 - Brake lining
2.2.7 - Chlorine cell diaphragms
2.2.8 - Paint
etc.

It would be most effective to consider for each use the amount, type, ultimate fate or, what does that use contribute to the various environments, and what are the future prospects and possible substitutes. Such information would be useful to the decision makers dealing with waste disposal of asbestos. Perhaps new reference No. 3a will be helpful in several ways.

To continue, 2.3 Properties. It would seem desirable to reorganize this section to deal with the various asbestos types separately and organize the discussion of each separately.

For example:

2.3.1 - Serpentine: Chrysotile
2.3.1.1 - Composition
2.3.1.2 - Physical properties
2.3.1.3 - Chemical properties
etc.

2.3.2 - Amphiboles -- general description and discussion
2.3.2.1 - Ortho-amphiboles:anthophyllite
2.3.2.1.1 - Composition
2.3.2.1.2 - Physical properties
2.3.2.1.3 - Chemical properties
etc.
2.3.2.2 - Clino-amphiboles-tremolite-actinolite, cummingtonite-grunerite(amosite),crocidolite.
2.3.2.2.1 - Tremolite-actinolite
2.3.2.2.1.1 - etc.
2.3.2.2.2 - Cummingtonite-grunerite (amosite). Amosite is a commonly used acronym (nonmineral) for Asbestos Mines of South Africa). A statement of the sort. . . "Because of its common use in the literature it is retained, even though it is not a proper mineral term."

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Its mineral equivalence to cummingtonite-grunerite series should be noted. Until approximately 10 years ago amosite was mis-identified as anthophyllite due to small extinction angle.

2.3.2.2.2.1 - etc.

Perhaps the following points will be useful for expanding the above section:

Chrysotile has a fairly constant stoichiometry. Arches sheets (misfit at the atomic level) give a TEM tubular appearance and high porosity, low apparent density, etc. Sometimes the tubular vacancy is filled with other material. Many articles on this appear in the American Mineralogist. Also see Rickards, 1973.

Ortho-amphiboles: Anthophyllite: Polymorph of cummingtonite. Variable Fe, Mg, and Al substitutes for Si. Often Mg is greater in anthophyllite than in cummingtonite, although there is overlap.

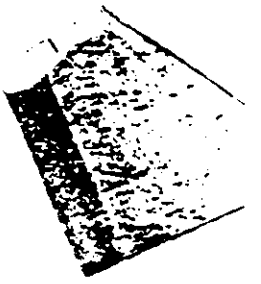
Clino-amphiboles: Tremolite-actinolite: Continuous series between tremolite and ferro-actinolite; e.g. continuity of optical properties, cell parameters, stoichiometry.

Cummingtonite-grunerite: Variable Fe, Mg, with minor Al, Ca substitution. Due to lack of big cations (Ca, Na), a and b cell dimensions are smaller than other clino-amphiboles.

Crocidolite: Variable substitution Mg for Fe, Ca for Na (Al for Si). Cleavage is strongly developed parallel to the c axis, and along with crystal growth determines the acicular (fibrous nature) of the amphibole asbestos. Contrasts with serpentine asbestos.

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Occurrences are generally in retrograde metamorphic deposits. Because of the multiple defects and substitutions in the amphiboles, it is often difficult to specifically identify each fibre at the specific mineral level. (See Beaman and File for example on well documented occurrences). All of the above named minerals occur as fibrous and nonfibrous varieties. A table summarizing their properties, typical occurrences, variable composition, and optical properties would be useful, also a comment on kinds of occurrences in nature.

2.4 This section needs to be expanded and brought up-to-date so as to deal with many of the intricacies of technique required to obtain reliable results. Much progress has been made in this area recently and the new techniques need to be brought into focus. In order to be helpful a number of new references are listed at the end of this commentary. For example, 3a treats new analytical methodology and analyzes the procedural problems; 3b gives new data with respect to X-ray diffraction methods; 9a covers a wide variety of topics in an up-to-date manner. Since this is an EPA report it should have access to work done for Dr. C. Anderson of EPA in Athens, GA, by Battelle (Contract No. 68-03-2199), which tells how to separate chrysotile from diatomaceous earth using a two phase, aqueous-benzene system.

It also appears that the authors may be confused about energy dispersive spectrometry (EDS). It can be used effectively on <u>both</u> TEM and SEM type instruments.

The listing of equipment on pages 15 and 16 seems useless in view of the above.

2.4.1 As a suggestion, perhaps the following outline may be useful to expand and update this section.

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ANALYTICAL METHODS

A. Measurements that are commonly desired
Concentrations-mass
fibre count

sizing + L/W
Mineral ID
Elemental composition
Surface--charge, morphology, degradation,
trace substances

B. Methods

Match methods to A and differentiate in a classification bulk analysis from fibre analysis:

BULK (mass)	FIBRE ANALYSIS (count)	
	High Magnification Microscopy	Optical
SRD, AA, IR etc	<2-3 µm (SEM), TEM, elemental analysis etc.	>2-3 µm Phase contrast petrographic microscope etc.

C. Techniques

Follow the classification in B. NB on fibre counts of large particles where optical mike can be used, optical properties are quite definitive (Deer, et al, 1963 and a paper by McCrone). On small particles TEM + energy dispersive elemental analysis + SAEDA are more definitive (Beaman and File, and others)

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D. Sample handling air/water

a. Concentration (if required) filtration, ultracentrifuge
b. Grid transfer: solvent refluxing, ultrasonification, etc.
c. Counting reporting fibre ID procedures
d. Errors: large in TEM: contamination "everywhere" filter paper, separator paper, water solvents.

Asbestos fibres are ubiquitous even in a modern laboratory. Also all methods using TEM require a large concentration step of 10^5 to 10^6 typically in the analysis. The extreme difficulty of resolving very small particles (< .x um) into mineralogy and the problem of resolving amphiboles from other fibrous minerals and amongst amphiboles in the general environment should be emphasized.

2.4.2 Because of the many problems intrinsic in the analytical procedures, it is suggested that whatever methods are selected for recognition be tested in various laboratories in a "round-robin" type of exercise in order to determine the confidence limits within laboratories and between laboratories. Such data seem essential to a realistic approach to solving real-life problems. Perhaps a scheme can be developed.

2.4.3 Contaminants: Methodology for this needs to be developed and tested; i.e. 2.5.2 above.

2.5 References (old 2.5) Additional references need to be added if they are cited in the text as recommended.

01-0005603

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3a Beaman, D. R., F. P. Boer, C. T. Lichy, R. J. Moolenaar, F. W. Spillers, O. C. Taylor, and D. M. Young. Asbestos in Water in the Chlor-Alkali Industry. (Presented at Eighteenth Chlorine Plant Managers Seminar, New Orleans, Feb. 5, 1975) Proc. Plant Managers Seminar - Available from Chlorine Institute, Inc. 342 Madison Ave. New York, NY 10017 (Presented to EPA and other Government Agencies on Feb. 3, 1975).

3b Beaman, D. R. and D. M. File. The Quantitative Determination of Asbestos Fiber Concentrations Anal. Chem. 48: No. 1, 101-110, 1976.

3c Birks, L. S., M. Fatami, J. V. Gilfrich, and E. T. Johnson. Naval Research Laboratory, Report No. 7874, Feb. 28, 1975.

3d Choi, I. and R. W. Smith. Kinetic Study of Dissolution of Asbestos Fibers in Water. J. Colloid Interface Science 40, 253-62, 1972.

5a Deer, W. A., R. A. Howie and J. Zussman. Rock Forming Minerals, Vol. 2 and Vol 3. John Wiley and Sons, Publ. 1963.

9a Kramer, J. A., O. Mudroch, and S. Tihor. Asbestos in the Environment. McMaster University (L8S-4M1) for the International Joint Commission Great Lakes Research Advisory Board, May 1, 1974. Cited in February 1975 Report to the I.J.C. from the Great Lakes Res. Adv. Bd. entitled "Asbestos in the Great Lakes Basin with emphasis on Lake Superior."

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13a Parks, G. Aqueous Surface Chemistry of Oxides and Complex Oxide Minerals. Am. Chem. Soc. Advances in Chemistry Series, No. 67:121-160, 1967.

17a Rickards, A. L. Estimation of Submicrogram Quantities of Chrysotile Asbestos by Electron Microscopy. Anal. Chem. 45:809-811, 1973.

17b Speil, S. and J. P. Leineweber. Asbestos Minerals In Modern Technology. Environ. Res. 2:166-208, 1969.

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SECTION 3.0 -- Biological Aspects of Asbestos in Plants and Microorganisms

It is recognized that there is little information available relative to the effects of asbestos upon plants and microorganisms. There is need for data on the uptake of asbestos in plants, particularly edible plants, and animals grown on or in asbestos containing substrates.

Page 20, para 2, line 2. The conversion of inorganics to sugars needs more explanation.

SECTION 4.0 -- Biological Aspects of Asbestos in Animals

4.1 Page 22. Any indication of the intensity of the exposure (concentration and time) of the animals would be helpful.

4.2 Page 22, Para. 2. It is doubtful that intratracheal injection permits greater control over dose than inhalation. Statement is correct for other types of injection.

Para 3, line 1. What is the antecedent of "this?" Suggest reconstructing sentence.

Line 2. Extrapolation from animals to humans is difficult for many reasons.

Line 3. The amount of asbestos dust (mass/mass) usually. . . .

Another important reason is encountered when the route of administration employed in animals is an abnormal one, that is, not seen in man.

Page 23, line 10-11. Trace metal content and polycyclic hydrocarbons are no longer considered involved.

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4.3.1 Page 23, line 4-6. Suggest deletion of clause beginning with ". . ., but. . ., or document." Do not believe statement as made is true.

4.3.1.1 Page 23, line 9-10. 400 hours is wrong. Suggest . . . or as great as a lifetime.

Line 10-12. Restate to clarify. Interpretation of results is difficult. . . .

Page 24, line 2. Studies presented here are examples of attempts.

Page 26. Para. 2, line 2-3. Delete "and gastrointestinal cancers" or give reference.

4.3.1.2 Page 26, para. 2, line 2. . . .have been reported to penetrate. . . .

Line 7. after (1974). Suggest inserting: "In a Letter to the Editor, Gross (1974) pointed to anatomic barriers and the extensive experience of pathologists everywhere that would appear to contradict the results of the experiences of Volksheimer and Schreiber."

Page 26, line 10. ". . . stomach of rats have been reported in the blood. . ."

Page 27, line 4. After "contamination" add, because asbestos fibers were found in control animals.

Line 4-6. Begininning with, "Some cancers. . ." suggest deletion or rephrasing so as not to suggest a difference from controls.

01 000511

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4.3.1.3 Page 28, line 12-14. Wrong. Suggest, "The distribution of radio nucleotides, consistent with that which would be expected from chrysotile, was found in the heart. . . ."

4.3.1.3.4 Page 29, line 13. "absorbed" is wrong word. Suggest "distributed."

Para. 2. Add the following: The artifacts consist of a needle tract in the stomach wall which remained open and could have allowed the escape of asbestos fibers into the abdominal cavity and caused the contamination of the laparotomy incision. The fibers could have entered the open cut or torn vessels in the needle tract of the gastric wall and in the laparotomy incision.

4.4 Page 30, para 2, line 3-5. ". . . fibrosis is a relatively fast response to asbestos exposure, and tumor production may take a lifetime."

4.4.1.1 Page 30, para. 2, line 2. Types I and II are the preferred designation of alveolar epithelial cells.

4.4.1.2 Page 31, para. 5, line 1-3. ". . .proposed the generic term, ferruginous body, since structures similar to asbestos bodies were formed after exposure. . ."

Line 4. ". . . injection of fibers of . . ."

Line 6-8. Delete last sentence because it is inappropriate.

4.4.1.3 Page 31, line 2. More recent references are available, so suggest updating.

Page 32, line 12-13. Miller reference is inappropriate. How small is small? Dimensions should be given.

01-0205613

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4.4.1.3.1 Page 32, para. 3, line 8. However, the dust produced by Holt also contained long fibers, the effect of which cannot be ignored.

Line 9. How fine is very fine? Dimensions should be given.

Page 33, line 4-7. Incorrect and incomplete. Suggest, ". . . and hamsters by inhalation for 30 hours/week for 17 months at an average concentration of 86 mg/m^3. It was also injected intratracheally in one to six doses of 3.5 mg each into rats. Last line, ". . . and a progressive cellular consolidation of the lung tissue was noted."

4.4.1.3.2 Page 34, para 4, line 3. Should not Ferringer be Firminger?

Page 34, line 1. Change most to all asbestos fiber. . . .

4.4.1.3.3 Page 35, line 12. Incomplete. Suggest insertion after ". . . air passages. . ." of the following: This type of reaction has been reported to be an artifact attributable to the intratracheal injection (Gross, et al, 1970.)

Line 15. Suggest changing crystalline structure to morphology

Line 16. Add the following to the end of the paragraph:

Klosterkötter injected chrysotile and crocidolite fibers less than 5um long intratracheally and intra-abdominally into rats and noted no fibrogenic response whereas longer fibers were fibrogenic.

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Timbrell and Skidmore also observed that short fibers (90% were less than 4µm long) injected intratracheally were less fibrogenic than longer fibers (45% were longer than 4µm).

Webster found that exposure of monkeys to crocidolite fibers less than 5µm long resulted only in a pulmonary macrophage response. There was no fibrosis.

Maroudas, et al concluded that fibers shorter than 20µm "induce neither growth in vitro nor mesotheliomas in vivo."

Smith, et al noted that chrysotile fibers less than 1µm long injected intrapleurally into hamsters caused no cancer, whereas similar injections with longer fibers did cause cancers.

Wagner et al stated that only fibers less than 0.5µm thick and more than 10µm long were significant. By "significant" he considered the ability of the fibers to induce cancer production.

Para. 3. Miller reference is inappropriate. This paragraph is best deleted in view of the added citations.

4.4.1.3.4 **Page 35, line 3. Change fibrous-glass to fiberglass.**

4.4.2.1 **Page 36, line 2. Change silica to quartz.**

Line 3. Change reference to (Wagner et al 1973)

Para . 5, line 4. Change fibrous glass to fiberglass.

Page 38, para. 4 & 5. It is important that the doses administered be indicated in the citations.

01-0205615

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4.4.2.2 Page 39, para. 3. After end add reference. . . and (Gross and Harley, 1973).

Para 5. At the end of the paragraph add the following statement: On the other hand, no increased tumor production was observed by Pott, et al (1972) following the intra-abdominal injection of chrysotile and added BP into rats above that noted following the injection of chrysotile alone.

4.4.3 Page 43, para 3, line 5. Would it not be better to say vinylpyridine-N-oxide?

4.5 Page 44, No. 1. Kriedrichs should be Friedrichs.

No. 7 Brian should be Brain.

Page 46, No. 23. Sriedrichs should be Friedrichs.

Ref. 26a. Gross, P., et al. The pulmonary response to fibrous dusts of diverse compositions. Am. Indust. Hyg. J. 31:125-132, 1970.

Ref. 26b. Gross, P. and R. A. Harley. Asbestos induced intrathoracic tissue reaction. Arch. Path, 96:245-250, 1973.

Ref. 26c. Gross, P. Letter to the Editor. Arch. Environ. Health 29:298, 1974.

Ref. 40a. Klosterkötter, W. Experimentelle Untersuchungen über die Bedeutung der Faserlänge für die Asbestfibrose sowiet über die Beeinflussung der Fibrose durch Polyvinylpyridin-N-Oxid, in Biologische Wirkungen des Asbestes: Internationale Konferenz, 1968, Dresden, Berlin, Deutsches Zentralinstitut für Arbeitsmedizin, pp. 47-52.

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Ref. 44a. Maroudas, N. G., et al. Fibroblast anchorage in carcinogenesis by fibres. Lancet 1:807-809, 1973.

Ref. 63a. Smith, W. E., et al. Biologic differences in response to long and short asbestos fibers. Am. Indust. Hyg. Assoc. J. 33:A162, 1972.

Ref. 72a. Timbrell, V. and Skidmore, J.W. Significance of fibre length in experimental asbestosis. Internationale Konferenz, 1968, Dresden, Berlin, Deutsches Zentralinstitut für Arbeitsmedizin. pp. 52-56.

Ref. 78a. Wagner, J.C., et al. Mesotheliomata in rats after inoculation with asbestos and other materials. Brit. J. Cancer 28:173-185, 1973.

Ref. 79a. Webster I. The pathogenesis of asbestosis in: Pneumoconiosis: Proceedings of the International Conference, (Johannesburg, 1969) Shapiro, H. A. (Ed.) Cape Town, Oxford University Press, 1970, pp 117-119.

31-0205617

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SECTION 5.0 -- Physiological and Pathological Aspects of Asbestos in Humans

Throughout this section, care must be given to avoid the use of nonspecific terms. For example, the term cancer is used quite often and refers to different types at different times. The specific type should be used instead of the word cancer. Such words as "large," "small," "frequent," "rare" should be avoided and replaced by the appropriate numerical data. Instead of "asbestos" the specific type should be listed, or if unknown, it should be listed as such. It must be remembered that most individuals reading the document will not read the references quoted, thus the actual numerical data as to size, type of exposure, amount, duration, etc., should appear in the document.

Whenever possible, original articles should be quoted rather than "Anonymous," or other governmental documents.

Somewhere in this section, perhaps in 5.1, a table showing the number of individuals potentially exposed and at risk should be included. This is important to understand the extent of the various occupational exposures to asbestos as well as their potential for environmental contamination.

More tables or figures summarizing concepts should be included. (General Comment #4)

5.1 This section needs to be reorganized and generalizations and inaccuracies removed. Difficulty arises from the treating of asbestosis and asbestos associated malignancies in the same sentences and paragraph. Their mechanisms are different and should be separated in the summary.

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The definition of asbestosis should be separated into "tissue pathology" and other diagnostic criteria. A tissue diagnosis of asbestosis does not include "impaired lung function." Current diagnostic (clinical) criteria should be mentioned, i.e. 1. known asbestos exposure (occupational); 2. radiologic evidence of parenchymal and/or pleural fibrosis; 3. absence of other diseases known to cause pulmonary fibrosis. The pathologist's problems are different from those of the clinician.

Page 32, para 1, line 7: Delete impaired lung function.

Lines 8 to 10: The "50% of persons who develop asbestosis also develop lung cancer" is no longer an accurate statement. Suggest deletion of sentence, "It is estimated . . .lung cancer."

Lines 13 to 15: 30% is too definite. Suggest, "Epidemiological studies suggest that a high percent of the . . ."

Line 16: Care must be taken in interpreting epidemiologic data. Such studies make associations, but cannot produce cause-effect information, i.e. "attributed to" should read "associated with."

Lines 18 to 23: Suggest rephrasing. It is not clear what the term "dose-response" means in the context of the statements made. More specificity is needed. All epidemiologic and other studies show a definite dose-response relationship, especially for asbestos related lung fibrosis. What is non-existent is numerical (in terms of today's current fibers/mm^3 definition) data showing a "highest level of exposure" at which no pathologic response is seen. The issue of "TLV" must be treated separately from the demonstration of crude dose-response relationships.

01-0205619

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Para 2, lines 4 and 5: An example of a general comment #1 type error is in the last sentence of this section. The term "cancer" is used to mean lung cancer. Suggest rewording as: Cigarette smoking acts synergistically with asbestos in causing lung cancer. Delete "and fibrosis."

5.2.1 Page 53, para 1, line 13: Delete "efficiently."

5.2.2 5.2.2.1 might be better called "Cellular Transport" and be placed in section 5.2.3.

The rest of the subsection should be expanded to include descriptions of the process of fibrosis which is more important than the development of asbestos bodies and should be given equal space.

It would also be useful to include a discussion of the actual amounts (weight) of asbestos found in the lungs of urban dwellers as compared to occupationally exposed individuals. The location of the fibers in the lungs should be mentioned (lower lobes).

Mention should be made on the natural history of how fibers are handled by the lung.

5.2.2.2 Page 53: Suggest heading be relabeled "Cellular Response-Asbestos Body Formation."

It would be useful to state in 5.2.2.3 the relative number of uncoated fibers found for every coated fiber seen.

For all the studies quoted, fiber type, actual fiber size, and identification methods used should be stated. See 5.0, p. 29, par. 1.

01-0205620

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Page 54, para 2: This paragraph seems inordinately detailed in view of the lack of consideration of mechanisms of fibrosis formation. Perhaps this subject can be dealt with.

Para 5, line 2: Suggest replacing "in" with <u>together with</u>.

5.2.2.3 Page 55, para 2, lines 4 and 5: Suggest deletion of "probably . . .interactions." Avoid speculation.

5.2.3 The implied generalization to all asbestos-exposed individuals from data on mesothelioma cases is not properly supported.

Para 1, line 13: Once again the term "fiber" is used when a less ambiguous term is required.

Page 55, para 1, line 17: After 1973) add <u>the remainder being of unknown composition</u>.

Line 19: What abnormalities?

Para 2, line 4: Specify type of fiber.

Page 55, para 1, line 8: change "physiological" to <u>pathological</u>.

The last sentence in this section on page 59 concerning a possible link between pleural plaques and mesotheliom (mesothelioma should read <u>pleural</u> mesothelioma) is really too speculative to include in a document such as this. Suggest deletion.

5.2.4 The occupation and type of exposure should be mentioned as complicating factors may obscure the results of this paper. The limited scope of this study as well as its singular findings should be stressed.

01-020562

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5.3.1 The use of the Otte reference is confusing. Once again the difference between a tissue pathology diagnosis and its difficulties are greatly different from a clinical diagnosis perspective. Otte is speaking from a tissue pathologist's view point. Clinical criteria should be mentioned. The same comments hold for the outdated Gough reference.

The Gough statements are outdated because of the electron microscope. Fibers (asbestos-chrysotile) can be found in all lungs.

5.3.1.1 Page 57, line 1: Insert after . . ."fibrosis" identifiable by X-ray, ...

Line 3: Should reference be 1970b instead of 1970a? Once again care must be taken to separate "tissue pathology" from clinical diagnostic methods (non-invasive). The term interstitial lung disease is wrong as Solomon was speaking of radiologic evidence of interstitial lung disease. The MacKenzie reference is back to tissue microscopic pathology. It would be helpful to include in this section the inter-relationship of intensity of exposure, duration of exposure, and time elapsed since first exposure. It should be made clear that the 3 to 6 year figure for development of radiologic interstitial fibrosis is rare and occurs under extreme conditions of the previously mentioned factors.

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A discussion of the ILO U/C Pneumoconiosis Classification system which is now in wide use would be appropriate.

5.3.1.2 There should be a separate discussion of pleural plaques and diffuse pleural fibrosis. There is no mention of pleural fibrosis as a separate entity.

Line 1: Commonly? How frequently do these changes occur?

Page 58, para 1, lines 16 to 20: Too positive a statement.

Page 1, lines 9 to 11, para 2: Is there a contradiction here?

Para 4: Again type of asbestos needs to be specified.

Page 66, line 3: What mine workers exposed to what?

Line 13: What type of asbestos?

Page 66, paragraph #1 misquotes the Gross et al. paper.

Para 3, line 4: Delete "low".

Lines 18 to 20: Did Murphy say this? If so, quote him. If not, indicate opinion of whom?

Lines 22 to 24: References inadequate.

01-0205623

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Page 66-67, para. 2: includes editorializing which is inappropriate in this document.

This section needs to include a brief discussion on the changing methods of quantifying asbestos exposures and the impossibility of accurately interpreting past "particle counts" in terms of today's use of fibers/cc with individual fiber type identified. Perhaps an historical development of changing methodologies would provide the perspective needed to understand the papers mentioned at the end of the section. A table showing the fiber count range in each of the old methods might also be helpful.

With the above in mind, special care must be taken to be specific as to methods each paper used. The most confusing is on page 67, paragraph #3, the El-Sewefy work. Dust determination (weight) is construed to mean "asbestos dust" and then weight is changed to "counts." This paper needs to be carefully reviewed to see whether asbestos was actually measure or just a mixed dust. Terminology must be tightened up in this whole section.

Page 67, para 3: The use of one case report should be replaced with studies of larger numbers.

Page 68, para 1: In reality, the latency period is not between first exposure and the development of the lesion but between the exposure and the detection by X-ray.

Para 3: Counting is of asbestos bodies, not asbestos or fibers.

Page 68, para 4: Probably belongs in another subsection such as 5.3.2

5.3.1.3 This section could more accurately be titled "Pulmonary Pathophysiology."

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Page 60, para. 2. The Hunt statement is misleading. Asbestosis and related pulmonary defects are progressive even after ceasing exposure. The length of time the group was followed should be stated if the point is to be used at all.

5.3.2.1 It should be stated that cases of asbestosis having "rheumatoid-asbestosis lung" are few, but that individuals having both diseases require special observation because of their potentially rapidly progressive disease.

Suggest inclusion of last paragraph on page 68 (Badr and El-Sewefy study) in this section.

Mention should be made of asbestos warts.

5.3.2.3 Qualifying statements should be placed on this section. The interrelationship between heart disease as a secondary effect of chronic lung disease should be mentioned. It should not be construed that asbestos has a direct effect on the heart unless more evidence is mentioned.

5.3.2.4 This section needs to be updated. Suggest more recent papers by Morgan and also by Schnitzer.

5.3.3 Page 62: The introductory paragraph is inadequate. The comments made under subsection 5.1 are also relevant to this subsection.

Reference is not sufficiently specific.

Care must also be taken to state the specific environment being discussed; i.e. occupational or general?

Once again all studies mentioned should have fiber type and characteristic mentioned.

Page 63, line 6: What is meant by "environmental," occupational or general?

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5.3.4.1.2.1 This section needs more depth to include the relationship to various asbestos types. Frequency of occurrence should be mentioned as well as what is meant by "increasing frequency."

5.3.4.1.2.1 Para 2: Inadequate and inaccurate discussion. Invasion of lung parenchyma is rare. If pathology is to be discussed, it should be dealt with in more depth.

5.3.4.1.2.2 This section should include the relative frequency of peritoneal mesothelioma in relation to pleural mesothelioma.

a. and b. are not "common signs and symptoms" of peritoneal mesothelioma. This is an incorrect interpretation of the reference. They are signs of asbestosis, but are not a prerequisite for mesothelioma.

This section as well as the two previous ones should include location of tumors (for lung cancer section) and metastatic potential.

5.3.4.1.3 Line 13: Suggest inserting <u>has been interpreted as</u> before "indicating."

The appropriateness of paragraph 2, page 72 is questioned. It is suggested that it be rewritten to reflect views in contradiction to those of Merliss, 1971. Suggest reviewing papers by Haemzel et al (new ref. no. 45a) which expresses contrary views; a paper by Smith (new ref. no. 106a) which points out that Chile, not Japan, has the highest GI cancer rate and offers some possible reasons; and a paper by McDonald and Wolf (new ref. no. 72a) cited in the Smith paper referred to above.

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It must be stated more clearly in paragraphs 1 and 3 that information on penetration of asbestos fibers into human bowel is still speculative and such speculation should be separated from the more substantial epidemiologic incidence data. It must be stressed that the effects of asbestos ingestion are as yet unknown.

The step from incidence to mechanism is not warranted.

Para 3, line 9: Suggest inserting after about 20 years after "So far,"

5.3.4.2 The last sentence in paragraph 1 is false. There are several exceptions. Suggest use of recent Selikoff paper to support this point.

Para 2, lines 1 and 2: There are better references; for example, Nos. 97, 100, 104a, 104b.

Lines 7 to 9: Suggest deletion or refer to references 104a and 104b.

Para 3: Use of NIOSH reports is inappropriate. Use references of original papers cited therein.

5.3.4.3 The list of mechanisms is outdated and point a and b have been proven false and are of historical interest only, and should be treated as such.

Page 74: c. not a mechanism.

The use of Anonymous sources should be avoided.

01-02071-3

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Paragraphs 1, 2, and 3 on Page 74 do not deal with mechanisms and should be placed in the appropriate subsections, perhaps 5.3.4.1.2.

Para 4 and 5: Are no longer at issue. They are of historical interest only.

5.3.4.4 The Harries, et al reference (No. 46) is thought to refer to nonmalignant asbestotic disease and therefore should not be included in this section on carcinogenesis.

If this is the case it should be positioned elsewhere.

5.3.6.1 Pages 75 and 76, para. 1: needs a comment on the significance of the excess mortality found.

Once again, original articles should be used as references rather than governmental documents.

Page 76 and 80: McDonald references No. 71 and No. 72 should be discussed here.

5.3.6.2.1 Radiologic findings of neighborhood and household asbestos exposure should be in a separate paragraph from identification of fibers in lungs.

There are several other references which should be included here.

They are such papers as Anderson (3a), Hromek (51a), Zolov (137) and Udidjian (128).

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The Newhouse reference is wrong and should be Kiviluoto (55) instead. Newhouse only studied London populations.

5.3.6.2.2 Page 81, Para. 1: should broaden the term "occupationally exposed" to having had occupationally-related exposure. This will cover the disease found among family members and neighborhood people.

5.4 Page 86, ref. 54, line 3: Change Long to Lung.

References: The following should be added and discussed.

Page 82, ref. 3a, Anderson, H.A., et al., Household-Contact Asbestos Neoplastic Risk, N.Y. Acad. Sci., No. 502. In Press.

Page 86, new ref. 51a, Hromek, J., The mass incidence of characteristic pleural changes in citizens of the western part of the former Jihlava region. Rozhledy Tuberk, 22:405, 1962.

Page 89, ref. 83: Such a general reference is inappropriate in a document such as this.

New ref. 84a: Newhouse, M.L. and Thompson H., Mesothelioma of pleura and peritoneum following exposure to asbestos in the London area, Brit. J. Ind. Med., 22:261-269, 1965.

Ref. 85: Title of paper needs to be added.

Page 91, new ref. 104a: Selikoff, I.J., Epidemiology of Gastrointestinal Cancer, Envir. Health Perspectives, 9:299-305, 1974.

New ref. 104b, Selikoff, I.J., Asbestos Disease in the U.S. 1918-1975, Proc. Conf. on Asbestos Disease, Rouen, France. Oct. 27, 1975

01-0205629

SECTION 6.0 -- Environmental Distribution and Processes

A fair amount of perspective is evident in the treatment of this Section. However, there are some contradictions and areas where additional information would be helpful.

In several of the following paragraphs there is a mixing of units to designate concentrations. It is suggested that in each case units, preferably metric units be used, but do not confuse mass with counts of fibers. Some may be off by a thousandfold.

6.1 Asbestos in various forms has been with us since the beginning; this point needs to be empahsized.

It would seem most useful to include in this document a map of the United States and Canada showing where major deposits of the various forms of asbestos occur naturally and the location of mines, processing plants, and users. This, together with discussion of known movement would seem to be very useful in evaluating sources of community or general exposure.

Page 95, para 4: It seems a bit unfair to imply that a safe or a hazardous level of asbestos has not been been established because of the inadequacies of analytical methodology. This is only one of the limiting factors. Much progress has been made in analytical technology, perhaps more than in the biological areas. See Section 2.0.

6.2.1.2 Some very useful information has been published relative to the presence of asbestos in the drinking water in The Netherlands (Elzenga et al, 1974). The information is very pertinent to this report and should be included. (New Ref. No. 10a)

01-0205630

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6.2.1.3 Perhaps information presented by Zolov, et al, 1970 would be useful at end of this section. (New Ref. No. 23).

6.2.2 Mobility - in general other data (high concentration around cities, distance of transport from mining and manufacturing sites) could be added.

6.2.2.2 Settling data in Lake Superior is one person's speculation. Delete. Better use Baumgartner and Cook's sediment trap data of distance from source to show how far away cummingtonite was found. The statements, as made, are speculation and have been challenged in court.

6.2.3 Perhaps some data could be given relating the number of fibers and masses found in the environment normally and in areas surrounding occupational settings.

Is it possible to develop a table showing relative concentrations in air, water, and soil?

6.3 It is highly undesirable to use anonymous references. They are not appropriate for this document. Suggest including following references with appropriate discussion.

New Ref. 10a. Elzenga, C.H.J., P.B. Meyer, and J. Stumphius. A Preliminary Investigation into the Appearance of Asbestos in Dutch Drinking Water (Orienterend onderzoek naar het voorkumen van asbest in het Nederlandse drinkwater) (English translation by Leo Kanner Associates, Redwood City, CA. for NERC-Library, EPA. Overdruk uit H_2O Zevenda Jaargang 19: 406-410, September 12, 1974.

New Ref. 23. Zolov, C., T. Bourilkov, and L. Babadjov. Pleural asbestosis in agricultural workers. Environ. Res. 3:443-451, 1970.

01-0205631

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SECTION 7.0 -- Environmental Interactions and Their Consequences

7.2.1 The relative significance of the sources indicated should be discussed. Interpretation of the last 2 lines on Page 102 may be questioned. More explicitness is required. What is its significance as far as land use is concerned? What is the significance of recycling?

7.2.2 Suggest inclusion of a statement emphasizing need for consideration of research in this area.

7.3 Page 104, para. 2: There are several research projects underway which are supposed to shed light on the possible effects of ingesting asbestos and another is planned. Refer to section 4.3.1.2.1.

Para. 3: This is an overstatement. There are no data from which one can deduct that ingestion is a significant health hazard. It may be, but the data available do not so indicate. See page 31, Section 5.3.6.2.2, para. 2. Suggest deletion of paragraph.

01-0205632

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APPENDIX A

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C 20460

MAY 13 1975

OFFICE OF
RESEARCH AND DEVELOPMENT

Dr. Emil M. Mrak, Chairman
Executive Committee
Science Advisory Board
University House
University of California
Davis, California 95616

Dear Emil:

For the past several years, the Congress has been considering the passage of legislation to address the problem of protection of the public health and welfare against any dangers which might be associated with the disposal of hazardous substances to the soil. In anticipation of the passage of such legislation in the fairly near-term future, EPA's Office of Research and Development is in the process of gathering information which could serve as a basis for standard setting in these situations. This information is being organized into a set of reports on the effects and transport of critical pollutants (asbestos, mercury, etc.) which are components of materials commonly disposed to the soil.

Before we finalize these reports, I feel that it would be useful to seek, through the Science Advisory Board, the views of the scientific community as to their content. Specifically, I would like your comments as to the appropriateness and completeness of the information presented in the reports as well as their adequacy to serve as a basis for standards under the forthcoming legislation. The attached "perspectives" document, prepared by the Office of Solid Waste Management Programs, should be helpful to you in establishing the context in which this information would be used by the Agency.

The documents will be furnished to the Science Advisory Board Staff after internal review by the Office of Research and Development. I would hope that you would find a two month time period adequate for the review of these documents.

W K Talley

Wilson K. Talley
Assistant Administrator for
Research and Development

Attachment

01-0205633

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF SOLID WASTE MANAGEMENT PROGRAMS

SUBJECT: SHWRL Criteria Documents

DATE: MAY 8 [illegible]

FROM: John P. Lehman, Director
Hazardous Waste Management Division (AW-565)

TO: Dr. Thomas Bath, Executive Director
Science Advisory Board

In response to your request for some insight into the user's perspective on these criteria documents, may I first comment that we appreciate the SAB taking the occasion to review them prior to our receipt. In this way, the Agency benefits both from the fresh viewpoint provided by an extramural review as well as a level of scientific quality control beyond that already planned.

Based on our legislative mandate, these documents will be used by the Office of Solid Waste Management Programs in developing recommended procedures, guidelines, and, ultimately, standards governing the transport, storage, treatment, and disposal of hazardous industrial wastes. As you know, the focus of this program is on the non-radioactive portion of the approximately 260 million dry tons of industrial residuals which contain toxic chemicals, acids, caustics, explosives, carcinogens, etc. The possible direct effects of these wastes as well as of the processes applied to them on air, water (both surface and sub-surface), land, as well as the public health are of concern.

Specifically, we anticipate that the documents will:

(1) Provide an up-to-date compendium of information on toxicities/effects associated with exposures to specific substances contained in the air, water, and land media

(2) Provide insight into the effective soil and plant indicators for detecting the presence of substances

EPA Form 1320-6 (Rev. 6-72)

01-0205634

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(3) Provide general data on the complexity, cost, and reliability of state-of-the-art analytical procedures for determining the presence of substances

(4) Provide information on predictable reaction products of the substances to aid in the design of criteria relating to mixing of wastes

(5) Permit assessment of the need for additional air emission standards due to the operational characteristics of hazardous waste treatment sites

cc: Mr. H. Lanier Hickman, Jr. (AW-562)
Mr. William Sanjour (AW-565)
Dr. Robert Stenburg

01-0205633

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APPENDIX B

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 20, 1975

OFFICE OF THE ADMINISTRATOR

SUBJECT: Charge to the Ad Hoc Study Group to Review the Asbestos Document

FROM: Chairman
Hazardous Materials Advisory Committee (A-101)

TO: Members of the Ad Hoc Study Group to Review the Asbestos Document

For the past several years, the Congress has been considering the passage of legislation to address the problem of protection of the public health and welfare against any dangers which might be associated with the disposal of hazardous substances to the soil. In anticipation of the passage of such legislation, EPA's Office of Research and Development is in the process of gathering information which could serve as a basis for standard setting in these situations. This information is being organized into a set of reports on the effects and transport of critical pollutants including (asbestos and mercury), that are components of materials commonly disposed to the soil.

Before these reports are finalized the Agency is seeking, through the Science Advisory Board, the views of the scientific community as to the content of these reports. They will have had internal review by the Office of Research and Development, prior to their coming to the Science Advisory Board. The Executive Committee of the Board has decided to refer these requests to the Hazardous Materials Advisory Committee.

It is anticipated that the documents will:

- Provide an up-to-date compendium of information on toxicities/effects associated with exposures to specific substances contained in the air, water, and land media.
- Provide insight into the effective soil and plant indicators for detecting the presence of substances.
- Provide general data on the complexity, cost, and reliability of state-of-the-art analytical procedures for determining the presence of substances.
- Provide information on predictable reaction products of the substances to aid in the design of criteria relating to mixing of wastes.

01-020536

Asbestos Information Association trial exhibit AIA-64: Ad Hoc Study Group Report to the EPA Hazardous Materials... Published by AsbestosClaims.Law
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- Permit assessment of the need for additional air emission standards because of the operational characteristics of hazardous waste treatment sites.

The Hazardous Materials Advisory Committee acted at its last meeting to set up an ad hoc panel to report on the content of this document.

In order to provide the best possible criteria to the Agency I am asking the Ad Hoc Study Group to review the Asbestos Document, consider in detail the information contained therein, and to provide the Committee with a report. This report should include the following:

1. The Study Group's best assessment of the appropriateness and completeness of the information presented.

2. The study group's best assessment of the adequacy of this information to serve as a basis for standards under an anticipated legislative mandate.

The Study Group will be provided with the draft of "Review of the Environmental Aspects of Asbestos," and a copy of "Guidelines and Background for the External Review Panel." Representatives of the Office of Solid Waste Management Program and the Solid and Hazardous Waste Research Laboratory, Office of Research and Development will be available for consultation.

The Study Group report to the Hazardous Materials Advisory Committee is due December 15, 1975. It is important that this date not be exceeded in order for the asbestos document to be finalized and made available for its intended use.

Emil M. Mrak, Ph.D.

01-0205637

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APPENDIX C

FOR THE RECORD

DATE: November 13, 1975

FROM: Dr. John A. Moore, Chief
Environmental Biology & Chemistry Branch

SUBJECT: NIEHS Asbestos Projects

Background:

The NIEHS asbestos project is the result of a specific appropriation from Congress to assess the effects of oral ingestion of asbestos. The project reflects in a general way the protocol which was developed by the Subcommittee on Asbestos, DHEW Committee to Coordinate Toxicology and Related Programs.

Asbestos:

Several specific types of asbestos are to be used. The current thinking is to employ two forms of chrysotile, one which has a broad range of fiber length and another one which represents a range of fibers less than 20 microns in length. In addition to the two chrysotile samples, two forms of amosite (again reflecting the broad range of fiber length as well as a second sample which is restricted to the shorter fiber length). Tremolite and crocidolite will be evaluated. Great care is being given in the preparation and characterization of the asbestos material to insure that the samples are truly representative of asbestos per se.

Animal Studies:

The studies are to be done in either F-344 rats or hamsters. All materials will be tested in rats, whereas the two chrysotile samples and broad range amosite will be tested in hamsters. The hamster represents the "second species;" as such, it is being fed a material that represents a serpentine and an amphibole type of asbestos. Each material is to be fed continuously in the diet at a 1% level. The two short-range fiber sizes will be fed at something less than 1% to take into consideration the correlation of mass/fiber relationships.

01-0205638

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(AS REC'D)

All studies are to carry [illegible] the life span of the animal, which is defined as the [illegible] dying solid food until death. The gavage [illegible] incorporate exposure by gavage from birth to weaning, followed by consumption of asbestos in the diet till death.

The chemical carcinogens to be utilized is to be either diethylhydrazine or methylazoxymethanol. Both are known to cause tumors of the gastrointestinal tract.

Animals are to receive a complete gross and microscopic pathology evaluation.

The rat studies are to be performed under contract by Hazelton Research Laboratories, Vienna, Virginia; Dr. H. Rudder is Principal Investigator.

The hamster studies are to be performed under contract by Illinois Institute of Technology Research Institute (IITRI), Chicago, Illinois; Dr. Mary Henry is Principal Investigator.

01-0205639

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(AS REC'D)

11/13/73
MIMS

TENTATIVE COAL ASBESTOS ANIMAL TEST OPTIONS

HAMSTER

	CHRYSOTILE BROAD RANGE	CHRYSOTILE SHORT RANGE	AMOSITE BROAD RANGE	AMOSITE SHORT RANGE	CROCIDOLITE	TREMOLITE
tos diet	500	500	500	ND	ND	ND
tos diet plus ical carcinogen[a]	350	ND	ND	ND	ND	ND
aring asbestos ge plus tos diet	ND	ND	ND	ND	ND	ND
ol diet[b]	500	250	250	ND	ND	ND
ol diet plus ical carcinogen[a]	250	ND	ND	ND	ND	ND

TOTAL HAMSTERS: 3,100

bers may be adjusted pending results of dose ranging studies to determine 15 ± 5% tumor incidence in controls.

trol allocations are descriptive only; it is expected that experimental response will be evaluated against
al controls (1000). Subsets of control will reflect temporal differences in commencing phases of study
ch is expected to be aggregates of 250-350.

Not done.

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LAS REC'D)

TENTATIVE ORAL ASBESTOS ANIMAL TEST GROUPS

RAT

	CHRYSOTILE BROAD RANGE	CHRYSOTILE SHORT RANGE	AMOSITE BROAD RANGE	AMOSITE SHORT RANGE	CROCIDOLITE	TREMOLITE
is diet	500	500	500	500	500	500
is diet plus el carcinogen[a]	350	ND	350	ND	ND	ND
ing asbestos plus is diet	200	ND	200	ND	ND	ND
diet[b]	175	175	175	175	175	175
diet plus al carcinogen[a]	250	ND	250	ND	ND	ND

TOTAL RATS: 5,650

ers may be adjusted pending results of dose ranging studies to determine 15 ± 5% tumor incidence in controls.

rol allocations are descriptive only; it is expected that experimental response will be evaluated against l controls (1000). Subsets of control will reflect temporal differences in commencing phases of study l is expected to be aggregates of 250-350.

Not done.

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W. E

FEB 1 [illegible]

APPENDIX D

Documents Provided to the Ad Hoc Study Group

Anderson, Henry A., Rush Lilis, Susan M. Daum, Alf S. Fischbein, and Irving J. Selikoff. 1975. Household Contact Asbestos Neoplastic Risk. New York Academy of Sciences Monograph 502. In Press.

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Beaman, D. R., F. P. Boer, C. T. Lichy, R. J. Moolenaar, F. W. Spillers, O. C. Taylor, and D. M. Young. 1975. Asbestos in Water in the Chlor-Alkali Industry. Proc. Plant Managers Seminar. Chlorine Institute, Inc. New York.

Flowers, Earl S. 1974. Relationship between Exposure to Asbestos, Collagen Formation, Ferruginous Bodies, and Carcinoma. Amer. Ind. Hyg. Assoc. 35(11):724-729.

Kramer, J. A., O. Mudroch, and S. Tihor. Asbestos in the Environment. McMaster University (L8S-4M1) for the International Joint Commission Great Lakes Research Advisory Board. May 1, 1974. (56 pages plus references).

Memorandum. November 13, 1975. Department of Health, Education, and Welfare, Public Health Service. Protocol NIEHS Asbestos Projects.

Selikoff, Irving J. 1974. Epidemiology of Gastrointestinal Cancer. Environmental Health Perspectives. 9:299-305.

Selikoff, Irving J. 1975. Asbestos Disease in the United States 1918-1975. Presentation at the Conference on Asbestos Disease, Rouen, France, October 27, 1975.

Selikoff, Irving J. 1975. Environmental Cancer with Inorganic Micro-particulate Air Pollution in Monograph Persons at High Risk of Cancer. Academic Press.

U. S. Department of Labor, Occupational Safety and Health Administration. Occupational Exposure to Asbestos — Notice of Proposed Rule Making. October 9, 1975. Federal Register. 40(197), Part II:17652-17665.

U. S. Environmental Protection Agency. National Emission Standards for Hazardous Pollutants — Asbestos and Mercury. October 14, 1975. Federal Register. 40(199), Part V:48292-48311.

U. S. Environmental Protection Agency, Solid and Hazardous Waste Research Laboratory, Cincinnati. 1975. Guidelines and Background for the External Review Panel.

01-0205[illegible]2

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