

ON THE DERIVATION OF NIOSH POLICY:
DIESEL USE IN UNDERGROUND MINES

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Introduction

It is a pleasure to again be a part of the Conference on Mine Safety, Health, and Research at VPI. My best regards to our leader Dr. Dick Lewis and my compliments for sustaining this excellent annual get-together. With me today are five scientists from NIOSH who have been involved in various aspects of research and policy on the health effects of diesel exhaust. They are Bob Glenn, Director of our Division of Respiratory Disease Studies, whom you all know; Dick Lemen, Director of our Division of Standards Development and Technology Transfer in Cincinnati; Dr. John Gamble, also an epidemiologist with DRDS, Morgantown, Dr. Trent Lewis, a toxicologist with our Division of Biomedical and Behavioral Sciences in Cincinnati; and Bob Reger, Biostatistician with the Division of Respiratory Disease Studies in Morgantown. Each of these people have made significant contributions to our understanding of the health effects of diesel exhausts. Taken as a whole, they are probably as knowledgeable on this issue as any group of five people in the World. Please take advantage of their presence by raising any questions, or issues which may interest you.

August in Virginia--and a young man's fancy lightly turns to thoughts of football...ugh! twice-a-day scrimmages in the boiling sun! Couple Friday nights ago I felt like I had just been through the first week of football practice. I mean, I was battered and bruised. In the course of 5 days I had met with delegations representing three of the major national organizations involved with coal mining in the United States. They all had one thing in common--they all wanted to know "what is the NIOSH policy on the use of diesel equipment in underground coal mines?" That is where the commonality ended! In two of those meetings, the groups were eager that NIOSH take a particular stance on the question. Problem was, that what each wanted was 180 degrees opposite! As I understand it, one group wanted NIOSH to affirm the use of diesel equipment in underground coal mines (as long as appropriate controls are followed in accordance with existing MSHA standards for underground coal mines), while the other group wanted NIOSH to condemn the use of diesel equipment in underground coal mines. The third meeting of the week was with Mr. David Zegeer, Administrator of MSHA and his staff. He helpfully commiserated with me and said "Don, that's how it is in occupational

health." A sort of "welcome to the National Football League!" The thing that interested me most, once the bumps and bruises passed, was that well-intentioned, well-informed, and conscientious people dealing with the same scientific information could reach such totally different conclusions and have such totally different expectations of NIOSH. Both expected us to render a definitive decision on this issue, in their favor.

In light of that, I thought it would be worthwhile today to review the history of the issue and to briefly acquaint you with the types of scientific findings available on the health effects of diesel exhausts.

At the outset it is well to remember two things:

- (1) "Diesel exhaust" is not one thing--it's many things. Diesel exhaust contains at least five major categories of pollutants (a) particles, (b) sulfur oxides, (c) nitrogen oxides, (d) carbon oxides, and (e) hydrocarbons. Also, diesel exhausts vary tremendously from engine to engine and even in the same engine from time to time, depending on the particular demands on the engine at the time.
- (2) Secondly, while individual extracts of components of diesel exhaust behave one way when tested in animals, the exhaust, when inhaled as a whole, seems to behave differently. Thus a component of a diesel exhaust can be seen as a carcinogen in one set of tests, while the exhaust as a whole does not demonstrate carcinogenicity.

THE HISTORY OF A POLICY

Diesel engines have been with us awhile, even in mining. The diesel engine was first introduced into a U.S. coal mine in 1946. Thirty years later

when NIOSH was only 5 years old, the Institute, then directed by Dr. Jack Finklea, took its first "stand" on the health effects of diesel exhaust. That policy appeared in a letter written from Dr. Finklea to Mr. John Barrett of MESA (the forerunner of MSHA) on June 7, 1976. In it, Dr. Finklea wrote:

"We remain concerned about the possible enhanced health effects of long-term exposure to a combination of coal dust, a known pneumoconiotic agent, and the gases and vapors of diesel exhaust which are also known to be pulmonary irritants, e.g., nitrogen dioxide and certain organic compounds."

Further he wrote:

"In addition, we know very little about the possible carcinogenic potential of chemicals which may be formed by the interaction of gases and vapors from diesel exhaust and organic substances which may be present in the coal mine atmosphere. Although we are concerned about the possible health effects, we do not now have adequate human or animal studies to justify a recommendation at this time that existing diesel usage in underground coal mines be prohibited."

In concluding his letter, Dr. Finklea referred to pending research and wrote:

"We feel it prudent to inform all concerned in the coal mining industry that further introduction of diesel equipment into underground coal mines pending completion of these studies might result in future economic disruption should their use pose an unacceptable health risk."

Four years later the National Research Council, at the behest of EPA, the Department of Energy, and the Department of Transportation, convened a special panel to examine the health effects of diesel exhaust. In transmitting the report, Dr. Philip Handler, Chairman of the National

Research Council, wrote in his cover letter the following:

"The report provides a careful analysis summarizing and critically reviewing the less than satisfactory state of information concerning the effects of diesel engine emissions on humans. Materials moderately active as mutagens in various assays and as carcinogens when painted on the skins of susceptible animals have indeed been partially purified from diesel exhausts. However, no evidence of carcinogenesis has been noted in animals breathing diesel exhaust fumes or in epidemiological studies of relatively heavily exposed human populations. Unfortunately, almost all of the studies are reported to have been defective in some manner and, hence, do no permit definitive conclusions at this time."

In 1981 the Environmental Protection Agency convened an International Symposium on the toxicology of diesel emissions in North Carolina. Dr. Norton Nelson, an eminent figure in this field, in his summary of the meeting, said:

"I start with the premise that I can't really see how there can be a serious doubt in anybody's mind that diesel exhaust is potentially carcinogenic for humans."

He further said:

"I think we can conclude quite straight-forwardly that a major increase in the diesel fleet (Note: the Symposium was focused on the issue of increasing use of diesel engines in motor vehicles) is not going to produce a disastrous epidemic of lung cancer. I think at the other extreme that we are probably not in a position now today to reach a meaningful judgment as to the quantitative impact of such an expansion. It may be that it's going to be negligible. That's quite possible. However, it may be that the impact will be a level

that will require some difficult social decisions. I don't know."

He concluded:

"What we need...is to make an estimate of whether the problem is trivial or socially significant. Thus risk assessment should be the ultimate goal."

In the light of these comments by prominent scientists and organizations, NIOSH proceeded to plan and execute studies in animals, and to make observations in various groups of workers exposed to diesel exhausts.

Last year, various interested parties began to advise us that NIOSH should issue a new policy on the use of diesel equipment in underground coal mines. On December 12, 1984, following a meeting with representatives of the American Mining Congress, I wrote:

"As regards the use use of diesel equipment in underground mining, we plan to issue a policy statement, most likely a Current Intelligence Bulletin, in the Spring of 1985. Whether or not we conclude there are significant health consequences depends on a thorough review of all the literature on observed effects in animals and humans as well as consideration of environmental levels and current mining operations."

We also asked the Mine Health Research and Advisory Committee to review the available information and report to us their advice on the use of diesel equipment in underground coal mines. Having done all that, we offered this topic for discussion at this meeting, thinking that by now we would have already issued a sparkling new policy on the issue. Like everybody else, we expected that a thorough review of the available literature, perhaps enriched by the results of one or two well done studies just around the corner, would permit us to clearly answer the question. Well, is hasn't happened.

Most of you are familiar with the MHRAC report sent to us at the end of April, 1985. Their conclusion is worth quoting:

"It is our opinion that although there are some data suggesting small adverse health effects associated with exposure to diesel exhaust, these data are not compelling enough to exclude diesels from underground mines. In cases where diesel equipment is used in mines controls should be employed to minimize exposure to diesel exhaust."

Since last December, as we got deeper into this issue, and new data began to appear (including a definitive study in animals by Dr. Trent Lewis), we began to realize that the complexities of the issue demanded a more expansive summary than is characteristic of a "Current Intelligence Bulletin." Finally, in early July 1985, Bob Glenn proposed the development of a formal Criteria Document on the subject, including formal recommendations for a standard for the use of diesel equipment in underground coal mines. That, in brief, summarizes the evolution of NIOSH policy on this issue over the past decade.

HOW NIOSH DEVELOPS AND DISSEMINATES POLICIES

At this point let's look briefly at the ways in which NIOSH sets forth its policies.

NIOSH policy appears in one of four principal categories.

- (1) **Criteria Documents:** These are exhaustive reviews of a subject concluding with specific recommendations for standards, including quantitative recommended exposure levels (REL) where appropriate.
- (2) **Current Intelligence Bulletins:** These are short reviews summarizing new scientific findings and providing an

interpretation of their implications for prevention.

- (3) **Responses to Regulatory Actions of the Department of Labor:** These are up-to-the-minute written responses to specific regulatory actions, usually proposed by OSHA or MSHA. These responses may be introduced as testimony in hearings during the regulatory process.
- (4) **Others:** A number of other forms of documents are prepared which may communicate NIOSH policy. These include Alerts, Bulletins, Guidelines, Hazard Reviews, Pocket Guides, Risk Assessments, etc.

In the case of the health effects of diesel exhausts, we initially thought a Current Intelligence Bulletin would be appropriate, we later concluded this was not appropriate, and have decided to initiate a formal Criteria Document instead.

SUMMARY OF THE AVAILABLE INFORMATION ON THE EFFECTS OF DIESEL EXHAUSTS ON HEALTH

Now I would like to acquaint you with the information on which we must base any policy position on the use of diesel equipment in underground coal mines. As regards the health effects of diesel exhausts, there are three types of scientific information available:

- (1) Studies of mutagenicity, i.e., observations of genetic damage.
- (2) Studies of cancerous and non-cancerous health effects in animals.
- (3) Studies of cancerous and non-cancerous health effects in humans.

We shall attempt to address these in sequence.

First of all lets look at studies of mutagenicity. Many of these have been done and as can be seen in Table 1, the results are mixed. Extracts of diesel exhaust particulates caused mutagenic changes in a high proportion of tests done in bacterial systems and mammalian cell cultures. In tests of whole diesel exhausts in animals, however, changes occurred in a minority of tests. These apparently discrepant results raise questions. In the animal, do the carcinogens on the surface of the particle adhere so tightly that they are not readily released to cause mutagenic changes? Do the animal's defense systems rapidly detoxify these agents? We simply don't know the answers.

Now let us look at the studies in animals. First in studies of the immunologic effects of exposure to diesel exhausts by inhalation, there is clear evidence that diesel exhaust damages the immune systems in the lung, permitting infections to occur (Table 2). Moreover, as is shown in Table 3, there is clear evidence also that inhaling diesel exhausts produces chronic lung disease in experimental animals; both obstructive and restrictive chronic lung disease have been observed after exposure of animals to inhaled diesel exhaust. However, the findings have not documented synergism between diesel exhaust and coal dust in producing these effects.

As is shown in Table 4, there is clear evidence of skin cancer in animals whose skins have been painted with extracts of diesel exhaust. However, as is shown in Table 5, there is no unequivocal evidence of cancer in experimental animals after exposure to diesel exhausts by inhalation.

Now we turn to various studies in humans. Basically, these studies report observations of symptoms, signs, and/or tests of pulmonary function in various types of miners and other workers exposed to diesel exhausts. From all of these studies, there are only two unequivocally positive findings; both shown in Table 6:

(1) In salt miners there were acute reversible changes in pulmonary function (before and after shift) related specifically to NO in the diesel exhaust; (2) also, there was an unequivocal finding of eye irritation among workers exposed to diesel exhaust in garages. Other signs and symptoms were observed in increased incidence, but these could not be casually related to diesel exhaust. In studies of the chronic effects of exposure to diesel exhaust, again many signs and symptoms were found in increased incidence among those studied, but none of these could be specifically casually related to exposure to diesel exhausts (Table 7).

Next we turn our attention to epidemiologic studies exploring the relationship between exposure to diesel exhausts and the incidence of cancer among exposed workers (Table 8). Here again, the results are quite ambiguous. Almost without exception these investigations suffer from a myriad of methodologic problems including (1) incomplete information on the extent of exposure to diesel exhausts (requiring estimations of these exposures from job titles); (2) an insufficient passage of time from first exposure to diesel exhausts until one could reasonably expect the appearance of cancer, and (3) confounding variables such as smoking and exposure to asbestos or ionizing radiation, which make it almost impossible to draw definitive conclusions as to the cause of any excesses of cancer observed. It is fair to point out, as did the MHRAC Committee in its report, that four of these epidemiologic studies did show elevated "risk ratios" of 1.2-1.4, i.e., a 20-40% excess of cancer over the expected, but that in each of these studies confounding variables made it very difficult to interpret these results.

Table 9 seeks to summarize all of this information. If the table looks confusing, it is because the information is confusing. The results are very mixed, some positive, some negative, some equivocal, and some uninterpretable. In the important

studies in workers, without exception there are confounding variables that make it extremely difficult to conclude anything with assurance.

SUMMARY

It is important to identify those findings which are clearly (i.e. indicate injury or disease) "positive" in an overall picture of this information: (1) we have good evidence that in animals, diesel exhausts cause chronic lung disease, (2) we have good evidence that in humans, diesel exhausts cause acute eye irritation, and (3) acute changes in pulmonary function. These casual relationships are documented. There are also some suggestive epidemiologic hints of increases in cancer deaths in workers exposed to diesel exhausts, but the significance of these observations is questionable. The available studies of animals exposed to diesel exhausts by inhalation, have produced no unequivocal evidence of carcinogenicity.

I come away from these data with the impression that there are a few clearcut hazards from diesel exhausts, and that these are well worth our attention. This is especially true with respect to underground coal mines where other atmospheric pollutants are already a continuing concern. Because of all the ambiguities in the scientific findings, and in the attempt to be helpful, we are doing the following:

- (1) NIOSH is developing a systematic written review of the results of available research which will attempt to analyze all the results and to synthesize the findings into an intelligible interpretation.
- (2) NIOSH will prepare a Criteria Document to assist MSHA on promulgating standards for the use of diesel-powered equipment in underground coal mines.

Based on the current scientific

knowledge about the health effects of diesel exhaust, with its contradictions and ambiguities, NIOSH cannot, with clear conscience, neither affirm nor condemn the use of diesel equipment in underground coal mines. Instead, it seems to me prudent public health practice that NIOSH encourage appropriate regulation of its use.

We feel that human exposures to diesel exhausts should be maintained below the levels specified in existing MSHA standards (or NIOSH recommendations, whichever are lower), and that controlling respirable particulates is especially important given the uncertainties about their potential carcinogenicity. We also believe that these levels of control can be accomplished without great difficulty with existing technologies.

We are convinced that existing standards should be improved and broadened so as to assure that non-cancerous respiratory disease from exposure to diesel exhausts, is prevented. We will be preparing the necessary criteria to recommend such regulatory changes, in the months ahead.

Thank you.

TABLE 1
RESULTS - STUDIES OF MUTAGENICITY

<u>TEST MATERIAL</u>	<u>NO. OF EXPERIMENTS</u>	<u>POSITIVE</u>	<u>NEGATIVE</u>
Extracts of Diesel Exhausts Tested <u>In Vitro</u>	42	31	11
Whole Diesel Exhausts Tested <u>In Vivo</u>	14	3	11

TABLE 2
RESULTS - STUDIES OF SUSCEPTIBILITY TO INFECTION*
IN ANIMALS EXPOSED TO DIESEL EXHAUSTS

<u>NUMBER OF STUDIES</u>	<u>POSITIVE</u>	<u>NEGATIVE</u>
3	2	1

*Influenza and Streptococcus

TABLE 3

RESULTS - STUDIES OF CHRONIC LUNG DISEASE IN ANIMALS
EXPOSED TO DIESEL EXHAUSTS

<u>HEALTH EFFECT DOCUMENTED</u>	<u>NUMBER OF STUDIES</u>
Restrictive Lung Disease	4
Obstructive Lung Disease	1

TABLE 4

RESULTS - STUDIES OF TUMOR PRODUCTION BY PAINTING THE SKIN
OF MICE WITH EXTRACTS OF DIESEL EXHAUSTS

<u>NUMBER OF STUDIES</u>	<u>POSITIVE</u>	<u>NEGATIVE</u>
4	2	2

TABLE 5

RESULTS - STUDIES OF CANCER IN ANIMALS
EXPOSED TO DIESEL EXHAUSTS

<u>NUMBER OF STUDIES</u>	<u>AUTHOR'S INTERPRETATION OF OBSERVATIONS</u>			<u>SIGNIFICANT CONFOUNDING VARIABLES</u>
	<u>POS.</u>	<u>NEG.</u>	<u>EQUIVOCAL</u>	
5	0	3	2 ^{†*}	2

[†]Rats, but not mice, were positive but results confounded by occurrence of focal pneumonia in test animals; not a lifetime exposure (White et al., 1983).

*Enhanced tumor production in hamsters pretreated with a carcinogen (Heinrich et al., 1982)

TABLE 6

RESULTS - STUDIES OF ACUTE HEALTH EFFECTS IN
WORKERS EXPOSED TO DIESEL EXHAUSTS

<u>OCCUPATION</u>	<u>HEALTH EFFECT WITH INCREASED INCIDENCE</u>	<u>COMMENT</u>
Salt Miners	Reversible pulmonary changes (before and after shift)	Causally Related to NO ₂ in Diesel Exhausts
Bus Garage Workers	Eye Irritation	Causal Relationship to Diesel Exhausts
	Cough, Labored Breathing, Chest Tightness, Wheeze	Causal Relationship Not Established
Coal Miners	None	

TABLE 7

RESULTS - STUDIES OF CHRONIC HEALTH EFFECTS
IN WORKERS EXPOSED TO DIESEL EXHAUSTS

<u>OCCUPATION</u>	<u>HEALTH EFFECT WITH INCREASED INCIDENCE</u>	<u>COMMENT</u>
Salt Miners	Cough and Phlegm	Causal Relationship to Diesel Exhausts Not Established
Potash Miners	Cough and Phlegm	"
Trona Miners	Cough and Phlegm	"
Coal Miners	Cough and Phlegm	"
Coal Miners	Decrements in Pulmonary Functions	"
Bus Garage Workers	Phlegm, Wheezing Chronic Stuffy Nose	"

TABLE 8

RESULTS - EPIDEMIOLOGIC STUDIES OF MORTALITY DUE TO
CANCER IN HUMANS EXPOSED TO DIESEL EXHAUSTS

<u>TYPE OF STUDY</u>	<u>NO.</u>	<u>AUTHOR'S INTERPRETATIONS OF RESULTS</u>			<u>SIGNIFICANT CONFOUNDING VARIABLES</u>
		<u>POS.</u>	<u>NEG.</u>	<u>EQUIVOCAL</u>	
Cohort Mortality	13	2	5	6	13
Case Control	9	2*	3	4	9

*Information on one case control study was available only from an abstract.

TABLE 9

SUMMARY - BIOLOGIC EFFECTS ASSOCIATED WITH
EXPOSURE TO DIESEL EXHAUSTS

<u>TYPE</u>	<u>NO.</u>	<u>RESULTS</u>			<u>SIGNIFICANT CONFOUNDING VARIABLES</u>
		<u>POSITIVE</u>	<u>NEGATIVE</u>	<u>EQUIVOCAL</u>	
<u>STUDIES OF MUTAGENICITY</u>	56	34	22	--	
<u>STUDIES IN ANIMALS</u>					
Susceptibility to Infection	3	2	1	--	
Restrictive Lung Disease in Animals	6	4	2	--	
Obstructive Lung Disease	6	2	4	--	
Tumorigenicity					
Skin Painting	4	2	2	--	
Cancer in Animals	5	0	3	2	2
<u>STUDIES IN HUMANS</u>					
Acute Lung Disease	3	2	1	--	
Chronic Lung Disease	5	0	0	5	5
Cohort Mortality	13	2	5	6	13
Case Control Mortality	9	2*	3	4	9

*One case control study was positive, but only an abstract is available.

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