

From
W. N. JOHNSON

December 12, 1972

Mr. F. H. Larrison/
Mr. E. A. Piersall

DEC 14 1972
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For your information.

Bill.

A 19525

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A 19527

Asbestos Information Association/North America

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November 27, 1972

Gentlemen:

On Wednesday, November 8, I traveled to Washington with a group of asbestos filter manufacturers to meet with members of the Food and Drug Administration's recently established task force on asbestos. The FDA representatives at the meeting included Dr. R. Schaffner, Director of the Office of Product Technology; Dr. Armand Cassola; Dr. A. D. Berneking; Mr. Taylor Quinn of the FDA Office of Compliance; and Mr. Milo Prochaska.

The purpose of the meeting, which was requested by the filter industry at my suggestion, was to discuss FDA plans with regard to Dr. Selikoff's recent findings of electron microscope sized asbestos fibers in a number of injectable drugs (presumably the result of the drugs having been filtered through asbestos-cellulose filter pads), and also the use of asbestos-containing filters in the food and beverage processing industry. The meeting lasted for approximately an hour and a half (an afternoon meeting was held with additional FDA people in Rockville, Maryland, which I did not attend), and the basic points discussed and attitudes expressed can be summarized as follows:

1. The use of asbestos filter pads and media is extremely widespread (a copy of a brief description of the industry prepared by one of the industry leaders and distributed at the meeting is attached). The FDA people thought that asbestos filters were hardly used at all.
2. The FDA representatives indicated that they knew very little about asbestos and that most had been assigned to the task force within the past few months.

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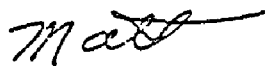
3. Despite this admitted lack of experience and knowledge, they said that their basic goal was to identify and ban any and all asbestos-containing products that come in direct contact with foods, drugs or beverages during any stage of the processing procedure and could thus release fibers into the finished product. This would include not only asbestos filters but also such products as gaskets used in pressure cookers in the soup industry, etc. This last item is their example, not mine.
4. In response to a direct question from me, Dr. Berneking stated that the FDA considers any exposure to asbestos to be hazardous, no matter what the level; and that the FDA feels no obligation to produce evidence or even a logical argument for the banning of any asbestos-containing product. According to him, if a product contains asbestos, that's evidence enough.
5. I pointed out to the group that asbestos has existed in our environment for probably millions of years so that there is a measurable background level to which people have been exposed, both in the air they breathe and in the water they drink, throughout man's history on the planet. This point seemed to impress the FDA representatives, and they agreed that if the industry could prove to the FDA's satisfaction that the use of asbestos filters would not result in concentrations of asbestos in the finished product greater than the background level of asbestos normally found in water, they would not ban the use of such filters. Fortunately, the filter industry assures me that a relatively low-cost after-filter system can be added to existing asbestos filter systems to catch any fibers released from the asbestos filter.
6. The industry was given sixty days to prepare data for the FDA on the use of after-filters and on background levels of asbestos in water and air. I agreed to collect the data on background levels, and also on the health effects of the ingestion of asbestos fibers.

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While it appears likely that asbestos-containing filters and filter media will not be banned by the FDA (some sort of control practices standard will be promulgated requiring the use of after-filters), the disturbing thing about the FDA's attitude toward asbestos is their stated intention to ban asbestos-containing products whether or not the medical evidence indicates that a ban is necessary. In fact, the FDA people admitted to us that they had intended to propose a complete ban of asbestos filters within a few weeks had not the industry stepped in with information on after-filters, background levels, etc.

The general philosophy of the FDA seems to be: we don't know enough about the health effects of asbestos to intelligently decide whether a use is safe or not, therefore we will ban all asbestos-containing products unless the industry can prove to us that the ban is unnecessary. This "guilty until proven innocent" philosophy will, quite obviously, prove very difficult for the industry to contend with in its dealings with the FDA in the future.

Sincerely,



Matthew M. Swetonic

A19530

Asbestos-Cellulose Filter Material

Asbestos fibers have been in use as filter media since at least 1887 - 85 years ago. First asbestos-cellulose pads since 1917 - used in brewing, wines, etc., extensively in Europe.

First manufacture of asbestos-cellulose filter pads in the United States was 1931-32 again for potable products. Uses spread over the years to include not only wines and whiskeys, but also foods, beverages, chemicals, lotions, tonics, oils, pharmaceuticals, soaps, etc.

In July 1937, experimental use of asbestos-cellulose pads for the preparation of infusion fluids started at New York University Surgical Division of Bellevue Hospital in New York City. Supervision of a 42 month trial was done by Drs. Co Tui and A. M. Wright and written up in a report in the September 1942 issue of the "Annals of Surgery".

Prior to 1937, there had been no truly effective way of filtering intravenous solutions to achieve nonpyrogenicity on a production basis. This new technique allowed for the processing of large quantities of solutions such as sodium citrate, dextrose, heparin, blood, plasma, as well as all the antibiotics which came along, starting during World War II.

There were practical difficulties encountered during this trial work and the most serious difficulty noted was the presence

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of shreds and particles in the filtrate. While the injection of solutions containing these particles into numerous experimental animals caused no detectable symptoms, their presence was none the less objectionable. After 16 months of evaluation, the difficulty was overcome by the use of an aloxite fiber eliminator between the asbestos-cellulose filter and the collecting chamber. Among some of the rejected after-filters, were Jena, Chamberland and Berkefeld filters.

The ability of asbestos-cellulose pads to remove pyrogens as well as other less critical contaminant is due to adsorption or adhesion and not to sieving. The uniqueness of this type of filter media is a result of the electrophoretic characteristics of the media. This is all due to the positive charge of the chrysotile fibers which are blended in with the cellulose fibers to form a firm filtration bed with depth and strength.

The grade and quality of asbestos fiber used in filtration is high and the price of said material is also expensive. Generally the asbestos is cleaned and acid treated to remove leachables. As an industry we would be interested in a less expensive and less controversial material for manufacture of filter media. We have seen many new products enter the scene, but nothing to take the place of what we have.

Asbestos filter media is being used in the manufacture of hundreds of products offered by every segment of industry handling free flowing liquids. As an example, one manufacturer of loose

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asbestos filter media considers the vegetable oil industry probably their single greatest outlet - one customer alone producing one million pounds of edible fats and oils per day. Another industry is the production of wines - consider the fact that two manufacturers of asbestos-cellulose pads and loose media located plants in California, primarily serving the wine industry.

To sum up these comments, our filter media serves a definite need to not only the economy, but to mankind. Consider the fact that penicillin would not have been as readily available during World War II. Also, millions of filter pads were used by the armed forces for drinking water with one small filter unit per platoon. Water from ditches being typhoid free after filtration with asbestos-cellulose pads.

Asbestos Information Association/North America

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WTH

Copies:
T. Myers
Larriison
Piersall
"your info"
my work

December 6, 1972

Gentlemen:

On November 13, a memo was distributed by the Association concerning a proposed rule making by the Bureau of Mines that would establish a two fiber asbestos dust standard in coal mines throughout the United States.

Since that memo was distributed, the Association has gathered a considerable body of information with regard not only to the proposed rule making but also with regard to an upcoming proposal from the Bureau for a new asbestos dust standard in asbestos mines and mills. The basic facts are as follows:

Responsibility for the promulgation of health and safety standards within the Department of the Interior is centered in the Bureau of Mines Health and Safety Division, headed by Donald Schlick. Under Schlick are two main branches: the Metal and Non-Metal Safety and Health Branch, (which has authority for asbestos mines and mills), headed by Arthur Nelson; and the Coal Mine Safety and Health Branch, headed by John W. Crawford. Each branch has two main departments, one dealing with safety and the other with health. The health division of the Coal Mines Safety and Health Branch is headed by Murray Jacobsen. The health division of the Metal and Non-Metal Safety and Health Branch is headed by Dr. Aurel Goodwin.

To compound this division of responsibility, each Branch operates under different statutory authority. The basic law governing the activities of the Coal Mine Branch is the Federal Coal Mine Health and Safety Act of 1969, and for the Metal and Non-Metal Branch the basic law is the Federal Metal and Nonmetallic Mine Safety Act of 1966. A simple chart outlining the organization of the Bureau in these two health areas is attached.

The most basic difference between the authority granted to the Bureau under the two Congressional acts listed above is that the Coal Mine Safety and Health Branch has absolutely

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no authority to develop and revise health standards for coal mines. This authority is vested solely in the Department of Health, Education and Welfare, specifically in the National Institute of Occupational Safety and Health (NIOSH). The law states that: "The Secretary of Health, Education and Welfare shall ... develop and revise, as may be appropriate, improved mandatory health standards for the protection of life and the prevention of occupational diseases of (coal) miners.... Mandatory health standards which the Secretary of Health, Education and Welfare develops or revises shall be transmitted to the Secretary (of the Interior), and shall thereupon be published in the Federal Register by the Secretary (of the Interior) as proposed mandatory health standards."

The law further states that any comments received by the Department of the Interior with regard to a proposed coal mine health standard will not be reviewed by Interior, but shall be transmitted to HEW for consideration, and that HEW has sole authority for deciding whether a proposed health standard needs modification. In addition, if a public hearing is called for on a proposed coal mine health standard, HEW runs the hearing, not Interior, and once again, the final decision on the standard rests with HEW.

Thus, while the proposed two fiber asbestos standard in coal mines was published by the Department of the Interior and will be enforced by the Bureau of Mines, the standard itself was prepared by HEW/NIOSH. Interior had no say in the matter at all!

Fortunately, this is not the case with regard to asbestos mines and mills. The Metal and Nonmetallic Mine Safety Act places sole responsibility for developing health standards in mines of this type on the Department of the Interior. HEW is not mentioned in the act at all, not even as a consulting or recommendatory body. The law does allow the formation of Advisory Committees to assist in the development of standards, and a nine member (three management, three labor and three state representatives) permanent advisory committee is in existence for the review of proposed metal and non-metal mine health standards.

With regard to the uses of asbestos in coal mines, attached are copies of three articles (the first dating back more than a year ago), from "Occupational Safety and Health Reporter." The use in question is that of "asbestos cloth and roll board" for the lining of strip mining shovels while under repair. NIOSH investigated the situation and found no concentration of asbestos higher than 1.41 fibers per cc.

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With the above facts in mind, it is easy to see the progression of events leading to the recommended two fiber standard in coal mines.

1. HEW (NIOSH) has sole authority to set health standards for coal mines.
2. The NIOSH position, as set forth in the Criteria Package, is that two fibers is the only safe limit for exposure to asbestos.
3. NIOSH was asked by the United Mine Workers to investigate the use of asbestos in the repair of strip mine shovels.
4. The results of their investigation showed that feasibility was not a problem with regard to a two fiber standard.
5. NIOSH, consequently, proposed a two fiber standard for coal mine operations.

With NIOSH reviewing whatever comments are submitted to the Department of the Interior on the proposed standard, it is highly unlikely that they will reverse their decision and change the standard to five. Nevertheless, it is important that the asbestos industry submit data and comments on this subject to Interior within the 45 day period allowed under the law (the last date for submission is December 22). The Association will be submitting comments as will others in the industry. While it would appear that there is little hope for success, it is vital that the industry place itself on record as being opposed for medical reasons to any standard lower than five. If not, our silence can be used against us.

While investigating the proposed coal mine standard, we learned that a new standard was also being prepared for asbestos mines and mills. Consequently, a meeting was held in Washington on December 5 with Dr. Aurel Goodwin (see chart). Attending on behalf of the industry were Mike Donovan of Johns-Manville; Bill Johnson of Union Carbide; Bill Fassuliotis of GAF, and Matt Swetonic of AIA/NA.

The meeting lasted for approximately an hour-and-a-half and was quite friendly and informal, as well as being extremely informative. The single most important piece of information obtained was the exact wording of the new asbestos standard which has been proposed by the Bureau and which will be published in the Federal Register probably within three to six weeks. The new proposed standard is as follows:

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"The Time Weighted Average airborne concentration of asbestos dust to which employees are exposed shall not exceed five fibers per milliliter greater than five microns in length as determined by the membrane filter method at 400-450 X magnification (four millimeter objective) phase contrast illumination. Concentrations above five fibers per milliliter, but not to exceed ten fibers per milliliter, may be permitted up to a total of 15 minutes in an hour for up to five hours in an eight hour day."

You may recognize the above as being the same exact wording contained in the OSHA emergency standard of December 7, 1971. The new proposed standard was developed by Dr. Goodwin sometime last spring, was approved by his Advisory Committee in July, and has spent the last five months climbing the Bureau's ladder of red tape (the asbestos standard is only one part of a whole package of proposed alterations and modifications of existing standards, which probably explains the five months delay). Dr. Goodwin is none-the-less hopeful that the package will be published before the end of the year, but January is probably more realistic.

Other information obtained from Dr. Goodwin can be summarized as follows:

1. He has studied the NIOSH Criteria Package and other medical data on asbestos (including Dr. McDonald's study), and is convinced that, whatever the reason, the mining of chrysotile asbestos is less hazardous than either manufacturing or insulation work. He also indicated that he would like to meet with Dr. McDonald to discuss his study further.
2. Dr. Goodwin has no data on the feasibility of two vs. five fibers in mining and milling operations. The technical feasibility of the proposed standard was not taken into account in its development.
3. The proposed asbestos standard was rubber stamped by the Advisory Committee without objection from the three labor people on the committee (two from the Steelworkers and one from the Electrical Workers). No member of the Advisory Committee has any first hand knowledge of asbestos mining operations, or of the asbestos-health question.

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4. The Cement, Lime and Gypsum Workers Union has been pressuring Dr. Goodwin to develop an entire set of regulations on asbestos similar to the OSHA regulations. Strangely enough, they have not shown interest in the two vs. five fibers controversy. Dr. Goodwin said that such a set of standards is completely out of the question. He considers them unnecessary as well as impractical.
5. When the proposed standard is published, all interested parties will have 45 days to submit comments. Dr. Goodwin asked that the industry submit as much data as possible on (1) the safety of the five fiber level, and (2) the technical infeasibility of two fibers. He warned us that if he receives comments only in opposition to five fibers, he will be forced to lower the standard, but that if the comments are divided, he will be able to justify his original proposal.
6. Even if a public hearing is requested on the proposed asbestos standard, Bureau of Mines regulations state that the request need not be honored if the standard in question was approved by a Bureau Advisory Committee. The asbestos standard does, of course, have this type of approval. Dr. Goodwin said that he is completely opposed to holding a public hearing on asbestos, and he would not do so, even if requested, unless political pressure forced him into it.
7. Dr. Goodwin said that he has been considering a regulation prohibiting on-the-job smoking in asbestos mines and mills. He indicated that he would probably react favorably to a recommendation from the industry, in its written comments on the standard, for such a prohibition.

Finding out weeks in advance the contents of the proposed new asbestos mining and milling standard gives us a tremendous advantage that we have never enjoyed in the past, and one that we should take advantage of.

All companies in the industry that have mining operations in the United States or in Canada should begin immediately to gather data on the infeasibility of two fibers in their operations. While Canadian mining operations are obviously

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not directly affected by United States regulations, things of this nature have an unpleasant habit of creeping across national borders (as example, witness the effect of the British two fiber standard on United States governmental thinking).

Those in a position to submit medical data on the proposed standard should begin now to compile their information and plan their mode of attack. Consideration should also be given to the possibility of the smoking ban and whether it is advisable to include such a recommendation in our submissions. The ceiling concentration section of the proposed standard should also be looked at to determine whether it is more or less acceptable to the industry than the more simple ceiling standard adopted by OSHA.

While Dr. Goodwin is opposed to a public hearing on the standard, we should nevertheless not exclude the possibility that Dr. Selikoff and the unions can apply enough pressure to force him to hold one.

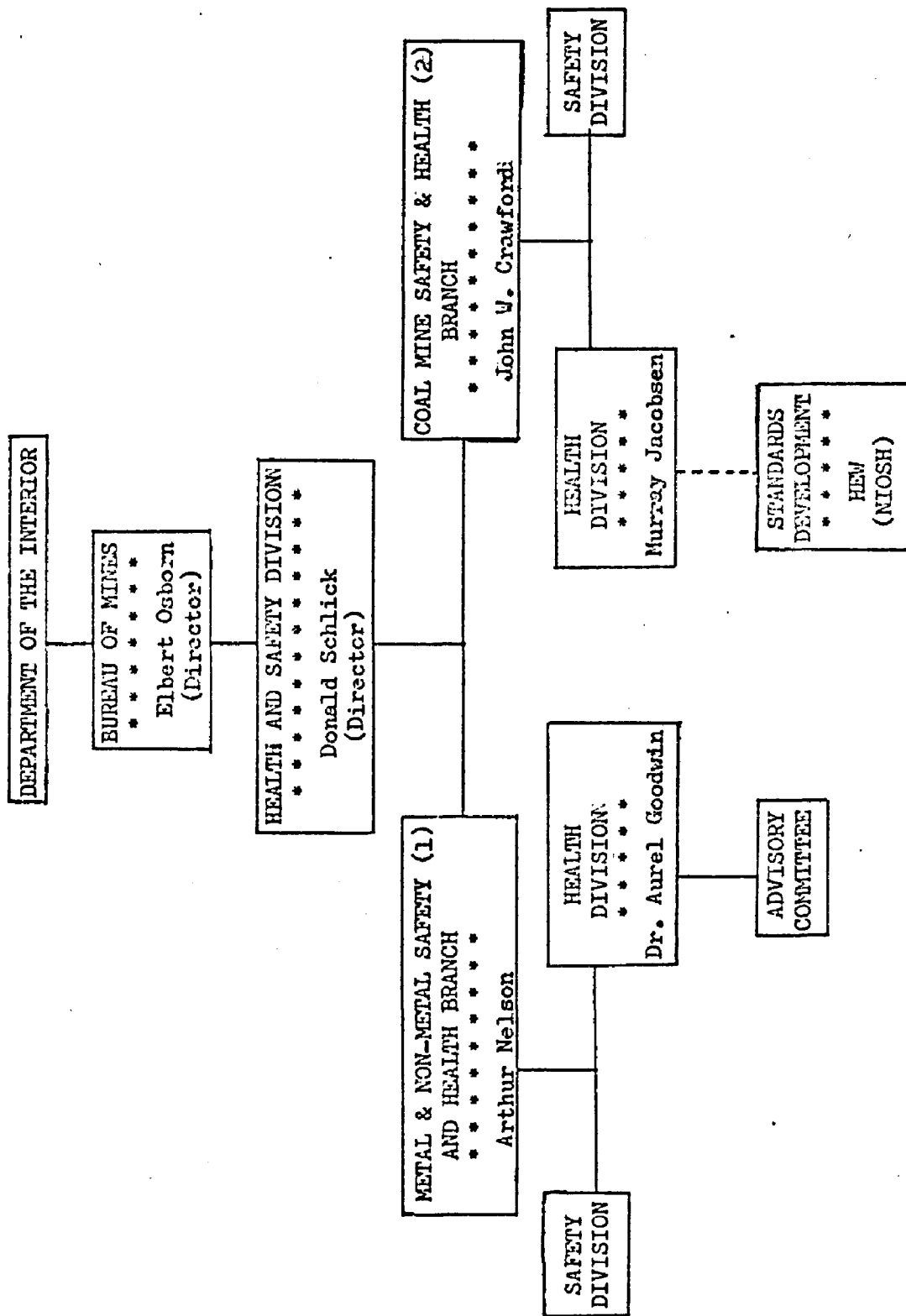
The only way that we can assure the continued well-being of the asbestos mining and milling industry in this country, and perhaps in Canada as well, is to apply to this standard the same organized effort that worked so successfully for the industry with regard to the OSHA standards. While we have a distinct advantage in this situation in that we can support the standard as proposed (with perhaps some slight modifications or additions), to let down our guard in the face of the known strong opposition would be a serious mistake.

Sincerely,

Matthew M. Swetonic

Enclosures

A19533



- (1) Statutory Authority: Federal Metal and Nonmetallic Mine Safety Act of 1966
- (2) Statutory Authority: Federal Coal Mine Health and Safety Act of 1969

A19540

Coal Mines

10/21/71

ASBESTOS DUST HAZARDS ARE SUBJECT OF JOINT NIOSH-MINE WORKERS RESEARCH

The elimination of dust hazards in strip mining is the goal of work being conducted jointly by the United Mine Workers of America and the National Institute for Occupational Safety and Health.

"Two UMWA districts have investigated the use of asbestos to protect workers repairing shovels and other strip mining equipment," UMWA president W.A. Boyle, said. "Local union officers and union staff members have looked into the problem and based upon their findings we have called for help from the Institute which has responded affirmatively."

Investigation has shown that a huge amount of asbestos cloth and roll board are used to line the buckets of the big strip shovels under repair which are heated to 400 degrees Fahrenheit before the repairs are started, Boyle said. Heavy concentrations of hazardous dust and fiber from the asbestos cloth are suspended in the air.

"Asbestos dust is so dangerous," the union said in a directive to UMWA districts, "that you are requested to determine as quickly as possible the existence, if any, of such exposure in your district. All such information should be forwarded immediately to Dr. Lorin E. Kerr, UMW occupational health director."

Asbestos dust causes asbestosis as well as lung cancer, the directive said.

Asbestos

11/6/72

MINE WORKERS HEALTH OFFICER INDICATES CONCERN FOR EMERGENCY ASBESTOS STANDARD

The recently promulgated emergency standard for exposure to asbestos dust "is appreciably higher than the non-hazardous level" specified in recent medical publications on the subject, according to Lorin H. Kerr, M.D.,

chief of the Department of Occupational Health for the United Mine Workers of America.

Kerr, in a letter to Assistant Labor Secretary George Guenther, said the UMW is "equally concerned that this emergency standard is restricted in its applicability to construction workers." The standard was published in the Federal Register December 7, 1971 (Current Report, December 9, p. 623).

Noting that the standard does not affect coal miners because they are covered by the Coal Mine Health and Safety Act, Kerr said the union is "deeply disturbed about this standard in view of recent information concerning the possible exposure of some strip miners to asbestos."

Kerr urged that the standard be lowered to a "medically acceptable non-hazardous level at the earliest possible date and that it apply to all workers exposed to asbestos dust."

Coal Mines

3/23/72

UMWA SEEKS MORE INFORMATION FOLLOWING NIOSH ASBESTOS SURVEY

An evaluation of asbestos hazards at the Hanna Coal Company, Cadiz, Ohio, made by the National Institute for Occupational Safety and Health at the request of the United Mine Workers, has been accepted with reservations by Dr. Lorin E. Kerr, UMWA Director of Occupational Health.

At Kerr's request NIOSH made an investigation of potential exposures to asbestos among workmen who use asbestos cloth for insulation in welding operations in strip mining equipment repair. The NIOSH Division of Technical Services conducted the survey of the Hanna installation November 22-23.

Investigation Results

Personal and area samples were taken to determine exposure to asbestos dust evolved from asbestos cloth and as insulation in the welding process. Atmospheric samples also were collected and analyzed for welding fumes. The results of the study showed the levels of asbestos exposure to be well below the emergency hygienic standard of five fibers greater than five microns in length per cubic centimeter, Dr. Bobby Craft, acting director of the Division of Technical Services, wrote Kerr. "Samples collected for various metallic fume also were below recommended limits," he said. "Therefore, on the basis of the conditions observed at the time of this investigation it is concluded that this operation offers little serious potential for health risk."

Because the situation did not exceed the emergency limits, NIOSH did not recommend a change in operations, but did state "if a substitute material such as fiberglass or mineral wool is used the problem of asbestos could be alleviated. This statement is made with the knowledge that the problem of welding such large masses of steel as is done at the workplace is a complex one, and with the understanding that the personal safety of welders, who must have a heat insulation material to protect them from contact with the hot metal, must be considered as well."

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OCCUPATIONAL SAFETY & HEALTH REPORTER

(CONTINUED FROM PREVIOUS PAGE)

A type of ventilation recommended by the American Conference of Governmental Industrial Hygienists should be used for each welder when possible, NIOSH said. "The exhausted air from such a set up should be released outside of the enclosure and in such a manner as to prevent the fumes from re-entering the workplace. In cases where the recommended set-up is extremely difficult or impossible some effort should be made to remove the fumes from the breathing zone of the worker and to prevent a buildup of a cloud of fumes inside the enclosure."

Kerr's Response

"I am dismayed to see the hazard being evaluated on the basis of the emergency standard of five fibers per milliliter," Kerr wrote Craft. The five fiber limit is an emergency standard but "in the face of recommendations by NIOSH, the standard should be two fibers," he said.

"It was heartening to note that the highest asbestos exposure was 1.41 fibers per cubic centimeter" but in view of the extreme danger of asbestos the UMWA urges "that any future studies be conducted on the basis of the two fiber level with a pervading recognition of the probable danger of any continued exposure to a level higher than one fiber."

The standards promulgated by the Occupational Safety and Health Administration are not applicable to hazards covered by the Federal Coal Mine Health and Safety Act, Kerr said. "There is nothing in the report to indicate any exposures the men may have to asbestos other than welding. The UMW has evidence of workers having close exposure to stacked batts of asbestos, he said, which should be included in the report.

"Will you please forward this additional information to us along with there visions and strengthening of your recommendations for materials which can be substituted for asbestos," Kerr said.

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