TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF:)
)
EXPOSURE OF UNDERGROUND MINERS) Docket No. MSHA-2014-0031
TO DIESEL EXHAUST)

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BEFORE THE U.S. DEPARTMENT OF LABOR
MINE SAFETY AND HEALTH ADMINISTRATION

IN THE MATTER OF:) Docket No. MSHA-2014-0031

EXPOSURE OF UNDERGROUND MINERS TO DIESEL EXHAUST

S Room 7 West 204
MSHA Headquarters
201 12th Street
Arlington, Virginia

Tuesday,
July 26, 2016

The parties met, pursuant to the notice, at 12:03 p.m.

MODERATOR: SHEILA McCONNELL, Office of Standards, Regulations and Variances, MSHA

PANEL:

CHRIS FINDLAY, Metal and NonMetal Safety and Health

GREGORY MIEKLE, Coal Mine Safety and Health

Also Present:

ALFRED DuCHARME, Office of the Solicitor

Speakers:

MARK ELLIS, Industrial Minerals Association-North America

RICHARD PASQUIER, Tronox Alkali

DR. ROGER McCLELLAN, Diesel Emissions Task Force, IMA-NA

APPEARANCES: (Continued)

Speakers:

LINDA RAISOVICH-PARSONS, United Mine Workers of America

JOSH ROBERTS, United Mine Workers of America

ED GREEN, Murray Energy Corporation, Bituminous Coal Operators Association, Bridger Coal Company

DR. ROGER McCLELLAN, Murray Energy Corporation, Bituminous Coal Operators Association, Bridger Coal Company

HUNTER PRILLAMAN, National Lime Association

P R O C E E D I N G S

(12:03 p.m.)

MS. McCONNELL: Okay. So, with that, good afternoon, and my name is Sheila McConnell. I am the Director, Office of Standards, Regulations and Variances, Mine Safety and Health Administration. I am the moderator of this public meeting on the Agency's Request For Information on Exposure of Underground Miners to Diesel Exhaust, which was published in the *Federal Register* on June 8, 2016. On behalf of Assistant Secretary Joseph Main, I want to welcome all of you here today and thank you for your attendance and participation.

Let me introduce members of our panel. To my right is Chris Findlay, Metal, and Nonmetal Mine Safety and Health. I'm sorry. To my right is Chris Findlay, and to my left is Greg Miekle, Coal Mine Safety and Health. And I'd also like to introduce Pam King, who is helping me out in the back of the room.

This is the third of our four public meetings. The final meeting will take place next week, on August 4, in Birmingham, Alabama. Last week we held meetings in Salt Lake City, Utah, and Pittsburgh, PA.

The purpose of this public meeting is to receive information from the public that will help MSHA evaluate the Agency's existing standards and policy guidance on controlling miners' exposures to diesel exhaust and to evaluate the effectiveness of the protections now in place to preserve miners' health.

This meeting will be conducted in an informal manner. Speakers and other attendees may present information to the court reporter for the rulemaking record. MSHA will accept comments and other information for the record from any interested party. If you have not done so, please sign the attendance sheet in the foyer in the front of this room so that we may have an accurate record of your attendance. We have copies of the Request For Information and the notice announcing the public meetings also alongside the sign-up sheet.

The verbatim transcript may be viewed at regulations.gov and on MSHA's website at www.msha.gov.

I also want to note that we have received a request for an extension of the comment period which closes on September 6, 2016. The Agency is taking this request into consideration.

Before we hear from you I want to provide some background on why MSHA is reviewing the Agency's existing standards. MSHA regulates miners' exposures to diesel exhaust to reduce the health risk and to prevent material impairment of health to miners. Diesel engines are widely used in mining operations because of their high-power output and mobility. Many mine operators prefer diesel-powered machines because they are more powerful than most battery-powered equipment and can be used without electrical trailing cables that can restrict equipment mobility.

In March 2012, the National Institute of Occupational Safety and Health and the National Cancer Institute completed the Diesel Exhaust in Miners Study. This epidemiological study was conducted to determine whether breathing diesel exhaust could lead to lung cancer and other health outcomes.

In June 2012, the International Agency for Research on Cancer concluded that there is sufficient evidence of carcinogenicity in humans from diesel exhaust exposure to upgrade its classification of diesel exhaust to classify it has a human carcinogen.

Following the International Agency for Research on Cancer's classification of diesel exhaust as a human carcinogen, MSHA issued two health hazard alerts: one on diesel exhaust and diesel particulate matter in underground coal and metal/nonmetal mines and one on nitrogen dioxide emissions in underground coal mines. MSHA issued the first hazard alert in partnership with OSHA on January 10, 2013. MSHA issued a second hazard alert on August 6, 2013. This alert reinforced the dangers of platinum-based particle filters as a source of increased concentrations of nitrogen dioxide in underground coal mines.

This Request For Information seeks information and data on the effectiveness of MSHA's existing standards in controlling miners' exposures to diesel exhaust, including diesel particulate matter. MSHA specifically requests information on a series of questions related to:

One, the use of non-permissible light-duty diesel-powered equipment in underground coal mines;

Two, maintenance of diesel-powered equipment in underground coal mines and recordkeeping requirements;

Three, the types and effectiveness of after-treatment and engine technologies used in coal and metal and nonmetal underground mines. MSHA is interested in best practices for selecting and using after-treatment devices;

Four, under MSHA's existing standards for metal and nonmetal underground mines, total carbon measurements are used as a surrogate for diesel particulate matter when determining miners' exposures. MSHA is seeking information on alternative surrogates other than total carbon to estimate a miner's diesel particulate matter exposure.

MSHA is also seeking information on the advances in sampling and analytical technology and other methods for measuring a metal and nonmetal miner's exposure to diesel particulate matter.

MSHA is also interested in data and information on existing controls that were most effective in metal and nonmetal miners' exposures, and what are the technological challenges and relative costs to reducing diesel particulate matter exposure from the existing standard of 160 micrograms of total carbon per cubic meter of air.

MSHA is interested in receiving any other data or information that may be useful to MSHA in evaluating miners' exposure to harmful diesel exhaust emissions, including the effectiveness of existing control mechanisms for reducing harmful diesel emissions and limiting miners' exposure to harmful diesel exhaust emissions.

We have several speakers. At this time, our first speaker is Mark Ellis, Industrial Minerals Association-North America. And there's going to be several on your panel?

MR. ELLIS: Yes.

MS. McCONNELL: Okay.

(Pause.)

MR. ELLIS: I had to look at my watch, but good afternoon.

MS. McCONNELL: Yes.

MR. ELLIS: I'm Mark Ellis. I'm President of the IMA-NA, the Industrial Minerals Association-North America. IMA-NA is a nonprofit 501(c)(6) trade association representing North American producers and processors of industrial minerals and associate members that support the industrial minerals industry.

Industrial minerals are feedstocks for the manufacturing and agricultural sectors. They are the ingredients for many of the products used in everyday life, such as glass, ceramics, paper, plastics, paints and coatings, cosmetics, pharmaceuticals, and laundry detergent. Our companies and the people they employ are proud of their industry and the socially responsible methods they use to deliver these beneficial resources. IMA-NA represents producers and processors of ball clay, barite, bentonite, borates, calcium carbonate, diatomite, feldspar, industrial sand, Kaolin, soda ash, talc, and wollastonite.

Safety and health are of paramount concern to IMA member companies, which is why we have come before you today to address MSHA's Request For Information on Exposure of Underground Miners to Diesel Exhaust. With me today are Mr. Richard Pasquier, General Counsel of Tronox Alkali, and Dr. Roger McClellan, an advisor on toxicology in human health risk analysis. Mr. Pasquier serves as the Chairman of IMA's Diesel Emissions Task Force, and Dr. McClellan serves as an advisor to the task force.

IMA appreciates the opportunity to put these comments before MSHA for consideration. Written copies of our oral presentations are available to the reporter preparing verbatim transcripts and to the MSHA panel for the rulemaking record.

So, without further ado, please allow me to turn the microphone over to Mr. Pasquier and Dr. McClellan, and we'll be prepared to answer questions at the conclusion of our testimony.

MS. McCONNELL: Okay.

MR. PASQUIER: Good afternoon. I'm Richard Pasquier. I'm General Counsel at Tronox Alkali, a unit of Tronox Limited, a global leader in mining, production, and marketing of inorganic materials and chemicals. I'm very glad to be here this morning.

MS. McCONNELL: I just want to make sure, can the court reporter hear Mr. Pasquier?

He may not be on. There's a button right on -- right there, right where your finger is. There we go.

MR. PASQUIER: Can you hear me now?

(Chorus of yeses.)

MR. ELLIS: Do you want me to go back and do mine?

MS. McCONNELL: Oh, did you hear Mr. --

THE COURT REPORTER: Not well.

MS. McCONNELL: Not well. Do you want to go ahead -- do you want him to redo his intro?

MR. ELLIS: You can do it from my written transcript.

MS. McCONNELL: Okay. Is that okay?

THE COURT REPORTER: Yeah, I hear him now.

MS. McCONNELL: Okay. Go ahead.

THE COURT REPORTER: I can just tell the transcriber.

MS. McCONNELL: All right. Okay. Go ahead.

MR. PASQUIER: Okay. Good morning. I'm Richard Pasquier, General Counsel at Tronox Alkali, a unit of Tronox Limited, a global leader in the mining, production, and marketing of inorganic materials and chemicals. Tronox Alkali operates alkali chemical business that Tronox Limited acquired from FMC Corporation last year, April 1, 2015. Very happy to be here this morning.

Tronox Alkali is the world's largest producer of natural soda ash, with mining and processing facilities located in Green River, Wyoming. We employ approximately 950 employees in Green River and nearly 60 employees in Philadelphia. We mine more than 4 million tons of trona annually for use in essential everyday products like commercial and residential glass, computer screens, pharmaceuticals, baking, and personal care products.

Tronox Alkali is a member of the Industrial Minerals Association-North America, IMA-NA, a trade association whose membership includes other trona producers and nonmetal mining and processing companies, as Mark Ellis, President of IMA-NA, has already described to you.

Approximately one year ago IMA-NA formed a Diesel Emissions Task Force in which Tronox Alkali is an active participant and for which I serve as chair. I offer this statement today in my capacity as chair of the task force. The task force was formed to enable us to learn as much as possible about the health effects of diesel exhaust in order to protect our employees. The task force also promotes and is interested in the exchange, testing, and verification of scientific information concerning the use of diesel equipment in mining operations.

The task force is made up of operators of underground mines producing trona, calcium carbonate, industrial sand, and wollastonite. All of the members of the task force use at least some diesel equipment in their mining operations, and we all share a commitment to health and safety of our employees.

Some of those members include the study mines that participated in the Diesel Exhaust and Miner Study, known as DEMS, conducted by the National Institute for Occupational Safety and Health, NIOSH, and the National Cancer Institute, NCI. Tronox Alkali's Green River operation was one of those study mines when it was owned by FMC. We agreed to participate in that study to advance scientific understanding of the potential effects of diesel exhaust and because we believed our participation would ultimately benefit our workforce.

Thousands of hours were spent assembling and organizing background information on the mining operations, use of diesel equipment from 1956 through 1998, and the records of 2,400-plus employees.

The task force and its members had a keen interest in the publications that have resulted from the DEMS project, including papers published by both the original NIOSH/NCI investigators and subsequent analyses by independent analysts, including by a consultant to Tronox Alkali and the task force, Dr. Roger McClellan, who's sitting next to me.

The literature on health hazards of exposure to diesel exhaust is voluminous. It's constantly changing and challenging to interpret. To assist us in this task, the IMA-NA Diesel Emissions Task Force has engaged Dr. McClellan as an advisor. As I said, he's here with us today and he's going to offer his initial thoughts on the MSHA Request For Information on Exposure of Underground Miners to Diesel Exhaust published in the *Federal Register* on June 8, 2016.

The Diesel Emissions Task Force will work with IMA-NA and Dr. McClellan to respond to the RFI and appreciates the opportunity to do so. We support MSHA's desire to evaluate the effectiveness of MSHA's current diesel regulations to ensure that they are protective of employees' health, a value that is the core to our own operations. But it is critical that MSHA's inquiry be thoroughly grounded in science, meaning that due consideration be given to all of the currently available scientific work, not only the original DEMS papers but also the re-analysis work that has been done with the DEMS data. MSHA also must take into account workplace practices and operators' experiences in complying with current regulations.

IMA-NA asked Dr. McClellan to participate in today's meeting and to review the comment on Section B of the RFI entitled "Recent Research". As he will explain, the RFI's summary of DEMS is incomplete. This is a critical conclusion since this summary is the scientific basis for the issuance of the RFI and any subsequent analyses and actions that may lead to a change in existing regulations.

It's important that the panel realize that DEMS is a historical backwards-looking study and that there are substantial uncertainties in its use of estimated exposures, a proxy, an estimate of using respirable elemental carbon (REC) for diesel particulate matter. Dr. McClellan will describe alternative estimates of REC as it's in an acronym, the use of which he and other independent researchers looking at DEMS data have discovered result in substantially different characterization of lung cancer risk for the DEMS miners.

Moreover, he will emphasize as well that all the analyses, both the original NIOSH/NCI investigators and independent analyses, relate to older diesel engine exhaust emissions and exposures that occurred in 1982 and earlier because of the 15-year lag time between exposure and any significant response. Any serious look at DEMS must take into account the fact that over the past three decades improvements in diesel engine technology and fuels, most notably major reductions in sulfur content, have resulted in substantially reduced particulate emissions.

The IMA-NA Diesel Emissions Task Force has initiated an analysis of specific questions posed by the RFI. It is readily apparent that these questions are not only extraordinarily technical but also may be best addressed by working with the manufacturers of diesel engines and suppliers of mining equipment.

As I mentioned, there have been substantial improvements in diesel engine technology and exhaust after treatment systems over the past quarter century which largely were driven by the EPA's diesel engine standards. Engine equipment manufacturers would be much more familiar with those changes than mine operators.

As a result, Tronox Alkali and IMA-NA propose that MSHA and NIOSH work with the mining industry, both metal and nonmetal and coal, diesel engine manufacturers, diesel mining equipment manufacturers, and representatives of organized labor to form a diesel exhaust health effects partnership to address these complex issues and reach consensus on the path forward.

At this meeting, the task force is submitting a letter to NIOSH and MSHA formally requesting the formation of that partnership. In order to allow this partnership to begin work, we are also requesting, I believe that's the request that you mentioned in your opening comments, a request to extend the RFI response period by 90 days. That extended amount of time is critical in any event to allow the regulated industry to respond to a detailed question -- to the detailed questions that MSHA has posed.

Before I conclude my remarks I note that we were pleased to see MSHA acknowledge the substantial progress made in reducing average miner exposures in metal and nonmetal operations from 2006 through 2015.

It would be useful if MSHA were to share this matrix of exposure data with the partnership we are requesting to be formed. Indeed, we earnestly hope this partnership will address diesel technology improvements and best practices for monitoring miner exposures, as well as achieving further reductions in exposures to diesel engine exhaust if further reductions are deemed necessary.

In summary, Tronox Alkali and the other members of IMA-NA Diesel Emissions Task Force are committed to providing a safe and healthful work environment for all of our employees. This requires a management approach that addresses a wide range of factors, including exposure to diesel engine exhaust.

Like MSHA, we were pleased with the continuous reductions in diesel exposure in nonmetal mines since the 1980s. We look forward to working collaboratively with MSHA, NIOSH, and other stakeholders in a partnership to better understand the basis of those reductions and identify best practices for future use -- for the future to ensure worker exposures are held to levels that are protective of miners' health.

MS. McCONNELL: Would you like to --

MR. PASQUIER: Dr. McClellan.

DR. McCLELLAN: Thank you for allowing me the opportunity to speak today. I'm Roger McClellan, an advisor on toxicology, human health risk analysis matters, with emphasis on issues concerning airborne materials and their potential health effects in workers in the general population. I've had a special interest in and conducted research on the health hazards of diesel exhaust emissions since the 1970s.

Let me note as an aside, as I began preparing my remarks for this meeting, I recalled with pleasure serving on the Department of Labor MSHA Advisory Committee in the late 1980s, so we're back again and it's a pleasure to be with you.

I offer this statement on behalf of the Diesel Emissions Task Force of the IMA-NA. I advise that task force on scientific developments regarding the potential health effects of exposures of workers to diesel exhaust. I have also offered advice on these matters to Tronox Alkali, visited their mining operations, looked closely at the activities going on there.

Tronox and the other nonmetal mines in the task force all use diesel exhaust to some and I would say variable degree and I have found to be very interested in learning the latest developments in our understanding of the potential health effects of diesel exhaust to ensure the safety and health of their employees.

The task force and I have read with interest MSHA's Request For Information on Exposure of Underground Miners to Diesel Exhaust that was published June 8, 2016. It's my understanding that MSHA issued the Request For Information, holding this and other public meetings to gather information to enable the Agency to review its existing standards and policy guidance on controlling miners' exposure to diesel exhaust to evaluate the effectiveness of the provisions now in place to preserve miners' health. We appreciate this opportunity to submit information and statements to assist MSHA in gathering the relevant facts and evidence.

I am here to urge that MSHA ground its inquiry in science and to consider all of the currently available science on the potential health effects of exposure to diesel exhaust. It's critically important in this initial phase of MSHA's review that the currently available scientific information on health hazards and risks of exposure to diesel exhaust, including all of the uncertainties, be accurately and completely depicted. In short, it's very important that MSHA get the science right.

This is the case because that science will ultimately be used to inform, and I want to emphasize inform, policy decisions on exposure levels and durations for standards that demonstrate on the basis of the best available evidence that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards involved.

Let me emphasize the importance at this stage of all parties to the proceedings recognizing that the science informs a particular policy outcome. Science alone and scientists insufficient to set the standard because science alone cannot establish that bright line between levels and duration of exposure with or without impairment of health. It is science informing the policy decisions that allow those risk management decisions to be made.

MSHA's review of its diesel regulations was inspired by certain developments in the ever-evolving scientific inquiry into diesel exhaust exposure and whether such exposures could lead to lung cancer and other health outcomes. MSHA summarized some but I want to emphasize not all of that research in Section 1(b) of the RFI entitled "Recent Research".

As I'll explain later, it is clear that MSHA is focused on the Diesel Exhaust in Miners Study or, as we'll call it from here on, DEMS, to the exclusion of other work that has been done with the DEMS data. The DEMS study was conducted by the National Cancer Institute and National Institute for Occupational Safety and Health and published initially, you know, in 2012.

Beginning in 1997, NIOSH and NCI investigators reviewed the historical -- skip that, I want to make certain I don't skip a page here. Okay, beginning in '97, NIOSH and NCI investigators reviewed the historical data for eight nonmetal mines that were volunteered by their management to be part of the study. The DEMS analyses therefore are based on estimates, and I want to emphasize estimates, of exposure for 1997 and earlier, with the most influential exposures occurring in 1982 and earlier because, as the analyses have revealed, a use of a 15-year lag period yields the most significant results regarding the health hazards of death from lung cancer. Those were the results that were published in 2012 by the NIOSH/NCI investigators.

To fully understand and interpret the DEMS data, it's important to go beyond those two papers.

MSHA must also critically evaluate the five papers describing the original estimates of respirable elemental carbon exposure for the DEMS workers developed by the original NIOSH/NCI investigators, and I've given the references there.

And as I'll discuss today, independent researchers working with the DEMS data have identified important limitations of DEMS that must be considered in any future assessment. I'm one of those researchers. I and my colleagues have published several papers with the results of our work in the peer-reviewed journal, *Risk Analysis*, and we were able to do that because we had excellent cooperation particularly from John Howard at NIOSH and the NCI personnel, National Center for Health Statistics, so that we could use the DEMS data, and since they're viewed as confidential data that usage was under some very carefully defined and very stringent conditions.

So the DEMS results and the results of a second epidemiological study of diesel exhaust exposure in U.S. truck workers were used by the International Agency for Research on Cancer in 2012, as Ms. McConnell has indicated, to review the hazard classification of diesel exhaust. I attended that meeting as an observer.

They used the results and concluded there was sufficient epidemiological evidence that diesel exhaust was carcinogenic and to change the categorization of diesel exhaust from probably carcinogenic, as was determined in 1988, a panel that I served on for IARC. And in this case, with sufficient epidemiological evidence, the hazard classification was upgraded to carcinogenic to humans.

After that, EPA and the industry sponsors of the Health Effects Institute, a nonprofit entity which I've also been associated in the past, asked the HEI to assemble an epidemiology panel to evaluate DEMS and the trucker study to determine whether these studies could be utilized in future quantitative risk assessment. And at this juncture, I think it's very important that we draw a distinction in terms of hazard and risk, and in my opinion, the RFI that you put forth was premised in part on that hazard categorization by IARC.

I think it's important to recognize that its upgrading of the hazard characterization did not necessarily premise that there was an increased risk associated with diesel exhaust. That was a hazard characterization, and they said the data is now more certain in 2012 than it was in 1988 and that there was sufficient epidemiological evidence they could move it into what I'll call Category 1, as I'll describe later.

So, to understand why that quantitative risk assessment is significant, I'll go into a little more detail about that difference between hazard and risk. The term "hazard" is used to characterize the likelihood that an agent or workplace circumstance -- this is a situation here really of blending the two, diesel exhaust exposure -- may under some exposure circumstances cause cancer.

The carcinogenic hazards are typically described in qualitative terms like those used by IARC in its monogram program, and it has five different categories. The highest, Group 1 is carcinogenic to humans; 2A: probably carcinogenic to humans. That was a categorization if you recall in 1988 based on insufficient epidemiological evidence and at that time sufficient animal evidence. 2-B: possibly carcinogenic to humans; 3: not classifiable as to carcinogenicity to humans; and 4: probably not carcinogenic to humans. Let me say that's a tough hurdle in that last one. There's only one agent listed in that group.

So these kinds of hazard identifications, as

I said, they're qualitative in nature. IAR does not make quantitative estimates of the potency of the agents for causing cancer.

Turning to risk, risk on the other hand is a quantitative concept defined as the probability that the consequence, in this case occurrence of cancer, will occur as a result of a specific exposure, duration, concentration, particular time in life to an agent or workplace circumstance identified as being capable of causing cancer, i.e., it has a carcinogenic hazard. The calculation of the probability of occurrence of a particular disease, such as cancer, occurring as a result of the specific exposure requires knowledge of both exposure and the potency of that hazardous agent for causing cancer at a particular exposure level and duration.

Now various agencies, including the U.S. Environmental Protection Agency and NIOSH, have developed quantitative estimates of cancer-causing potential for only a few agents. Whereas perhaps we've had over 1,000 agents evaluated as to their carcinogenic hazard, many, many fewer of those have been evaluated in terms of the quantitative cancer-causing potential of potency and then aligning that with the estimates of exposure.

Now neither EPA nor NIOSH have formally developed quantitative estimates of the cancer-causing potential of diesel exhaust exposure. It's my understanding that NIOSH is in the preliminary stages of doing so. I note, however, that the development of a quantitative estimate of cancer-causing potency for an agent is not necessarily required for regulatory action to limit exposure, i.e., your previous actions. They were not based on a detailed quantitative risk assessment. And EPA's extensive regulations of diesel engines are not based on quantitative estimates of cancer risk.

In fact, I served on a panel, and finally in 2002, we issued a health assessment for diesel exhaust, and that assessment indicated that the evidence at that time was not sufficient to bring together to develop a quantitative estimate of risk.

Now we've recently had the HEI epidemiology panel review, as I said, the most recent evidence, and they concluded that these studies were well designed, carefully conducted, embodying the attributes of epidemiological studies that are considered important for risk assessment, and that is stated in the RFI. However, there's more to the HEI panel's conclusion than the RFI acknowledges. It's incomplete in this area.

The HEI panel concluded that the DEMS and the trucker study provided a useful basis for quantitative risk assessment of exposure to older diesel engine exhaust. A very important conclusion. The DEMS investigators, and we have reaffirmed, my colleagues and I, that the most influential exposures resulted in increasing cancer risk were those 1982 and earlier. The investigators did not measure exposure in newer diesel engine emissions, thus did not take into account the dramatic changes in technology in diesel engines, diesel fuels, and emissions.

The HEI panel also acknowledged that both studies had significant uncertainties and cautioned that those uncertainties must be factored into any attempt to derive an exposure/response relationship for diesel exhaust particulate matter in a quantitative risk assessment. The RFI in my opinion does not acknowledge these important qualifications, but MSHA's work in the future must certainly do so.

I want to make clear that I extend my compliments to the investigators who conducted DEMS and the senior officials of the two agencies at NIOSH and NCI for sponsoring that work and to the operators and employees of the eight mines that participated in

DEMS. The database available from DEMS is really truly remarkable and still being analyzed and I submit will continue to be analyzed and interpreted for some time.

In my opinion, what has occurred with the DEMS data and the multiple analyses will ultimately be recognized as a landmark set of epidemiological analyses. It's extraordinarily rare that a large and complex data set, such as DEMS, is shared. Now that may seem strange, particularly to laypeople, but science operates sometimes in silos and sharing of data is, quite frankly, not that common.

In this case, we have data that's being used by multiple investigators beyond the original team. This is laudatory. It's possible -- this is possible because DEMS data is public property. It's the U.S. Government's. So we had access to the data.

Moreover, the independent scientific analysts, including myself, were able to obtain funding from a coalition of sources led by the Engine Manufacturers Association that were willing to provide financial support to conduct the analyses without controlling the analytic process or having the right to prior review of the publication prior to publication. This is a great example of the way science should work, especially when the science is going to be used for regulatory purposes like here.

And so, as the analysts learned, myself included, there are substantial uncertainties in the estimates of respirable elemental carbon exposure in the DEMS data set. That was the measure used as a surrogate measure for diesel exhaust, and those uncertainties carry over into the original -- the association between diesel exhaust exposure and lung cancer made by the original NIOSH/NCI investigators, and they carry over into the analyses that we did on it, although it's very important, as I'll note, that we extended our analyses beyond the original estimates of REC, alternative estimates of REC, and we also took into account a very important point, that the miners in some cases were also exposed to radon, a well-known lung carcinogen.

In the DEMS project, respirable elemental -- REC was used as a metric for diesel exhaust exposure. However, it's important to note there were no, and I want to emphasize, no direct measurements of REC pre-1997, during the time period of the DEMS study. So no actual measurement of those. So we went to make back extrapolations. So, in the absence of measured REC concentrations, all of the REC exposures used in the analysis by the original investigators and by myself and the colleagues I worked with are estimates, and that's a very, very important point.

And, again, I've called attention to the various papers that were developed there by the original investigators and the work of my colleagues and I. Those are all very important that MSHA have those. We'll make certain that they're entered into the record.

But going forward, it's important that MSHA recognize the serious limitations in the analyses of the DEMS data. First of all, MSHA must give consideration to the papers reporting the results of the analyses conducted by the independent analysts, the Moolgavkar, et al. paper, the Crump, et al., Crump and Van Landingham and McClellan. These papers are not cited in the RFI, and we'll make certain you have them.

Using the DEMS data, it's important to recognize that we first replicated the analyses of the original investigators. That allowed us to verify we're using the same DEMS data set. Most importantly then in another step, the analysts extended the analyses using alternative models, alternative exposure estimates, and controlling for radon.

So, at the request of the IMA-NA, I prepared a critique of the Health Effects Institute's special report and, in doing so, also a critique of DEMS, and we're making that available to you. So, in doing that, I drew on my four decades of experience following the literature, conducting research on the health hazards of diesel exhaust.

I also, as I noted, participated in the IARC panel in 1988, attended the review in terms of 2012, and my personal participation in conducting these extended analyses.

Let me just digress a bit to describe DEMS, and in doing so I want to emphasize the underpinnings of any epidemiological study, the exposure assessment for that population, the population that's under consideration, and the vital statistic, vital data, and the analytic methods. It's a three-legged stool, and if one of those legs is broken, I'm sorry, the other two legs can't make up for it. It influences the overall uncertainty in the study.

So, if we look up on the screen behind Ms. McConnell, we see eight panels here, and these are alternative respirable elemental carbon metrics, and there are two of them there. The red line is the one developed by the original investigators, and this went through a rather complex and elaborate process by which they collect the data at the end of each one of those time lines in 1998, 1999, and then using the mine data back extrapolated.

A key part of that was the assumption that carbon monoxide was a useful or appropriate metric, a surrogate metric for respirable elemental carbon. That is a key assumption that was made and one that's been substantially debated.

The other line is the blue line, and that is an alternative estimate of REC that was developed by Crump, et al. I was a part of that team. In this case, we focused just on the horsepower of the diesel equipment and the ventilation because, as you know, you're always concerned with the source, that's the horsepower of the diesel equipment, and the ventilation, CFM.

So we start in the -- I won't go through all these individual panels, but you'll note they extend back with the first dieselization, I think, may have been in Mine A up in the upper left-hand corner. That's a limestone mine, and I think that was dieselized back in 1946-'47, and we carry forward.

So each one of the other panels we have one of the DEMS mines represented. You'll note the most substantial deviation between the estimates that we developed using horsepower and CFM, the blue line, or in the case of Mine A, the limestone mine, and going down on the right-hand side the salt mine, both of those used substantial horsepower, i.e., heavy-duty haul equipment. In the case of the Mine A, that's the primary way ore is moved from the face to the surface. The salt mine, likewise, has considerable hauling.

I believe, to the best of my knowledge, most of the other mines are making use of electrical-powered conveyors in terms of moving ore and thus substantially less horsepower, and in some cases mines are heavily ventilated because they're gassy mines, such as the trona mines, and so what is shown becomes a combination of the emission source, the equipment, and the ventilation condition.

MS. McCONNELL: So why does the deviation diminish and evaporate by the time it gets to year 2000?

DR. McCLELLAN: By what?

MS. McCONNELL: Why does the deviation -- why does the deviation between the lines kind of evaporate by the time you get to -- the trend seems to bring them together. What's going on there?

DR. McCLELLAN: Well, that's a

combination -- let me go to the next slide if I could. This shows the eight mines are listed here and their characteristics, and as you'll note, we've got four different kinds of ore that are being mined: limestone, salt, pot ash, and trona. We've got four different states involved. And then you see the ventilation there in the fourth column over, natural versus mechanical, and ventilation is changing over time in essentially every one of those mines. There's a difference in the year of first diesel usage, and then we have this complex situation in terms of the primary mode of operation, in terms of conventional and haulage in the case of the limestone mine, and you see various other combinations down.

Now let me say where we see all years these are data on carbon monoxide, CO, and radon. My understanding, that the principal source of these data actually is MSHA databases, and one of the things I'll call attention to is the variable degree to which we -- numbers of samples available, and then the number of these, the percentage that are over the limit of detection both for carbon monoxide and for radon.

And then coming more directly to your question, Ms. McConnell, 1982 activity, and I focused on 1982 because that was the year that we think the exposures are most influential in this analysis, that year and earlier. And so you see the CFM in terms of ventilation, quite variable across the mines, and then we see the usage of diesel equipment in the right-hand side from that very substantial usage in Mine A down to the more limited usage in terms of the trona mines.

So it's those coming together, and in the data set, diesel equipment usage and time utilized is tracked in the system, so we have that for every year. So, when we look at this, some of this is changes in terms of equipment and most importantly the substantial changes that occurred in terms of reduced emissions from diesel engines, and in the critique I'm providing you'll see a key graph in there in which there is a substantial reduction in diesel exhaust particulate emissions from engines associated with use of improved technology.

MS. McCONNELL: Okay. So 1982 seems to be your critical juncture point.

DR. McCLELLAN: Yep.

MS. McCONNELL: And in that I'm just trying to make sure I understand.

DR. McCLELLAN: Yeah, yeah. No, please.

MS. McCONNELL: Okay. So 1982 is the

critical junction point, and at that point you're saying you have observed improved ventilation or increased ventilation as well as --

DR. McCLELLAN: No, let me -- let's go back to the other if we could. I don't want to confuse the causes and effect here.

MS. McCONNELL: Okay.

DR. McCLELLAN: These are the respirable elemental carbon estimates, in red developed by the original investigators, in blue those developed by myself, Crump and others.

MS. McCONNELL: Mm-hmm.

DR. McCLELLAN: And ours is a very simple and straightforward approach utilizing horsepower and CFM. The same database that the original investigators used except they used a very complicated procedure in which they said we think carbon monoxide can be used as a metric.

MS. McCONNELL: Okay.

DR. McCLELLAN: We don't think that's appropriate.

MS. McCONNELL: Okay.

DR. McCLELLAN: We also think it's appropriate that in the analysis you take account of changes in the emissions from the technology.

Now, as it turns out, when you do the analytic analysis in the epidemiologic study, you determine that the most significant exposures are for 1982 and earlier.

MS. McCONNELL: Mm-hmm.

DR. McCLELLAN: But that is determined from the analysis, not dictated by any shape of these or change, whatever.

So the point is that we have a data set, very substantial, but it's most relevant to telling us what happened 1982 and earlier.

MS. McCONNELL: Mm-hmm.

DR. McCLELLAN: So we need to be cautious in terms of how we move forward in terms of our extrapolation of that.

MR. PASQUIER: Roger, why don't you clarify again 1982 was the --

DR. McCLELLAN: Fifteen years earlier than 1997, with a 15-year lag period in your analysis.

MS. McCONNELL: That's right. I got you.

DR. McCLELLAN: It's well known that, you know, you go out in the bright sunlight today, you're not going to have a melanoma tomorrow, but you may have one 15, 20, 30 years from now. That's what we call a lag period in the analysis. So we take care of that analytically.

Let me say then that I've described particularly the exposure as one of the legs of that epidemiologic study. The population, we've already talked about coming from these eight mines. They were followed up 'til December 31, 1997, and so we have deaths that occurred up 'til then in lung cancers. And as I'm going to relate, that's about 200 lung cancers that are available for analysis. And then the third leg of the stool is our analytic procedures.

Let me now return to my prepared text on nine, the first bullet point. The DEMS data set has been analyzed by multiple analysts with widely varying results. These results emphasize serious uncertainties in the underlying data that should be acknowledged when the results are used to inform public policy decisions.

Two, as I've already related, it's important to recognize there are substantial differences among the eight mines studied in DEMS that we've already gone over. These are meaningful differences related to mode of operation from conventional mining with truck haulage to continuous long haul mining operations with conveyor belt movement of ore, ventilation varying from natural ventilation with limited air movement to very substantial ventilation, 16,030 cubic feet per minute in the one mine, and wide differences in diesel equipment usage, from 638 horsepower to 6,892. Now I've shown these as adjusted horsepower. That's because each piece of equipment was evaluated and working in conjunction with the mine operator to determine was it being used all the time, was it being used 20 percent of the time or never.

MS. McCONNELL: Mm-hmm.

DR. McCLELLAN: So these are adjusted so that we could take account of differences in terms of the different mines.

And then, as I note, moreover, the mines are located in four different states -- Ohio, Missouri, Wyoming, New Mexico -- very different cultural, economic, and work environments. You always try to take account of that in your analyses, but it is very, very difficult. So it's important to recognize these differences are such that it's challenging to control for all the potential variables in the epidemiologic analyses and treat all the workers as being drawn from a single population.

Three, the worker population in the eight facilities were engaged in very different work activities and hence differences in exposure to diesel exhaust. Approximately one-third of the workers always worked on the surface, 4,008 workers, and I show less than 81 lung cancers. That's because it conformed to the rules that had been laid down for using this data. Sometimes we don't use the precise number to avoid issues around confidentiality.

Another one-third always worked underground, 4,080 workers and 82 lung cancers, and the other one-third spent some time on the surface, some time underground, and for an unexplained reason yet, this 4,227 workers had less than 44 lung cancers, and you immediately look at those and say, well, gee, that's only about half the others, but they were about the same population.

Now I emphasize these are crude incidents, and in our statistical analyses, we take account of the age of the population, and it may be that this consists primarily of younger workers who worked in both. We don't know that because of some of the restrictions placed on the analyses.

Four, the epidemiological HEI panel individual and collectively, as they analyzed the reports, I want to emphasize they had limited professional knowledge of underground mining operations and use of diesel equipment in the operations.

One member of the panel is still well-recognized internationally as an expert on diesel emissions. However, he had never been in an underground mine. However, the other panel members had limited professional knowledge of diesel technology, nor had they ever visited an underground mine.

I'm here to tell you that my own personal experience, until you've actually been in different mining operations, you're clueless about how they actually use diesel equipment. I think that was a serious deficiency. I'm disappointed. The HEI panel failed to accept our invitation to visit at least one of the mines.

So, as I've noted, the most serious uncertainty in the DEMS data set, and I'll say in most epidemiological analyses, it's exposure environments. So, in this case, it's the fact we have no actual measurements of respirable elemental carbon. So they're all estimates. And the estimates of the original team, I think they're heroic, they used this extrapolation CO, and as we've said, there are striking differences with what we developed using horsepower and ventilation.

The differences in REC estimates are most substantial for the limestone, salt facilities, which use substantial diesel horsepower in terms of their haulage activities and had less ventilation compared to the other mines. So the limestone and salt mines also had the highest portion of radon measurements above the limits of detection. Not surprising when you look at the ventilation data.

Six, it's important to recognize differences in the several metrics used for diesel exhaust exposure. As we noted, DEMS used REC. This is very important, very important now. This is different than the diesel particulate matter metric used by MSHA for the permissible exposure level. As you know --

MS. McCONNELL: Yeah.

DR. McCLELLAN: -- that metric is based on total carbon, which includes both elemental carbon and organic carbon. And I'll simply note as an aside that over this time period of this study there were substantial changes in diesel technology, fuels, that at the earlier times I'm quite confident they had much, much more organic carbon associated with them. As the technology improved, you tended to get rid of that organic carbon first, and then as I'll relate later, newest technology moves towards reducing the elemental.

A major strength, seven, a major strength of the DEMS data set is the availability of smoking history data for the case control study, and that's data we have on 198 lung cancer cases and 562 incident density sampled control subjects.

Now it would have been great if we had smoking history on the total population. That simply wasn't economically feasible. But as we all know, smoking is a major, major risk factor. So our challenge in any of these studies is trying to tease out whether over and above that lung cancer hazard from cigarette smoking in the population we have some added risk or hazard that can be teased out for REC and/or radon.

In eight, both the original NIOSH/NCI investigators and the independent analysts observed the smoking status, never, former, current, and smoking intensity, former smoker, over two packs a day to a never smoker, and I've shown the data there. The odds ratio, 5.4; for the current smoker of over two packs a day the odds ratio more than doubled, 12.41. Exposure levels make a difference.

The original investigators found that among never smokers, ever underground workers, and surface workers had a similar odds ratio, suggesting the lung cancer risk by surface workers only was mainly due to the smoking. So we have low diesel exposures of surface workers, but smoking is driving that lung cancer risk.

MR. PASQUIER: In a trona mine, you can't allow people to smoke underground, so that underground population from a very early stage would not be smoking.

MS. McCONNELL: Mm-hmm. Okay.

DR. McCLELLAN: So that becomes a key difference, also the cultural differences in smoking as you look across these four different parts of the country.

Nine, the original investigators found the lung cancer risk was substantially higher for surface workers than those who ever worked underground for both current and former smokers. For current smokers of one to less than two packs a day compared to never smokers, the surface only workers had an odds ratio of 13.34; two, 39.53 compared with an odds ratio for the similar exposure groups of 4.51 and 13.58 under, ever underground.

So this unusual and unexpected finding was not adequately explained and suggests, again, a high degree of caution should be exercised in using a group that combines individuals who spent some time on the surface, some time working underground, and then always underground workers. That's precisely the analysis that the NCI/NIOSH investigators did.

They took the two groups, the roughly 4,000 that always worked underground, and combined with that individuals who spent time on the surface and underground. It gave you greater statistical certainty, but it creates great uncertainty as to how well you're controlling for the cigarette smoking.

Ten, the analyses of the original investigators, the analyses of the independent analysts, both identify strong differences in lung cancer hazard associated with REC exposure among the different mine populations. The greatest lung cancer risk was in the limestone workers, with lower lung cancer risk associated REC exposure in the pot ash and trona workers. Indeed, the odds ratio for the pot ash workers was statistically significant only at the highest quartile of cumulative REC.

Moreover, for the trona workers, the odds ratio for neither average REC intensity nor for cumulative REC were statistically significant.

MS. McCONNELL: So what's the difference?

Why is there a difference depending on the commodity?

MR. ELLIS: Ventilation could be a major factor because both pot ash and trona mines are gassy mines and the limestone isn't.

MS. McCONNELL: And some use electrical powered versus diesel? No, they all use --

MR. ELLIS: No, they would be the same. It's just the quantitative amount, then it's ventilation that's used.

MS. McCONNELL: Okay.

DR. McCLELLAN: That drives it. We see that again up here --

MS. McCONNELL: Yeah, that's true.

DR. McCLELLAN: -- in terms of the differences among those mines. But clearly, and I want to emphasize this is the find -- these are the findings of Silverman, et al., the original NIOSH/NCI. These are -- we did a slightly different analysis, and I would -- I do think these are correct. I think Dr. Silverman and colleagues did get it right there.

Eleven, the HEI report building on the work of independent analysts developing alternative exposure estimates in a detailed Appendix F encouraged the development of an alternative REC exposure estimate based on mine diesel equipment horsepower and ventilation, just what we've done here. So building on that, we went back and we actually did then the epidemiologic analyses using these data.

Twelve, using the horsepower/CFM-based REC exposure estimates, none of the trend lines for the odds ratio were statistically significant. Moreover, these trend lines were smaller by roughly factors of five without control for radon and factors of 12 with control for radon. Radon, as you know, is a well recognized carcinogenic hazard. And the 95 percent confidence intervals for these trend slopes had only minimal overlap with those for the slopes in the original analysis.

Could we move to the -- these are a somewhat complicated set here, but we'll walk our way through them. These are reported in the Crump, Van Landigham, McClellan paper. And, again, these are using the DEMS data and in the red they're using the REC exposures of the DEMS original investigators. In the blue are shown our analyses using the HP/CFM REC.

MS. McCONNELL: Okay.

DR. McCLELLAN: So Silverman at the top, you can see the quartiles of average REC intensity. We see the number of cases. We see the number of controls, and we see a very clear evidence there, the odds ratio, the lowest quartiles referred group, and then we see 0.74, 1.54, 2.83. So it's pretty clear there's a exposure/response relationship there. We see the P value for the trend, 0.001, and we see the slope, 0.00073 cancer risk per microgram per cubic meter exposure. We see the confidence intervals.

And then the next set down we've got basically another variant of that. But most importantly I want to drop down to the blue. Now we have what we think is an equally good or superior REC estimate, simply straightforward, horsepower/ ventilation, and you see again the cases, the controls, and it looks like in that third block down we've got a marginally statistically significant effect there, odds ratio of 2.37, and it's got a P value of 0.06, and that goes through -- now, when we do with the radon controls, and you see that the odds ratios are lower and it's no longer statistically significant clearly at 0.63. So we see the impact of using what we think are the improved REC estimates and control for radon.

Let's go to the next visual if we can, Mark.

So now, as I said, Silverman, et al., in that field, they group together all subjects whoever worked underground. We have to realize now about half of this population always worked underground. The other half had surface and underground. And so we see with Silverman's analysis there above a clear exposure response. We use the REC estimates from Silverman and without radon control. We see the values.

Now most significantly, we drop down to the blue and we see, again, it looks like at the third panel down there's a exposure/response relationship, but it's no longer statistically significant, 0.16, and then, when we bring in radon controls, it's gone.

Next slide.

Then the novel part of our analyses and one that I say is open to criticism, we said the people we have most confidence in knowing their exposure must be that group of individuals who only worked underground. So this is an analysis that you'll find only in our paper and clearly here there is no signal. There simply is no signal, and whether you -- without radon control, and with radon control it drops even further.

MR. FINDLAY: What are the dates?

DR. McCLELLAN: What?

MR. FINDLAY: The dates, what years does this correspond to?

DR. McCLELLAN: This is -- all of this is the same cohort.

MS. McCONNELL: Same cohort.

DR. McCLELLAN: They started from the time of -- well, they were assembled in 1998, but the population that was assembled, and that meant winnowing down the probably 16,000 workers to 12,000 workers because some workers didn't have complete records, whatever. All of that was done by the original investigators, and it was determined that vital data would be followed through December 31, 1997. So what we have in this panel here are showing those workers, out of the 198 lung cancer cases, the subjects who only worked underground and incident match controlled.

MR. FINDLAY: So you're kind of correlating this with our current standard? Is that what you're --

DR. McCLELLAN: Well, I've got it. Let me kind of jump out of this.

The current, the current standards were put in place, what, 2006.

MR. FINDLAY: Mm-hmm.

DR. McCLELLAN: They were based on the epidemiologic evidence that existed through about 2000.

MR. FINDLAY: Right.

DR. McCLELLAN: Okay. And it was decided in the case of the metal and nonmetal mines that you would use a PEL to limit exposure. In the case of the coal mines, you put your limit on the diesel equipment, as we'll discuss later for good reason. So that was based on the scientific database then.

The assumption behind your current rule is that perhaps the risk has gone up. I'm here to tell you that we really don't have any evidence at this point in time. A quantitative risk analysis, if one wanted to do it, might show you that retrospectively the risk was this based on data available through 2000, and it's this level based on inclusion of the DEMS data or exclusively the DEMS data.

It is quite possible that it could actually show a lower risk. That's why I say the fact that you have a more certain characterization of hazard does not automatically translate somehow there's a greater risk to be controlled. That's why it's important to get this right at the beginning of the rulemaking process. Make certain the science is in place so that you can make that determination as to whether that current standards are appropriate or not.

MR. FINDLAY: Would you say this data is more applicable to like a retrospective?

DR. McCLELLAN: Oh, absolutely, that's right. I have told my clients that if you're involved in litigation with regard to workers who were exposed in 1997 and earlier, more particularly, 1982 and earlier, this is the data set that's applicable, but changes in diesel technology or such, you can't say that this has direct applicability today.

MR. FINDLAY: Correct.

DR. McCLELLAN: I'm going to come back to that later.

Are there any other questions on this particular table? I've included it here in my testimony, but it's also in my critique.

MS. McCONNELL: I don't have one right now.

DR. McCLELLAN: Okay. Thank you.

So let me just state, thirteen, in my opinion, the results of the original analyses of the DEMS data and those of the independent analysts in aggregate are probably adequate for evaluating the carcinogenic hazard of exposure to traditional diesel exhaust characteristic of diesel engines, high sulfur fuel content used in 1988 and earlier. That was your very good question. And as the HEI panel recognized, DEMS does not investigate, nor is it relevant to exposures to the newer diesel engines or fuels.

In my opinion, the uncertainties in the results from the analysis of the DEMS data are so substantial that extraordinary caution should be exercised in moving beyond their use in hazard characterization, this qualitative assessment that's been done, to using any single analytic result based on the DEMS population for quantitative risk assessment.

Indeed, our quantitative understanding of the lung cancer risks of diesel exhaust exposure may be no better today than existed when MSHA made policy judgments, published a final rule on May 18, 2006, phasing in a final diesel particulate permissible exposure limit of 160 micrograms of total carbon per cubic meter.

Fifteen, it is my understanding that NIOSH has already initiated preparation of a diesel exhaust risk assessment (DERA) which will be available to MSHA and OSHA for use in regulatory decision-making. I'm eager to share my critique with the NIOSH scientists developing that DER so they can be fully informed about the serious limitations in the original analyses conducted by the NIOSH/NCI investigators and the need to consider the later results published by independent analysts.

Recognizing that any risk assessment developed by NIOSH will have potential use for MSHA in regulatory rulemaking, it's very, very important that MSHA encourage NIOSH to make public the agency's risk assessment protocol and related activities for public review and comment at the earliest possible date.

MS. McCONNELL: Thank you very much, and you've given us a lot to digest.

DR. McCLELLAN: Yeah.

MS. McCONNELL: And I have a very simplistic question right now.

DR. McCLELLAN: Okay.

MS. McCONNELL: And that is, and I take your point that the DEMS study and the HEI panel's recognition that the DEMS study did not investigate for newer diesel machines and newer diesel engines or fuel, but I guess my question is, in terms of our existing mines, underground mines, what is their inventory? Have they been replacing these older engines with newer engines? Are they using more effective after-treatment technologies? I mean, are the conditions as they were when the estimates were made?

MR. ELLIS: I sort of roll back to what Mr. Chajet said at an earlier hearing. MSHA probably is best positioned to have that information available to it. I know that in the situation of underground coal mines you've got diesel inventories for all the equipment that's out there. I think this is the kind of information that we feel would benefit this collaboration that we're suggesting be formed under this NIOSH partnership.

There's a lot of information out there, and nobody has really tried to pull it all together to see how it affects the analysis and the conclusions you're going to try to reach in this process.

So I think that one of the things that we are going to ask for as part of this partnership is that information be made available, you know, freely so that it can be digested by other people, debated, see where there's area of consensus, find out where there's other research opportunities to fill the gaps that are out there.

MS. McCONNELL: Okay.

DR. McCLELLAN: I think your question -- also just let me go beyond it and say I was truly impressed, and I spent many, many days going through the DEMS data on the mines, and this was the data that was developed by the mine operator year by year, specific pieces of equipment, year of manufacture, year put in use, percentage time use. It was really a remarkable data set on the sources of exposure.

What was also very important was that it included year-by-year ventilation data on each of the mines. That was extraordinarily valuable. And I would say a third point that looms today is, you know, an engine can't produce emissions unless it's fueled.

MS. McCONNELL: That's true.

DR. McCLELLAN: Fuel quantity.

MS. McCONNELL: It's not running, is it?

DR. McCLELLAN: No, no.

MS. McCONNELL: Okay.

DR. McCLELLAN: No. But many people miss that.

MS. McCONNELL: Yeah.

DR. McCLELLAN: I submit that a very good estimate of what's in the air in a mine determined in part by diesel equipment and fuel usage and ventilation, and one of the things we do know today or at least the mine operators that I have worked with have moved to using ultra-low sulfur fuel as a sole in terms of must be used today in terms of on-road operations. That's 15 ppm and lower, and work that I have done show that most times delivery at the pump is 10 ppm sulfur and lower. And I know going back to earlier times to give us a benchmark we had fuel that was being marketed that was 1500 ppm and moved down some 500.

So it's important to recognize that that's a blanket -- that's a situation there and I suspect most mine operators have gone to that high-quality fuel.

MS. McCONNELL: Okay.

MR. ELLIS: If I can just add a little bit to what we've been talking about here in terms of the data that's available. Looking at the changes that have been made in diesel technology, diesel control technology, diesel fuel types, MSHA in the RFI notes the reductions in diesel particulate exposures that have happened since the rule went into effect.

MS. McCONNELL: We do.

MR. ELLIS: You know, we actually have exposure readings now, and to be able to correlate that with changes in technology, changes in control technologies, changes with fuel types, I mean, there's a lot of insight that could be gained by getting all this information out there and doing some analysis of it.

MS. McCONNELL: Okay. That's very good.

Greg, did you want to -- I know this is not your purview, but did you have any questions?

MR. MIEKLE: The ventilation studies were on the fan or on the workplace?

DR. McCLELLAN: The data that I reviewed were data in terms of total mine ventilation. So I would suspect -- I know from personal knowledge ventilation is costly, so you want to use it effectively to try to reduce exposure. But that data was not available within the DEMS data set.

MS. McCONNELL: Okay. Thank you. You've given us a lot to think -- a lot of food for thought.

DR. McCLELLAN: I'll be pleased to address any other questions you may have later on these.

MS. McCONNELL: Okay. Thank you.

DR. McCLELLAN: We will make certain that you have these key papers.

MS. McCONNELL: Yeah, that would be good to have so we can add that to the record.

DR. McCLELLAN: Yeah.

MS. McCONNELL: Excellent. Thank you.

MR. ELLIS: Thank you.

MS. McCONNELL: Okay. Our next speakers are Linda Raisovich-Parsons and Josh Roberts. Are you testifying together?

MR. ROBERTS: We can.

MS. McCONNELL: Okay. They're with the

UMWA, United Mine Workers of America, for the record, for the court reporter.

MS. RAISOVICH-PARSONS: Good afternoon.

MR. ROBERTS: Good afternoon.

MS. RAISOVICH-PARSONS: Do you want me to go first?

MR. ROBERTS: Yeah.

MS. RAISOVICH-PARSONS: All right. Good afternoon. My name is Linda Raisovich-Parsons and I currently serve as the Deputy Administrator of the United Mine Workers of America, Department of Occupational Health and Safety. I'm here today to voice the United Mine Workers' support for the Agency's efforts to update diesel standards.

As MSHA points out, miners' exposures to diesel exhaust presents an increased risk of lung cancer. Epidemiological studies by NIOSH and the National Cancer Institute have concluded that exposure to diesel exhaust increases risk of mortality from lung cancer and have important health implications.

We applaud the Agency for addressing the much-needed update to the respirable dust rule which kicks into its final phase in August, which has taken much time and energy to finalize. However, the time has come to look towards the next chapter, and that chapter must be to move forward with a much-needed update to the diesel standards. This must be the next priority for the coal industry. I ask, what have we gained if we protect miners from pneumoconiosis but let them die of lung cancer?

MSHA indicated that it is revisiting the diesel exhaust controls because "of the carcinogenic health risk to miners from exposure to diesel exhaust and to prevent material impairment of miners' health". There is sufficient evidence in many from the scientific community who substantiate that diesel exhaust exposes miners to risk of lung cancer. Some of those include the Diesel Exhaust in Miners Study by NIOSH, the National Cancer Institute, the International Agency for Research on Cancer, and the Health Effects Institute, who have all confirmed that diesel exhaust contains carcinogens and pose a risk, a significant risk of lung cancer.

The Agency nor the mining community can continue to delay dealing with this serious hazard. The time has come. So I applaud the Agency for moving forward on this issue.

As pointed out, the States of West Virginia, Pennsylvania, and Ohio have moved forward with a much more progressive regulation and approach to the use of diesel equipment. In prior years most of these states completely prohibited the use of diesel equipment in underground coal mines. When the decision was made to permit the use of diesels through legislative change in these states, it was approached as a collaborative effort with industry, labor, and the state inspection agencies involved in developing the regulations for diesels.

The result has been effective regulations which produce efficient, clean-burning diesel engines. Those states require diesel-powered equipment, to include an exhaust emissions control and conditioning systems which meet stricter DPM emissions limits. They also limit ambient concentrations of exhaust and some limit ambient nitric oxide as well. In addition, they require certain testing, examination, and maintenance records.

I am far from being an expert on this subject, and most of my testimony today addresses generalities. However, our UMWA international representative, Ron Bowersox, who you heard from at Pittsburgh, PA hearing, serves on the Pennsylvania Diesel Commission, which approves all diesel equipment for use in underground mines in Pennsylvania. He is intricately involved in the testing and approval of diesel equipment for use underground in the State of Pennsylvania.

Since their introduction into coal mines diesel manufacturers have come a long way in the development of this technology. The emission scrubbers and catalysts used in those states are doing an excellent job. Ron relayed to me that in most recent instances in the approval of new equipment the emissions technology burned so cleanly that the new machines would pass the emission measurements on the untreated or the dirty side of the engine. This is a great improvement over those states still relying on the federal code. The miners in other areas of the country need and deserve the same protections.

Many of the questions MSHA raises in the Request For Information involves the cost of such improvements. I must question if it is fair to those coal operators in the states with stricter regulations to bear the cost of these improvements while the rest of the industry does not. Further, is it fair to provide those protections only to miners working in these three states and not to the rest of the nation?

This will only level the playing field as far as costs are concerned, and more importantly, health protections for our nation's miners. This is why it is only reasonable that we act now to update the diesel standards.

The improvements to diesel engines, scrubbers and catalysts are long overdue in the mining industry. The rest of the United States needs to play catch-up with the states that have moved ahead with these systems and are benefitting from them.

I have worked in the mining industry and with mine health and safety for 40 years this year. Over that time I have witnessed much change in evolution to mine health and safety. I can remember in the '70s and '80s the leading cause of mine deaths were roof falls, until the introduction of the automated temporary roof support system and remote-controlled miners. Now it is rare that we have a mine fatality attributed to a roof fall. Likewise, the new respirable dust rule will go a long way in reducing black lung in our mining industry.

The risk of lung cancer from the use of diesel engines underground is real, and the time to improve these standards and reduce that risk has come.

I thank you for your time.

MS. McCONNELL: Thank you, Linda.

MR. ROBERTS: Josh Roberts, Administrator of Health and Safety, United Mine Workers. It pleases me to hear that the Agency has decided to take steps in reviewing its current rules and regulations pertaining to miners' exposure to diesel exhaust. Since MSHA's final rules in 2001 for underground coal mines and 2006 for metal and nonmetal mines, studies from NIOSH have proven that exposure to diesel exhaust increases your chances of developing lung cancer. Studies have also shown that underground miners can be exposed up to 100 times more the typical environmental concentration of DPM and more than 10 times what might be found in other occupations.

With an ever increasing amount of diesel equipment being used in underground mines, the Agency must act quickly to address these issues and to protect miners from such negative health effects. The question before us is how do we do it. My recommendation is take a look at the Pennsylvania and West Virginia mining laws pertaining to underground diesel equipment and emissions. These agencies have created laws that are much more stringent than the current federal laws and are the gold standard when it comes to diesel rules in underground mines. It is my hope that MSHA will take a hard look at what they have done and model their own rules and regulations after them.

Some of these states' regulations and requirements include an exhaust emissions control and conditioning system that dilutes the DPM from -- dilutes the DPM to .012 milligrams when diluted by 100 percent of the MSHA approved ventilation rate; a DPM filter capable of reducing the DPM by at least 75 percent; an oxidation catalyst capable of reducing carbon monoxide emissions to 100 ppm or less; a system capable of reducing the exhaust gas temperature below 302 degrees; an automatic engine shutdown system that will shut off the engine before the exhaust gas temperature reaches 302 degrees; a sampling port for measurement of undiluted exhaust gases as they leave the engine and also before they enter the mine atmosphere; an on-board engine performance and maintenance diagnostics system capable of monitoring engine speed, operating hours, intake restriction, exhaust back-pressure, cooled exhaust temperature, coolant temperature, oil pressure, and oil temperature; exhaust gas limits for the mine atmosphere of 35 ppm for carbon monoxide, 25 ppm for nitric oxide, and 3 ppm for nitrogen dioxide; the requirement for an operator to develop a detailed and comprehensive maintenance plan, strict recordkeeping requirements of all emission tests, pre-operational exams, and maintenance and repairs, complete equipment maintenance performed every 100 hours; eight hours of diesel training every year separate from the requirements of 30 C.F.R. Part 48.

These states have these regulations for many years with much success. They also produced over 172 million tons of coal in the year 2014. This proves that these regulations can be in force while at the same time the mines be productive and competitive. It is my hope that industry will take a hard look at what these states have done with these regulations and apply them to their own rules and regulations.

I firmly believe that the current federal law is nowhere stringent enough to adequately protect miners from the negative health effects of diesel particulate matter in underground mines. The miners we serve deserve to have better protections in place for their health, not just protection from pneumoconiosis caused by coal dust but also from lung cancer caused by diesel particulates.

Thank you for your time.

MS. McCONNELL: Thank you.

Greg, do you have anything? No? I don't have any questions. I appreciate your coming here today and your testimony. Thank you very much.

MR. ROBERTS: Thank you.

MR. FINDLAY: Oh, hold on, please.

MS. McCONNELL: Well, do you have -- I'm sorry. There's one question.

MR. FINDLAY: Are you aware of any other states that might be working on rulemaking besides Ohio, Pennsylvania, and West Virginia?

(No verbal response.)

MR. FINDLAY: Nothing? No activity on that topic now?

MR. ROBERTS: No.

MR. FINDLAY: Okay. Thank you.

MS. McCONNELL: Thank you.

Our next speaker is Ed Green, BCOA, Murray Energy -- I can't read the last one.

MR. GREEN: Good afternoon, everybody. It's nice to be here on the home stretch as we finish this public meeting this afternoon, and, Sheila, I appreciate the distinction between the hearing and a public meeting. Thank you.

MS. McCONNELL: You're welcome.

MR. GREEN: My name is Ed Green, and I'm here today to present a statement regarding MSHA's RFI as published in the *Federal Register* for June 8. My statement is offered on behalf of Murray Energy

Corporation, the largest privately owned coal company in the United States; the Bituminous Coal Operators Association, a trade group that represents a number of entities dealing with the United Mine Workers; and Bridger Coal Company, which is a company in Wyoming, an underground coal company that provides coal to the Bridger Power Plant.

To begin, we're pleased to provide MSHA with this statement. We're reviewing the RFI with great interest, and our preliminary view is that it will help us and all stakeholders focus on a topic that is worthy of attention.

We want to say right off the bat that we support and agree with the statements of the Industrial Minerals Association proposing that MSHA and NIOSH establish a diesel health effects partnership and that MSHA grant at least a 90-day extension of the comment period from the current deadline of September 6. That extension will allow stakeholders to benefit from what we expect will be learned from the first meeting of the partnership.

I couldn't be more passionate in recommending this partnership, panel members. I think we all know that they've been extraordinarily valuable in other complicated technical topics. Sheila, you were at the meeting of the Refuge Alternative Partnership several weeks ago in Pittsburgh.

MS. McCONNELL: That's correct.

MR. GREEN: And I think it's fair to say you probably learned more in that short period of time than you were able to --

MS. McCONNELL: Actually, it was on proximity.

MR. GREEN: Proximity detection.

MS. McCONNELL: Right.

MR. GREEN: It gets confusing after a while for old people like me, you know. But in any event, it was a very, very worthwhile meeting I think you'll agree and you learned a lot.

MS. McCONNELL: I did.

MR. GREEN: I think the partnership would allow the same sort of attention to be brought to complicated problems, and I should add there is a Refuge Alternative Partnership too that is also dealing with a very, very complicated topic.

So what we want to do is describe -- what I want to do here is to describe briefly how MSHA currently regulates the exposure of underground coal miners to diesel exhaust. There are fundamental differences between those regulations and the MSHA rules that govern the exposure of underground metal and nonmetal miners.

And I'm going to also briefly address the recent research identified in the RFI, and I'm going to reintroduce Roger to the MSHA panel because he's also an advisor to the companies, as well as to the IMA-NA. And finally we'll address our understanding of the true underlying basis for the initiation of this RFI and we'll remind MSHA that at a time when the companies are dealing with the greatest ever economic downturn of the entire U.S. coal industry, MSHA must take into special account the economic feasibility of any regulatory steps MSHA may advance as a next step.

And from a personal perspective, I want the MSHA panel to know that I've been working frequently on diesel safety and health issues since 1972, first as a lawyer in the early days of the modern Federal Mine Safety and Health Programs; secondly, as the general counsel to the American Mining Congress, a precursor group to the National Mining Association. That's when I met Roger for the first time, when he was serving on the MSHA Diesel Advisory Committee; and lastly as an attorney in the nationally recognized mining practice at the Washington law firm of Crowell & Moring.

So let me speak quickly now to the current MSHA regulations as far as underground coal mines are concerned. Those are contained in several portions of 30 C.F.R., scattered around in the Code of Federal Regulations.

First, you have Subpart E of 30 C.F.R. Part 7 dealing with diesel engines intended for use in underground coal mines.

Second, you have Subpart F of Part 7, those are diesel power packages intended for use in areas of underground coal mines where permissible electric equipment is required.

Then you have 30 C.F.R. Part 36 that deals with approval requirements for permissible mobile diesel-powered transportation equipment. And then you have 30 C.F.R. Part 72, which are the health standards for coal miners in Subpart D, diesel particulate matter in underground areas of underground coal mines; and finally, 30 C.F.R. Part 75, mandatory safety standards in underground coal mines; Subpart D, diesel-powered equipment. Subpart D deals with things like maintenance, fuel requirements, fire prevention regulations, and a bunch of other miscellaneous issues.

But at the heart of those regulations are the provisions of Subpart D and Part 72. The various sections, 72.500, 72.501, 72.502, set forth grams per hour emission limits of diesel particulate matter for permissible diesel-powered equipment; in 72.500, non-permissible heavy-duty diesel-powered equipment, generators and compressors; and 72.501, in non-permissible light-duty diesel-powered equipment other than generators and compressors.

So there are some exceptions. Generally speaking, MSHA is going to determine compliance with these emission requirements, and this is a critical difference between the coal regulations and the metal and nonmetal regulations.

MSHA uses the amount of DPM emitted by a particular engine during the Part 7 engine approval testing. That amount is what is put on the machine as the grams per hour limit, and then once it's deployed underground, those engine emissions are -- the limits are not tested in real time for a very simple reason, because real-time testing would be unworkable in an underground coal mine considering that the ambient atmosphere contains particles of carbon from the coal being mined, as well as the carbon contained in the coal itself.

So a PEL like we have in the metal and

nonmetal regulations is not realistic for coal mines, and this regulatory scheme for exposure of miners to diesel exhaust is necessarily very different from that in underground metal and nonmetal mines where miners' exposure is based on a measured, real-time personal exposure limit of DPM expressed as total carbon, as set forth in 57.5060.

Now, with that important distinction in mind, the companies note that the RFI identifies key recent research on which the RFI depends. You've already heard from Dr. McClellan speaking for the IMA-NA in what I thought was a wonderful tutorial. Dr. McClellan is also a consultant for the companies, and as such, we not only endorse his presentation for the IMA-NA, but following my introduction Roger is going to have some additional commentary to give to you on our behalf.

We also want to remind the panel that pursuant to Mine Act Section 101(a)(6)(A) MSHA must consider all of the latest scientific evidence in the field, and in that respect, the companies also endorse Dr. McClellan's critique of the HEI report referenced in the RFI. And very importantly, the companies strongly, strongly agree with the idea of establishing an MSHA/NIOSH partnership with all of the stakeholders to discuss in detail the questions MSHA has raised.

Before the hearing started, and I'm certainly not speaking for the UMWA or for anybody else other than my clients, but I briefly talked with the folks from the UMWA. They can speak for themselves if they wish. And I think they are interested in the idea of a partnership, and I hope that MSHA will strongly consider that with your sister agency, NIOSH. It's an important solution to dealing with difficult technological issues, and we think it's a very, very important thing to do.

As far as our understanding of what the true basis for the RFI is, we've read the introductory language and we're aware of the Salt Lake City, Utah, and Pittsburgh hearings, and we've seen in the RFI that MSHA has said that the Agency's mind is open at this juncture as to whether additional rules dealing with exposure of underground miners to diesel exhaust are necessary. We like to hear that, but candidly we wonder about its accuracy.

We say that because we're aware of 2012 letters from UMWA and a group of public health academicians appearing to petition MSHA to promulgate stricter standards for both coal and metal and nonmetal mines than those currently in effect. We also understand and I think we heard here today that the UMWA called upon MSHA -- is calling upon MSHA for new and more stringent rules, as did the steel workers in Pittsburgh.

We want to say categorically that although we're not opposed to new rules we want to make sure that they are need- and science-based. Let me emphasize again need- and science-based. And we also need to address feasibility. So before reintroducing Roger McClellan to you for his specific comments, on our behalf, please allow me to reemphasize and support our endorsement of his critique of the HEI report, our endorsement of the establishment of a diesel exhaust health effects partnership.

And returning to Mine Act Section 106(a)(6)(A), the companies want to remind MSHA of its mandatory obligation to consider the feasibility of any new rules the Agency may adopt. Feasibility not only includes technological feasibility, which is difficult enough, hence our request for the partnership, but also economic feasibility, and in that regard, MSHA has to take into account that the U.S. domestic coal mining industry is under severe stress, with several major coal producers, public coal producers undergoing Chapter 11 reorganization as we meet here today, and with prices down and environmental regulatory pressure up. And with all of that in mind, I will turn to Dr. McClellan so he may give you his additional comments and another tutorial.

DR. McCLELLAN: Good afternoon. Thank you for allowing me the opportunity to speak to you today for a second time. I am Roger O. McClellan, advisor on toxicology and human health risk assessment matters, with emphasis on issues concerning airborne materials, such as diesel exhaust, and their potential health effects in workers in general population.

As I noted earlier today, I have a special interest in and have conducted research on health hazards of diesel exhaust emissions since the 1970s. I would like to ask that my written comments be entered into the record in their entirety, and since we've covered some of these points quite well earlier today I may offer some abbreviation in the interest of time.

I do offer this statement on behalf of the Murray Energy Corporation, the Bituminous Coal Operators Association, and Bridger Coal Company, the companies. I'm serving as an advisor to the companies on developments regarding the potential health effects of exposure to workers to diesel exhaust emissions.

The companies, their legal counsel and I have read with great interest MSHA's Request For Information on Exposure of Underground Miners to Diesel Exhaust. It's my understanding that MSHA issued that request for information and is holding these public meetings to gather information to enable the Agency to review its existing standards and policy guidance on controlling miners' exposure to diesel exhaust, to evaluate their effective -- the effectiveness of the provisions now in place to preserve miners' health.

The companies obviously value worker safety and health, welcome the opportunity to participate in this fact-gathering process. I'm here again, as I emphasized earlier today, to urge MSHA to ground its inquiry in all the science, consider all of the currently available information on potential health effects of exposure to diesel exhaust. It is a very complicated, very voluminous literature challenge to interpret. It's, as I said earlier today, critically important at this initial phase that MSHA review all the available information, get the science right, and as I said, it is a very complicated science.

I can digress and note that as I discuss with my scientific colleagues, this issue of the different metrics, their eyes start to glare over. Sometimes they're even befuddled as to what they used in their last analysis. They sometimes say, well, it was diesel particulate matter, and I ask, was it total carbon? Well, it was diesel particulate matter. That's what the industrial hygienists gave us. Did it include organics? I don't know.

So you've got that challenge because as you work through this data it's critically important we understand all the units and how it fits together.

As I noted earlier, it's important to recognize the science informs the policy decisions that are inherent. Science can't give the right number. It's the science that informs well-intentioned, well-informed policymakers that come up with the particular policy outcome.

I offered comments earlier today in terms of the recent research. I won't belabor a lot of that. Simply note first that we have only the two papers from the original investigators in DEMS that are cited in the RFI. That must be complemented by the five detailed papers that NIOSH/NCI developed on the exposure assessments, and it's important that we move beyond that and, as I note in Item 2, this work of the independent analysts.

This truly is a remarkable situation. We've had the Congress involved in debating thousands of hours, they've introduced bills in terms of secret science. All of these bills call for an openness in science, a sharing of data. The national academies, National Research Council has recently published a report on a conference that addresses this whole issue of sharing of data. I'm here to tell you this is a real-world example that the system can work, data can be shared, and independent analysts can sometimes come up with different answers in terms of that data.

So, in this case, we've had a very rich data set, DEMS, that has been used effectively by the original investigators and now by the independent analysts. So you'll need to get that into the system.

We went through this earlier today, the importance of REC and understanding that this rich data set can be used to come up with alternative estimates of REC, and I think when you examine those papers carefully you'll agree with me that the REC estimates that my colleagues and I develop based on horsepower and CFM are a very simple and direct approach and deserve at least as much attention, if not more, than those of the original investigators.

It's not necessary for us to say this is right, that's wrong. There is no right/wrong answer in terms of the REC estimate, but one does have to understand the uncertainty because that uncertainty is going to underlie then any of the policy decisions that are made.

Likewise, in terms of three, the Health Effects Institute and their panel, I certainly applaud that effort. I followed it very carefully. I know they were well-intentioned individuals participating. I am somewhat alarmed that one of the members of the panel stated publicly that he gave only secondary considerations on the part of the independent analysts because after all it was funded by industry.

I am here to tell you publicly that my position is science and the quality of science is not determined by the individual's employer but by the integrity of the individual scientists, and so I'm certainly not embarrassed to say that I've accepted money from federal agencies and from private entities and private companies, and my science is part of my integrity.

Four, when only the analyses of the DEMS data available were those of the original investigators, many scientists did believe that the epidemiological evidence for diesel exhaust being characterized as a human lung carcinogenic hazard was made stronger by DEMS when compared to the evidence available pre-DEMS, the evidence that MSHA used in its previous rulemaking.

In my opinion, when the results of the independent analysts using the DEMS data set are considered in addition to the original results of the original investigators, the classification of diesel exhaust exposure as a human lung carcinogenic hazard is much less certain than when only the original analyses were used.

To ensure that any future steps taken by MSHA are grounded in science, sound science, any quantitative estimates of lung cancer risk for exposure to diesel exhaust must consider the results of all of the analyses of the DEMS data, including both the original NIOSH/NCI investigators and the results of independent analysts. This is an important point that I think is very important that it be conveyed to our colleagues at NIOSH who will be taking a lead role in terms of any quantitative risk assessment that's done in terms of diesel exhaust focusing on occupational hazards.

Five, my earlier statement discussed the concept of hazard risk. As I said, they are not equals. One can have a more certain characterization of hazard and not alter the actual estimate of risk. It may go up. It may go down. And as we said, hazard is qualitative. Risk is a quantitative concept. I've long been an advocate of quantitative risk assessment, but I've also in recent decades come to better appreciate the fact that computers can crank out answers to four or five-digit points does not mean that we have more confidence in what those results are.

Six, an important point I'd like to build on as I reviewed the two approaches that MSHA has taken to regulate exposure to workers is to discuss this conceptual framework that links sources of emissions influenced by ventilation to workplace exposure environments, and workplace exposure environments are of ultimate concern because that's what the miner breathes, that is what may or may not give rise to disease. So that framework is really at the core of your strategic approach to regulating exposure of miners.

Seven, in your current regulations, you used two different approaches as I understand it. You regulate exposure to diesel exhaust in metal and nonmetal mines and coal mines differently where the metal and nonmetal mines, the regulations focus on the workplace environment and limiting exposure to diesel exhaust particulate matter to the PEL, specified as 160 micrograms total carbon per cubic millimeter averaged over eight hours. And as I said, it's very noteworthy, importanat to recognize total carbon metric for DPM includes both elemental carbon and organic carbon. This is different than the REC metric based only on elemental carbon estimated in DEMS used by both the original investigators and the team that I participated in.

In contrast, as well known to you, I'm sure to Mr. Miekle, is the worker protection of coal miners from exposure to diesel exhaust focuses on indirect control of the airborne mine environment by setting emission limits grams of diesel particulate matter per hour for diesel-powered equipment.

Now that approach is dictated, as you well understand better than I, by that complex atmospheric environment in coal mines with carbon present, coal dust, as well as in diesel exhaust, as well as carbon from other sources, and in both elemental carbon and organic carbon form.

At the very least, in assessing standards, the companies also do ask MSHA continue to be mindful of the difficulties coal operators face in accurately measuring the diesel exposure atmosphere for their workers. So we have this different situation in terms of the use of the PEL versus engine emission.

Eight, any review to evaluate the effectiveness of regulation now in place to preserve miners' health needs to be based on all the currently available scientific information on both potential health hazards and exposure to diesel exhaust. This is a case whether the strategy is based on PEL or on engine emissions. They both have to have that same science base that we're operating off of.

Nine, in my earlier statement on behalf of the IMA-NA task force, I emphasized that in considering any use of analyses based on DEMS data set or to recognize the strongest association between diesel exhaust exposure based on estimated REC and lung cancer was found when a 15-year lag between exposure and lung cancer is used.

This suggests that diesel exhaust exposures of greatest relevance to the workers in DEMS are for 1982, 15 years before the end of follow-up in December 31, 1997 and earlier. DEMS thus does not account for the revolutionary changes in diesel technology, engines, engine after-exhaust after treatment devices, fuels, and I would say computer control of the system that has occurred in recent decades.

I've been impressed by that and I have published a paper on that which I will provide you a copy of emphasizing how revolutionary these changes have been. I think it's one of the most significant revolutionary changes of the industrial age.

Those changes have largely in recent years been driven by the U.S. environmental agencies' diesel regulations, and the new technology has been first implemented in the heavy-duty on-road fleet and then later in other sectors. These are developments I follow very closely. There again is a significant literature, but I in particular would call attention, your attention to two papers by Khalek and colleagues, one in 2011 that relates to engines operating to meet EPA's 2007 rule and then in 2015 a publication relating to engines meeting the 2010, which is important because, as you know, 2010 rule considers both particulate emissions and the oxides of nitrogen, and obviously both are of concern to you.

Let me just say as an aside that the engines that were evaluated by Dr. Khalek in 2011 were used in conducting a long-term cancer bio assay at the

Lovelace organization in Albuquerque, New Mexico, an organization that I headed up for some 20-plus years, and in those studies, obviously the difference in particulate emissions that were being studied were remarkably different than what we studied in the 1980s and about 100-fold lower.

And what I'm pleased to note is the results of that study show that in the laboratory animal exposed essentially for lifetime there was no carcinogenic effect of exposure to maximum concentrations of the diluted diesel particulate matter. So that was reassuring in terms of those.

The new technology diesels have virtually no elemental carbon or organic carbon in the emissions. They are remarkably clean, and that's evident in the papers by Khalek. So MSHA must consider these revolutionary changes in technology, as well as the feasibility of their implementation.

Ten, finally the issue of relevance of any findings from the study of workers in nonmetal, salt, pot ash, trona, limestone operations like those followed in DEMS, and as we've already emphasized at the time, to the coal mine workers needs to be carefully examined.

And it's my understanding that our

underground coal mines typically are treated as though they at least have a potential for methane build-up, and thus as gassy mines they're ventilated accordingly. That's obviously very favorable to us when we look at the atmospheric environment and the impact of the two sources, the diesel engines and ventilation rates that impact on potential exposure to workers.

So thank you again for providing me the opportunity to speak to you today. Be happy to take any questions you have.

MR. GREEN: And let me just add something if I may that Roger's commentary prompts me to say, and that is with regard to the science. All of the science that MSHA relies on in the RFI has really no nexus to speak of to the underground coal mining industry, and I want to urge MSHA to consider that as you consider the next steps with regard to coal.

That's not to say, again, that there may not be a rationale for reexamining the underground coal mining regulations. The notion of the new requirements in West Virginia, Ohio, and Pennsylvania, if I recall them correctly from what the UMWA had to say, may be important to look at, but once again I urge the Agency to turn to its sister agency, NIOSH, and to at least to start with put all of these important issues into the context of a partnership so that all of us can learn together how best to address the problem.

And, again, returning to the science, we have lots of interesting science with regard to underground mining. Virtually all of it has to do with non-coal mines, if you will. Roger said that his understanding is that all of the underground coal mines have to some degree have to be ventilated. Well, as Greg knows and Sheila knows, and I think you know too, Chris, if you stand up straight in an underground coal mine, you'll be blown away by the ventilation that is coming into the working spaces.

So ventilation in underground coal mines is key because it blows away respirable dust as well as methane, and if it blows away respirable coal mine dust, it also blows away diesel exhaust, so there's a whole different, in my humble opinion, a whole different set of problems dealing with underground coal as opposed to the science that you've identified in the RFI.

DR. McCLELLAN: There's one other point I might raise in that I was given some feedback in terms of your previous meetings and I understand that there were perhaps some casual discussion of yet another metric of material in the airborne environment, and that's particle number, and I want to just briefly introduce that to you and say that the issue of regulating engine emissions, diesel engine emissions particularly, based on particle number has received a lot of consideration in Europe, and there have been individuals who have alleged that while we've reduced the particulate emissions, DPM or REC, we've "left unaltered or increased" inadvertently the particle number emissions, and that issue is discussed in some degree in one of the Khalek papers, but I just want to emphasize that that issue does deserve careful attention in my opinion.

The science is that the brief period of increased particle number emissions associated with package of diesel technology is very brief and that there's not a need to move out and start thinking about how we're going to regulate on that or in some way that takes away from these really revolutionary changes that have been made in reducing particulate matter emissions, both elemental carbon and organic carbon. So I just wanted to enter that into the record.

MS. McCONNELL: Okay. Thank you. I don't

have any questions for you, but, Greg?

MR. MIEKLE: I don't have any.

MS. McCONNELL: Well, thank you very much for your testimony. You've given us a lot to think about. Thank you.

That was our last speaker who officially signed the sign-in sheet. Is there anyone else who would like to please join -- for the record and for the court reporter, could you please state your name?

MR. PRILLAMAN: Yes. I'm Hunter Prillaman, Director of Government Affairs for the National Lime Association. I would just like to support the idea of a partnership or some effort of that sort to address this rule change, especially on the metal and nonmetal side. The current deadline to submit comments is about a little bit more than a month from now. I predict that you're going to get a lot of very general comments and that a process that's more of a partnership or an opportunity to work together, the sort of thing that resulted in the DEMS study, I think will be a more effective way for you to develop this rule.

I just think that if you simply take comments on September 6 you're going to have to go back to the well because they're going to be quite general in nature; not from everybody, but I think a lot -- some of my members are not really prepared to provide very detailed information in that period of time. So that's my comment.

MS. McCONNELL: Okay.

MR. PRILLAMAN: Thank you.

MS. McCONNELL: Thank you very much.

Anyone else?

(No response.)

MS. McCONNELL: So there doesn't seem to be anyone who wants to make another -- make a presentation or statement today. Therefore, I am going to conclude MSHA's public meeting on the Request For Information on Exposure of Underground Miners to Diesel Exhaust. On behalf of the Assistant Secretary, Joseph Main, we appreciate your participation in this rulemaking process and encourage you to submit your comments on or before September 6. Again, we have received several requests for extending that comment period, and those requests are under consideration.

So thank you again and have a good afternoon.

(Whereupon, at 2:17 p.m., the meeting in the above-entitled matter concluded.)

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REPORTER'S CERTIFICATE

DOCKET NO.: MSHA-2014-0031

CASE TITLE: Exposure of Underground Miners to Diesel Exhaust

HEARING DATE: July 26, 2016

LOCATION: Arlington, Virginia

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the U.S. Department of Labor, Mine Safety and Health Administration.

Date: July 26, 2016

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Statement for the Mine Safety and Health Administration Public Meeting on Request for Information on Exposure of Underground Miners to Diesel Exhaust
(Docket No. MSHA-2014-0031)
(RIN 112-AB86)
Mine Safety and Health Administration Headquarters
201 12th St, South, Rooms 7W204 and 7W206
Arlington, VA
July 26, 2016

By

Mark Ellis
President
Industrial Minerals Association – North America
Washington, DC

Good morning. I am Mark Ellis, and I am the President of IMA-NA -- the Industrial Minerals Association – North America. IMA-NA is a nonprofit 501(c)(6) trade association representing North American producers and processors of industrial minerals and associate members that support the industrial minerals industry. Industrial minerals are feed stocks for the manufacturing and agricultural sectors. They are the ingredients for many of the products used in everyday life, such as glass, ceramics, paper, plastics, paints and coatings, cosmetics, pharmaceuticals and laundry detergent. Our companies and the people they employ are proud of their industry and the socially responsible methods they use to deliver these beneficial resources. IMA-NA represents producers and processors of ball clay, barite, bentonite, borates, calcium carbonate, diatomite, feldspar, industrial sand, kaolin, soda ash, talc and wollastonite.

Safety and health are of paramount concern to IMA-NA's member companies, which is why we come before you today to address MSHA's Request for Information on Exposure of Underground Miners to Diesel Exhaust. With me today are Mr. Richard Pasquier, General Counsel of Tronox Alkali, and Dr. Roger McClellan, an advisor on toxicology and human health risk analysis. Mr. Pasquier serves as the chairman of IMA-NA's Diesel Emissions Task Force and Dr. McClellan serves as an advisor to that Task Force. IMA-NA appreciates the opportunity to put these comments before MSHA for consideration. Written copies of our oral presentations are available to the reporter preparing verbatim transcripts and to the MSHA panel for the rulemaking record. So, without further ado, please allow me turn the microphone over to Mr. Pasquier and Dr. McClellan.

Comments for Mine Safety and Health Administration Public Meeting on Request for Information on Exposure of Underground Miners to Diesel Exhaust

(Docket No. MSHA-2014-0031)

Mine Safety and Health Administration Headquarters

201 12th St, South, Rooms 7W204 and 7W206

Arlington, VA

July 26, 2016

By

Dr. Roger O. McClellan

Advisor, Toxicology and Human Health Risk Analysis

Albuquerque, NM 87111

On behalf of

Murray Energy Corporation

Bituminous Coal Operators' Association

Bridger Coal Company

July 26, 2016

Thank you for allowing me the opportunity to speak to you for a second time today. I am Dr. Roger O. McClellan, an Advisor on Toxicology and Human Health Risk Analysis matters with emphasis on issues concerning airborne materials and their potential health effects in workers and the general population. As I mentioned earlier, I have had a special interest in and have conducted research on the health hazards of diesel exhaust emissions since the 1970s. I provided an extended biography with my earlier comments on behalf of the Industrial Mineral Association – North America (IMA-NA).

I offer this statement on behalf of the Murray Energy Corporation, the Bituminous Coal Operators' Association and Bridger Coal Companies (the Companies). I am serving as an Advisor to the Companies on developments regarding the potential health effects of exposure of workers to diesel exhaust emissions.

The Companies, their legal counsel, and I have read with interest MSHA's Request for Information on Exposure of Underground Miners to Diesel Exhaust (Docket No. MSHA-2014-0031).[1] It is my understanding that MSHA issued the Request for Information (RFI) and is holding public meetings to gather information to enable the agency to review its "existing standards and policy guidance on controlling miner's exposure to diesel exhaust to evaluate the effectiveness of the provisions now in place to preserve miner's health."[2] The Companies value worker safety and health, and welcome the opportunity to participate in this fact-gathering process. I am here to urge MSHA to ground its inquiry in science and to consider *all* of the currently available science on the potential health effects of exposure to diesel exhaust.

It is critically important in this initial phase of MSHA's review that the currently available scientific information on the health hazards and risks of exposure to diesel exhaust,

[1] 82 Fed. Reg. 36,826 (June 8, 2016).

[2] *Id.* at 36,826.

including uncertainties, be accurately and completely depicted. In short, it is important that MSHA gets the science right! This is the case because that science will ultimately be used to *inform* policy decisions on standards and regulations that are intended to demonstrate "on the basis of the best available evidence that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards" involved.[3]

Let me emphasize the importance for all parties to these proceedings to recognize that the science *informs* the policy decisions inherent in setting the standards, the science does not in and of itself dictate a particular policy outcome. Science alone is insufficient to set the standards and regulations because science alone cannot provide a bright line between levels and durations of exposure with or without impairment of health and the associated conditions of diesel equipment usage and mine ventilation to meet the worker health objective noted above.

Earlier today, I offered a statement detailing analyses, conclusions and recommendations I made on behalf of IMA-NA related to Section I.B of the Request for Information (RFI) entitled "Recent Research." Let me briefly summarize key conclusions from that statement and discuss why those conclusions matter to the Companies and to the underground coal industry generally.

(1) In the RFI, MSHA focuses only on two papers relating to initial analyses using the Diesel Exhaust in Miners Study (DEMS) data base published by the original National Institute for Occupational Safety and Health (NIOSH) and National Cancer Institute (NCI) investigators. Those papers were a description of initial analyses of the cohort data by Attfield et al. (2012) and initial analyses of the nested case-control data by Silverman et al. (2012).

The RFI should have also referenced (and MSHA must give due consideration to) the five papers by NIOSH/NCI investigators describing the elaborate and complex process by which they developed estimates of Respirable Elemental Carbon (REC) exposure for DEMS workers from the beginning of dieselization at the study mines (as early as 1946 in one mine) through December 31, 1997 (Stewart et al., 2010; Coble et al., 2012: Vermeulen et al., 2012a and 2012b; and Stewart et al., 2012).

It was necessary to retrospectively estimate the REC exposures because there were no measurements of REC available for workers prior to the end of the DEMS follow-up – December 31, 1997. MSHA should acknowledge the highly uncertain nature of the NIOSH/NCI exposure estimates and criticisms offered by others. Moreover, a complete review of the science should note that the exposure estimate uncertainties carry over and result in major uncertainties in the epidemiological analyses of Attfield et al. (2012) and Silverman et al. (2012).

(2) The RFI fails to relate that other independent analysts have been provided access, under carefully controlled conditions, to the DEMS data. These analyses published in the peer-reviewed journal, Risk Analysis are a part of the current scientific landscape and MSHA must consider them going forward. They are Moolgavkar et al., 2015, Crump et al., 2015; and Crump et al., 2016.

These independent analysts replicated the results of the original NIOSH/NCI investigators, thereby demonstrating that a common DEMS data base was being used by both the original and independent analysts. The independent analysts also developed year-by-year REC exposure estimates based on Horse Power (HP) of diesel equipment and mine ventilation, expressed as Cubic Feet per Minute (CFM). These estimates do not assume that CO is a surrogate for REC, and thus are more certain than the original estimates developed by NIOSH/NCI investigators. Most importantly, the independent analysts have extended the original analyses conducted by NIOSH/NCI investigators using alternative models, alternative

REC exposure estimates and with and without control for radon, a well-known carcinogen in mines. In most occupational epidemiology studies, the major lung cancer hazard is cigarette smoking. Thus, the challenge is to attempt to determine if there is any potential hazard from other agents such as radon or diesel exhaust.

The weak carcinogenic lung cancer hazard signal found by the original NIOSH/NCI investigators was not found by the independent analysts using the same DEMS vital data on workers enrolled in DEMS. When the alternative REC exposure estimates are used, the lung cancer carcinogenic hazard signal of diesel exhaust is further reduced. Further, the findings are no longer statistically significant when radon exposures are controlled for in the analyses.

(3) The Health Effects Institute (HEI) convened an Epidemiology Panel to review recent findings, including those from the DEMS, for use in quantitative risk assessment (HEI, 2015). I have prepared a critique of that report (McClellan, 2016). That report is a useful contribution, however, it does not adequately address the alternative estimates of REC and the analyses of the independent analysts.

(4) When the only analyses of the DEMS data available were those of the original investigators, many scientists believed that the epidemiological evidence for diesel exhaust being characterized as a human lung carcinogenic hazard was made stronger by DEMS when compared to the evidence available pre-DEMS, that is, the evidence MSHA used in its previous rule-making. In my opinion, when the results of the independent analysts using the DEMS data set are considered in addition to the DEMS results, the classification of diesel exhaust exposure as a human lung carcinogenic hazard is much less certain than when only the analyses of the original agency investigators are considered. To ensure that any future steps taken by MSHA are grounded in sound science, any quantitative estimates of lung cancer risk for exposure to diesel

exhaust should consider the results of *all* the analyses of the DEMS data, including both the original NIOSH/NCI investigators and the results of the independent analysts.

(5) My earlier statement discussed the concepts of hazard and risk. Hazard is a qualitative concept and is a description of the likelihood that under some exposure conditions (intensity and duration) an agent or work place circumstance (such as exposure to diesel exhaust) may or may not cause cancer in humans. Risk is a quantitative concept that requires developing quantitative estimation of potency for a given intensity and duration of exposure. It is also important to recognize that increased strength of evidence does not automatically translate into evidence of increased potency for the agent and increased risk. Thus, even putting aside the limitations in DEMS, the availability of additional evidence does not necessarily mean that MSHA should tighten its standards.

(6) Building on the above discussion, I would now like to discuss the conceptual framework linking (a) sources of emissions, (b) influenced by ventilation to (c) workplace exposure environments that must be controlled to avoid adverse impact on worker health. This framework is at the core of MSHA's strategic approach to regulating the exposure of miners to diesel exhaust.

(7) MSHA, in the current regulations, uses two different approaches to regulating exposure to diesel exhaust in (a) Metal/Non-Metal Mines (MNM) and (b) Coal Mines. For MNM mines, the regulations focus on the workplace environment and limiting exposure to Diesel Particulate Matter (DPM) to the Permissible Exposure Limit (PEL) that is specified as 160 μg Total Carbon per m^3, averaged over 8 hours. It is noteworthy that the Total Carbon (TC) metric for DPM includes both Elemental Carbon (EC) and Organic Carbon (OC). This is

different than the REC metric based only on EC estimated in DEMS and used in analyses by both the original investigators and independent analysts.

In contrast, worker protection of coal miners from exposure to diesel exhaust focuses on indirect control of the airborne mine environment by setting emission limits (grams of Diesel Particulate Matter/hour) for diesel-powered equipment. This approach is dictated by the complex ambient atmospheric environment in coal mines with carbon present in the coal dust as well as carbon (both EC and OC) present in diesel exhaust particles and carbon emitted to the air from other sources. At the very least, in assessing its standards, the Companies ask MSHA to continue to be mindful of the difficulties coal operators face in accurately measuring the diesel exhaust exposure for their workforce.

(8) Any review to evaluate the effectiveness of the regulations now in place to preserve miners' health needs to be based on all of the currently available scientific information on the potential health hazards of exposure to diesel exhaust. This is the case whether the regulatory strategy is based on a PEL as in MNM mines or emission limits for diesel-powered equipment as in coal mines.

(9) In my earlier statement on behalf of the IMA-NA Task Force, I emphasized that in considering any use of analyses based on the DEMS data set, it was important to recognize that the strongest association between diesel exhaust exposure, based on estimated REC, and lung cancer were found when a 15-year lag between exposure and lung cancer was used. This suggests the diesel exhaust exposures of greatest relevance in DEMS are for 1982 (15 years before the end of workers' follow-up on December 31, 1997) and earlier. DEMS thus does not account for the revolutionary changes in diesel technology (engines, exhaust after-treatment and fuels) in recent decades resulting in substantial reductions in diesel exhaust emissions of

particulate matter and other pollutants (McClellan et al. 2012). Those changes have been largely driven by the U.S. Environmental Protection Agency diesel regulations. This new technology has first been implemented in the heavy-duty on-road fleet and then later in other sectors. Papers by Khalek et al. (2011 and 2015) document the substantial reductions in emissions and changes in composition of the emissions from the new technology diesels compared to the old technology diesels fueled with high sulfur fuel. The new technology diesels have virtually no EC or OC in the emissions. MSHA must consider these revolutionary changes in technology as well as the feasibility of their implementation.

(10) Finally, the issue of the relevance of any findings from the study of workers in non-metal (salt, potash, trona and limestone) operations like those studied in DEMS to coal miners needs to be carefully examined. It is important to recall that the strongest signal in some of the DEMS analyses came from the miners in the limestone mine that was naturally ventilated, i.e. very poorly ventilated. It is my understanding that underground coal mines typically have at least the potential for methane buildup. Thus, all underground coal mines are treated as "gassy" mines and ventilated accordingly.

Thank you again for providing me the opportunity to speak to you today.

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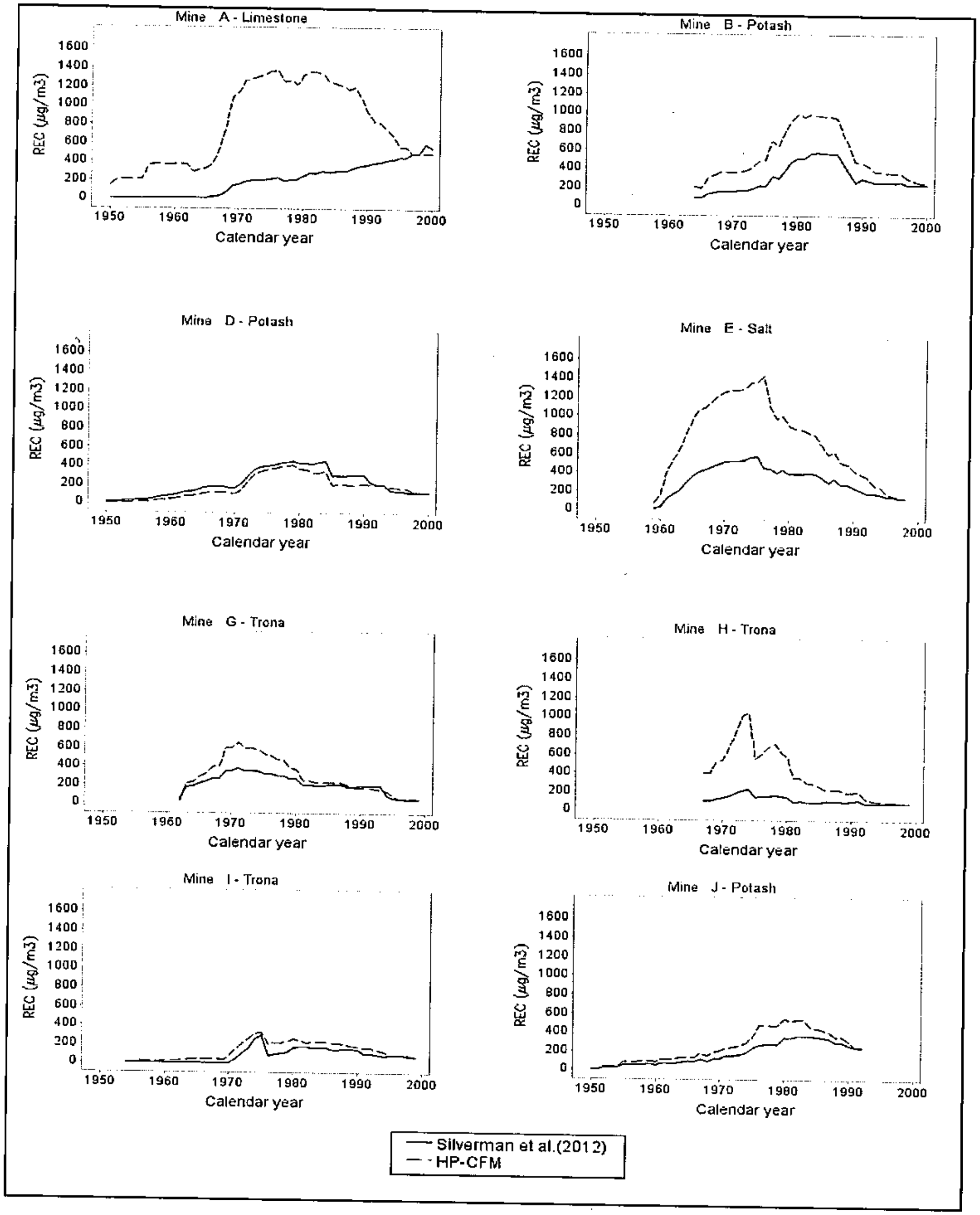

Figure 1:
Alternative Respirable Elemental Carbon Metrics Using CO (red), developed by the original investigators versus HP-CFM (blue), developed by Crump et al (2016)

Table 1:
Characteristics of the Mines in the Diesel Exhaust in Miners Study (DEMS)
(From Crump et al, 2016)

						All Years				1982 Activity	
						CO		Radon		CFM	Diesel
Mine	State	Ore	Ventilation	Year of First Diesel Use	Primary Mode of Operation	# Samples	% > LOD	# Samples	% >LOD	f^3/min (inthousands)	(Adj HP)
A	Missouri	Limestone	Natural	1947	Cv/H	248	70	37	84	–	6,862
B	New Mexico	Potash	Mechanical	1964	Cv/Con, Ct	447	62	18	44	250	892
D	New Mexico	Potash	Mechanical	1950	Cv/H, Cv/Con, Ct	323	54	61	39	360	2,326
J	New Mexico	Potash	Mechanical	1952	Cv/H, Cv/Con, Ct	178	52	13	38	240	1,421
E	Ohio	Salt	Mechanical	1959	Cv/H	207	66	39	70	233	2,804
G	Wyoming	Trona	Mechanical	1962	Cv/Con, Ct	276	50	17	24	450	638
H	Wyoming	Trona	Vlechanica	1967	Cv/Con, LW, Ct	2,361	39	40	15	950	1,110
I	Wyoming	Trona	Mechanical	1956	Cv/Con, Ct, LW	2,000	54	54	20	1,630	1,493
Total						6,040	50	279	42		

Notes: The above data were compiled from Stewart *et al.*(2010) and the substantial DEMS data files. Primary Mode of Operation: Cv/H, conventional with truck haulage; Cv/Con, conventional with conveyor belts; Ct, continuous with conveyor belts; and LW, long wall with conveyor belts. Specific data for ventilation rates and HP are shown for 1982 for illustrative purposes, as 1982 was the last year of effective exposure for workers, assuming a 15-year lag, as follow-up ended in 1997.

Table 2: Comparison of Conditional Original Logistic Regression Resulted (Silverman et al, 2012) with Results of Similar Analyses except based on New REC Estimates Defined Using HP and CFM (From Crump et al, 2016)

Analysis	Quartiles of average REC intensity, unlagged (μg/m³)	Cases	Controls	OR (95% CI)	p_{trend}	Slope $(\mu g/m^3)^{-1}$ 95% CI
All Subjects						
Silverman et al. (2012)	0 to < 3	49	158	1.0 (referent)	0.001	0.00073[a]
	3 to < 72	50	228	0.74 (0.40 to 1.38)		(0.00028,0.0012)[a]
	72 to < 536	49	157	1.54 (0.74 to 3.20)		
	≥ 536	50	123	2.83 (1.28 to 6.26)		
REC estimates from Silverman et al. (2012) and "without radon" controls (Crump et al. 2015)	0 to < 3	49	158	1.0 (referent)	0.0006	0.00082
	3 to < 72	50	228	0.79 (0.41 to 1.52)		(0.00035,0.0013)
	72 to < 536	49	157	1.62 (0.75 to 3.49)		
	≥ 536	50	123	3.24 (1.40 to 7.55)		
HP-CFM REC estimates and "without radon" controls	0 to < 6.6	49	172	1.0 (referent)	0.06	0.00016
	6.6 to < 129	50	191	1.05 (0.58 to 1.93)		(-0.000012,0.0003)
	129 to < 891	49	168	1.60 (0.79 to 3.24)		
	≥ 891	50	135	2.37 (1.02 to 5.50)		
HP-CFM REC estimates and "with radon" controls	0 to < 6.6	49	172	1.0 (referent)	0.63	0.00005
	6.6 to < 129	50	191	1.02 (0.55 to 1.90)		(-0.00016,0.00026)
	129 to < 891	49	168	1.20 (0.56 to 2.56)		
	≥ 891	50	135	1.37 (0.5 to 3.77)		

Table 2: Comparison of Conditional Original Logistic Regression Resulted (Silverman et al, 2012) with Results of Similar Analyses except based on New REC Estimates Defined Using HP and CFM (From Crump et al, 2016)(cont)

All Subjects Who Ever Worked Underground						
Silverman et al. (2012)	0 to < 81	29	92	1.0 (referent)	0.004	0.00065[a]
	81 to < 325	29	52	2.46 (1.01 to 6.01)		(0.00020,0.0011)[a]
	325 to < 878	29	69	2.41 (1.00 to 5.82)		
	≥ 878	29	51	5.10 (1.88 to 13.87)		
REC estimates from Silverman et al. (2012) and "without radon" controls (Crump et al. 2015)	0 to < 97	31	158	1.0 (referent)	0.01	0.00073
	97 to < 384	31	90	1.90 (0.78 to 4.63)		(0.00022,0.0012)
	384 to < 903	31	80	2.73 (1.08 to 6.88)		
	≥ 903	31	84	5.04 (1.77 to 14.30)		
HP-CFM REC estimates and "without radon" controls	0 to < 130	31	144	1.0 (referent)	0.16	0.00014
	130 to < 531	31	99	2.03 (0.83 to 4.96)		(-0.000062,0.0003
	531 to < 2149	31	99	3.45 (1.27 to 9.41)		
	≥ 2149	31	70	3.84 (1.07 to 13.74)		
HP-CFM REC estimates and "with radon" controls	0 to < 130	31	144	1.0 (referent)	0.69	0.00005
	130 to < 531	31	99	1.83 (0.73 to 4.61)		(-0.00020,0.00030
	531 to < 2149	31	99	2.47 (0.79 to 7.73)		
	≥ 2149	31	70	2.5 (0.49 to 12.79)		

Table 2: Comparison of Conditional Original Logistic Regression Resulted (Silverman et al, 2012) with Results of Similar Analyses except based on New REC Estimates Defined Using HP and CFM (From Crump et al, 2016)(cont)

All Subjects Who Only Worked Underground						
HP-CFM REC estimates and "without radon" controls	0 to < 106	14	26	1.0 (referent)	0.27	0.00024
	106 to < 410	15	28	1.89 (0.4 to 9.07)		(-0.000179,0.0
	410 to < 1486	14	17	3.15 (0.47 to 21.05)		
	≥ 1486	15	26	4.73 (0.58 to 38.84)		
HP-CFM REC estimates and "with radon" controls	0 to < 106	14	26	1.0 (referent)	0.36	0.00027
	106 to < 410	15	28	1.91 (0.38 to 9.75)		(-0.000316,0.0
	410 to < 1486	14	17	5.61 (0.61 to 51.33)		
	≥ 1486	15	26	9.39 (0.47 to 187.84)		

[a] Calculated by us after reproducing Silverman (2012) results.

Testimony of Linda Raisovich-Parsons
Deputy Administrator of the
UMWA Department of Occupational Health and Safety
On the
Request for Information on Exposure of Underground Miners to Diesel Exhaust
July 26, 2016

Good morning/afternoon. My name is Linda Raisovich-Parsons and I currently serve as the Deputy Administrator of the United Mine Workers of America's Department of Occupational Health and Safety. I am here today to voice the United Mine Workers of America's support for the Agency's effort to update the diesel standards. As MSHA points out miners' exposures to diesel exhaust presents an increased risk of lung cancer. Epidemiological studies by NIOSH and the National Cancer Institute have concluded that exposure to diesel exhaust increases risk of mortality from lung cancer and have important health implications.

We applaud the Agency for addressing the much needed update to the respirable dust rule which has taken much time and energy to finalize, however the time has come to look toward the next chapter. And that chapter must be to move forward with the much needed update to the diesel standards. This must be the next priority for the coal industry. I ask what have we gained if we protect miners from pneumoconiosis but let them die of lung cancer? MSHA indicates that it is revisiting the diesel exhaust controls because "of the carcinogenic health risk to miners from exposure to diesel exhaust and to prevent material impairment of miners' health." There is sufficient evidence and many from the scientific community who substantiate that diesel exhaust exposes miners to risks of lung cancer. Some of those include the Diesel Exhaust in Miners Study (DEMS) by NIOSH; the National Cancer Institute; the International Agency for Research on Cancer; and the Health Effects Institute who have all confirmed that diesel exhaust contains carcinogens and pose a significant risk of lung cancer. The Agency nor the mining community can continue to delay dealing with this serious hazard. The time has come. So I applaud the Agency for moving forward on this issue.

As pointed out, the states of West Virginia, Pennsylvania and Ohio have moved forward with a much more progressive regulation and approach to the use of diesel equipment. In prior years, most of these states completely prohibited the use of diesel equipment in underground coal mines. When the decision was made to permit the use of diesels through legislative change in these states, it was approached as a collaborative effort with industry, labor and the state inspection agencies involved in developing the regulations for diesels. The result has been effective regulations which produce efficient clean burning diesel engines. These states require diesel powered equipment to include an exhaust emissions control and conditioning system which meet stricter DPM emission limits. They also limit ambient concentrations of exhaust, and some limit ambient nitric oxide, as well. In addition, they require certain testing, examination, and maintenance records.

I am far from being an expert on this subject and most of my testimony today addresses generalities. However, our UMWA International Representative, Ron Bowersox, who you heard from at the Pittsburgh, PA hearing serves on the Pennsylvania Diesel Commission which approves all diesel equipment for use in underground mines in Pennsylvania. He is intricately involved in the testing and approval of diesel equipment for use underground. Since their introduction into coal mines, diesel manufacturers have come a long way in the development of this technology. The emission scrubbers and catalyst used in those states are doing an excellent job. Ron relayed to me that in most instances in approval of new equipment the emission technology burns so cleanly that the new machines would pass the emission measurements on the untreated (dirty) side of the engine. This is a great improvement over those states still relying on the federal code. The miners in other areas of the country need and deserve the same protections.

Many of the questions MSHA raises in the Request For Information involves the cost of such improvements. I must question if it is fair to those coal operators in the states with stricter regulation to bear the costs of these improvements while the rest of the industry does not? Further, is it fair to provide those protections to only miners working in these three states and not to the rest of the nation? This will only level the playing field as far as costs are concerned and more importantly health protections for our nation's miners. This is why it only reasonable that we act now to update the diesel standards.

The improvements to diesel engines, scrubbers and catalyst are long overdue in the mining industry. The rest of United States needs to play catch up with the states that have moved ahead with these systems and are benefiting from them. I have worked in the mining industry and mine health and safety for 40 years this year. Over that time I have witnessed much change and evolution to mine health and safety. I can remember in the 70's and 80's the leading cause of mine deaths were roof falls until the introduction of the Automated Temporary Roof Support Systems (ATRS). Now it is rare to have a mine fatality attributed to a roof fall. Likewise, the new respirable dust rule will go a long way in reducing black lung in our mining industry. The risk of lung cancer from the use of diesel engines underground is real and the time to improve these standards and reduce that risk has come. I thank you for your time.

July 25, 2016

Joseph A. Main
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Re: Request for Establishment of a Diesel Exhaust Health Effects Partnership and Request for Extension of Comment Period for Request for Information on Exposure of Underground Miners to Diesel Exhaust (Docket No. MSHA-2014-0031) by 90 days

Dear Mr. Secretary and Dr. Howard,

I write to you on behalf of the Industrial Minerals Association – North America (IMA-NA) Diesel Emissions Task Force. Formed approximately one year ago, the Task Force is made up of operators of underground mines producing trona, calcium carbonate, industrial sand, and wollastonite. All of the members of the Task Force use at least some diesel equipment in their mining operations and we all share a commitment to the health and safety of our employees. Some of the members of the Task Force also volunteered to participate as study mines in the Diesel Exhaust in Miners Study (DEMS) conducted by the National Institute for Occupational Safety and Health (NIOSH) and the National Cancer Institute (NCI).

The Task Force was formed to enable its member companies to learn as much as possible about the health effects of diesel exhaust in order to protect our employees' health. The Task Force also promotes and is interested in the exchange, testing, and verification of scientific information concerning the use of diesel equipment in mining operations.

As a result, the Task Force and its members have had a keen interest in the publications that have resulted from DEMS, including papers published both by the original investigators and subsequent analyses performed by independent analysts working with the DEMS data. The Task

Force also is interested in and plans to offer a response to the Mine Safety and Health Administration's (MSHA's) Request for Information on Exposure of Underground Miners to Diesel Exhaust (Docket No. MSHA-2014-0031).

The IMA-NA Diesel Emissions Task Force has begun to review the specific questions posed in the RFI. It is readily apparent that these questions are not only extraordinarily technical, but also may be best addressed by working with the manufacturers of diesel engines and suppliers of mining equipment. Engine and equipment manufacturers would be much more familiar with technical details and changes in diesel technology that were not accounted for in DEMS. In fact, these are important issues best addressed by all stakeholders working together to understand the evolving science on the potential health effects of worker exposure to diesel exhaust, as well as current technologies and current mining practices. Accordingly, we request that MSHA and NIOSH form a Diesel Exhaust Health Effects Partnership with the mining industry, including both coal and metal/nonmetal mines, diesel engine manufacturers, and representatives of organized labor. That Partnership would be best positioned to address these complex issues and reach a consensus on the path forward, informed by MSHA's fact-gathering efforts.

Relatedly, we also request that MSHA extend the comment period for the RFI by at least 90 additional days to allow the regulated industry to respond to the detailed questions MSHA has posed, and to allow time for the Partnership to begin work.

IMA-NA supports MSHA's desire to evaluate the effectiveness of MSHA's current diesel regulations to ensure they are protective of miners' health, a value that is at the core of our own operations. We look forward to working collaboratively with MSHA, NIOSH, and other stakeholders to better understand whether continued reductions in miner exposure are warranted and to identify best practices for the future to ensure our miners' safety and health.

Thank you for the opportunity to participate in this process and for your consideration of these requests.

Sincerely,

Mark G. Ellis
President

Statement for the Mine Safety and Health Administration Public Meeting on Request for Information on Exposure of Underground Miners to Diesel Exhaust
(Docket No. MSHA-2014-0031)
Mine Safety and Health Administration Headquarters
201 12th St, South, Rooms 7W204 and 7W206
Arlington, VA
July 26, 2016

By

Richard Pasquier
General Counsel
Tronox Alkali
Philadelphia, PA

I am Richard Pasquier, General Counsel for Tronox Alkali, a unit of Tronox Limited, a global leader in the mining, production, and marketing of inorganic materials and chemicals. Tronox Alkali operates the Alkali Chemicals Business that Tronox Limited acquired from FMC Corporation on April 1, 2015.

Tronox Alkali is the world's largest producer of natural soda ash with mining and processing facilities located in Green River, Wyoming. We employ approximately 950 employees in Green River and nearly 60 employees located in Philadelphia. We mine more than 4 million tons of trona annually for use in essential everyday products like commercial and residential glass, computer screens, pharmaceuticals, baking, and personal care products.

Tronox Alkali is a member of the Industrial Minerals Association – North America (IMA-NA), a trade association whose membership includes other trona producers and nonmetal mining and processing companies, as Mark Ellis, President of IMA-NA, already has described to you. Approximately one year ago, IMA-NA formed a Diesel Emissions Task Force, in which

Tronox Alkali is an active participant and for which I serve as Chair. I offer this statement today in my capacity as Chair of the Task Force. The Task Force was formed to enable us to learn as much as possible about the health effects of diesel exhaust in order to protect our employees. The Task Force also promotes and is interested in the exchange, testing, and verification of scientific information concerning the use of diesel equipment in mining operations.

The Task Force is made up of operators of underground mines producing trona, calcium carbonate, industrial sand, and wollastonite. All of the members of the Task Force use at least some diesel equipment in their mining operations and we all share a commitment to the health and safety of our employees. Some of those members include the study mines that participated in the Diesel Exhaust in Miners Study, known as DEMS, conducted by the National Institute for Occupational Safety and Health (NIOSH) and the National Cancer Institute (NCI). Tronox Alkali's Green River operation was one of those study mines when it was owned by FMC. We agreed to participate in that study to advance scientific understanding of the potential health effects of diesel exhaust and because we believed our participation would ultimately benefit our workforce. Thousands of hours were spent assembling and organizing background information on the mining operations, use of diesel equipment from 1956 through 1998, and the records of 2,451 employees.

The Task Force and its members have had a keen interest in the publications that have resulted from the DEMS project, including papers published both by the original NIOSH/NCI investigators and subsequent analyses by independent analysts, including by a consultant to Tronox Alkali and the Task Force, Dr. Roger O. McClellan. The literature on the health hazards of exposure to diesel exhaust is voluminous, constantly changing, and challenging to interpret. To assist us in that task, the IMA-NA Diesel Emissions Task Force has engaged Dr. McClellan as an advisor. Dr. McClellan is here today to offer his initial thoughts on the MSHA Request for Information (the RFI) on Exposure of Underground Miners to Diesel Exhaust, published in the *Federal Register* on June 8, 2016.

The Diesel Emissions Task Force will work with IMA-NA and Dr. McClellan to respond to the RFI and appreciates the opportunity do so. We support MSHA's desire to evaluate the effectiveness of MSHA's current diesel regulations to ensure they are protective of employees' health, a value that is at the core of our own operations. But it is critical that MSHA's inquiry be thoroughly grounded in science, meaning that due consideration be given to all of the currently available scientific work, not only the original DEMS papers but also the reanalysis work that has been done with the DEMS data. MSHA must also take into account workplace practices and operators' experiences in complying with current regulations.

IMA-NA has asked Dr. McClellan to participate in today's meeting and to review and comment on Section B of the RFI, entitled "Recent Research." As he will explain, the RFI's summary of DEMS is incomplete. This is a critical conclusion since this summary is the scientific basis for issuance of the RFI and any subsequent analyses and actions that may lead to a change in the existing regulations.

DEMS is a historical, backwards-looking study and there are substantial uncertainties in its use of estimated exposures to Respirable Elemental Carbon (REC). Dr. McClellan will describe alternative estimates of REC, the use of which he and the other independent researchers looking at the DEMS data have discovered result in substantially different characterization of the lung cancer risk for the DEMS miners. Moreover, he will emphasize that all of the analyses (both by the original NCI/NIOSH investigators and independent analysts) relate to older diesel engine exhaust emissions and exposure that occurred in 1982 and earlier because of the 15-year lag time between exposure and any significant response. Any serious look at DEMS must take into account the fact that over the past three decades, improvements in diesel engine technology and fuels, most notably major reductions in sulfur content, have resulted in substantially reduced particulate emissions.

The IMA-NA Diesel Emissions Task Force has initiated an analysis of specific questions posed in the RFI. It is readily apparent that these questions are not only extraordinarily technical, but also may be best addressed by working with the manufacturers of diesel engines and suppliers of mining equipment. As I mentioned, there have been substantial improvements in diesel engine technology and exhaust after-treatment systems over the past quarter century, which largely were driven by the Environmental Protection Agency's (EPA) diesel engine standards. Engine and equipment manufacturers would be much more familiar with those changes than mine operators.

As a result, Tronox Alkali and the IMA-NA propose that MSHA and NIOSH work with the mining industry (both metal/nonmetal and coal), diesel engine manufacturers, diesel mining equipment manufacturers, and representatives of organized labor to form a Diesel Exhaust Health Effects Partnership to address these complex issues and reach consensus on the path forward. At this meeting, the Task Force is submitting a letter to MSHA and NIOSH formally requesting the formation of that partnership. In order to allow this Partnership to begin its work, we also are requesting that the comment period on the RFI be extended for at least 90 additional days. That extended amount of time is critical in any event to allow the regulated industry to respond to the detailed questions MSHA has posed.

Before I conclude my remarks, I note that we were pleased to see MSHA acknowledge the substantial progress made in reducing average miner exposures in metal/nonmetal operations from 2006 through 2015. It would be useful if MSHA were to share this matrix of exposure data with the Partnership we are requesting be formed. Indeed, we earnestly hope this Partnership will address diesel technology improvements and best practices for monitoring miner exposures, as well as achieving further reductions in exposures to diesel engine exhaust if further reductions are deemed necessary.

In summary, Tronox Alkali and the other members of the IMA-NA Diesel Emissions Task Force are committed to providing a safe and healthful work environment for all our employees. This requires a management approach that addresses a wide range of factors, including exposure to diesel engine exhaust. Like MSHA, we are pleased with the continuous reductions in diesel exposure in nonmetal mines since the 1980s. We look forward to working collaboratively with MSHA, NIOSH, and other stakeholders in a Partnership to better understand the basis of those reductions and identify best practices for the future to ensure worker exposures are held to levels protective of miner health.

Comments for Mine Safety and Health Administration Public Meeting on Request for Information on Exposure of Underground Miners to Diesel Exhaust
(Docket No. MSHA-2014-0031)
Mine Safety and Health Administration Headquarters
201 12th St, South, Rooms 7W204 and 7W206
Arlington, VA
July 26, 2016

By

Dr. Roger O. McClellan
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Albuquerque, NM 87111

July 26, 2016

Thank you for allowing me the opportunity to speak today. I am Dr. Roger O. McClellan, an Advisor on Toxicology and Human Health Risk Analysis matters with emphasis on issues concerning airborne materials and their potential health effects in workers and the general population. I have had a special interest in and have conducted research on the health hazards of diesel exhaust emissions since the 1970s. I have included a more extended biography with these comments as Attachment A.

I offer this statement on behalf of the Diesel Emissions Task Force of the Industrial Minerals Association – North America (IMA-NA). I advise the Task Force on scientific developments regarding the potential health effects of exposure of workers to diesel exhaust emissions. I have also offered advice on these matters to Tronox Alkali. Tronox and the other non-metal mines in the Task Force all use diesel equipment to some degree and are interested in learning more about the potential health effects of diesel exhaust to ensure the safety and health of their employees.

The Task Force and I have read with interest MSHA's Request for Information on Exposure of Underground Miners to Diesel Exhaust (Docket No. MSHA-2014-0031) published in the Federal Register on Wednesday, June 8, 2016.[1] It is my understanding that MSHA issued the Request for Information (RFI) and is holding this and other public meetings to gather information to enable the agency to review its "existing standards and policy guidance on controlling miner's exposure to diesel exhaust to evaluate the effectiveness of the provisions now in place to preserve miner's health."[2] We appreciate the opportunity to submit information and statements to assist MSHA in gathering the relevant facts and evidence. I am here to urge

[1] 82 Fed. Reg. 36,826 (June 8, 2016).

[2] *Id.* at 36,826.

MSHA to ground its inquiry in science and to consider *all* of the currently available science on the potential health effects of exposure to diesel exhaust.

It is critically important in this initial phase of MSHA's review that the currently available scientific information on the health hazards and risks of exposure to diesel exhaust, including uncertainties, be accurately and completely depicted. In short, it is important that MSHA gets the science right! This is the case because that science will ultimately be used to *inform* policy decisions on exposure levels and durations for standards that demonstrate "on the basis of the best available evidence that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards" involved.[3] Let me emphasize the importance of all parties to these proceedings recognizing that the science *informs* the policy decisions inherent in setting the standards, the science does not in and of itself dictate a particular policy outcome. Science alone is insufficient to set the standard because science alone cannot provide a bright line between levels and durations of exposure with or without impairment of health.

MSHA's review of its diesel regulations was inspired by certain developments in the ever-evolving scientific inquiry into diesel exhaust exposure and whether such exposure could lead to lung cancer and other health outcomes. MSHA summarized some – but not all – of that research in Section I.B of the RFI, entitled "Recent Research." As I will explain, it is clear that MSHA is focused on the results of the Diesel Exhaust in Miners Study or "DEMS," to the exclusion of other work that has been done with the DEMS data. The DEMS study was conducted by the National Cancer Institute (NCI) and National Institute for Occupational Safety and Health (NIOSH).

[3] 30 U.S.C. § 811(a)(6)(A).

Beginning in 1997, NIOSH and NCI investigators reviewed historical data for eight non-metal mines that were volunteered by their management to be part of the study. The DEMS analyses are therefore based on estimates of exposure for 1997 and earlier, with the most influential exposure occurring in 1982 and earlier because a 15 year lag yielded the most significant results regarding increased risk of death from lung cancer. The investigators published the final DEMS results in 2012. (Attfield et al, 2012, and Silverman et al, 2012).

To fully understand and interpret the DEMS data, it is important to go beyond the two papers cited in the RFI (Attfield et al, 2012, and Silverman et al, 2012). MSHA must also critically evaluate the five papers describing the original estimates of Respirable Elemental Carbon (REC) exposure for the DEMS workers developed by the original NIOSH and NCI investigators (Stewart et al, 2010; Coble et al, 2010; Vermeulen et al, 2010a; Vermeulen et al 2010b; and Stewart et al, 2012). And, as I will discuss today, independent researchers working with the DEMS data have identified important limitations of DEMS that must be considered in any future assessment. I am one of those researchers, and my colleagues and I have published several papers with the results of our work in the peer-reviewed journal "Risk Analysis." With cooperation from NIOSH, NCI and the National Center for Health Statistics (NCHS), we were given access to the confidential DEMS data under carefully defined conditions.

The DEMS results and the results of a second epidemiological study of diesel exhaust exposure in United States truck drivers[4] were used by the International Agency for Research on Cancer (IARC) in 2012 to change its classification of the carcinogenicity of diesel exhaust. IARC used the results from DEMS and the Truckers Study to conclude there was "sufficient" epidemiological evidence that diesel exhaust was carcinogenic and to change its categorization

[4] (Garshick et al., 2012) (Truckers Study).

of diesel exhaust exposure from "probably carcinogenic to humans" (a conclusion IARC reached in 1988) to "carcinogenic to humans."

Thereafter, EPA and the industry sponsors of the Health Effects Institute (HEI) asked the HEI to assemble a Panel to evaluate DEMS and the Truckers Study to determine whether those studies could be utilized in a future quantitative risk assessment.

To understand why a quantitative risk assessment is significant, it is necessary for me to explain the difference between hazard and risk. The term "hazard" is used to characterize the likelihood that an agent or work place circumstance, such as exposure to diesel exhaust, may under some exposure conditions cause cancer. Carcinogenic hazards are typically described in *qualitative* terms, like those used by IARC in its Monograph evaluation process, which classifies agents in five categories: (1) carcinogenic to humans, (2a) probably carcinogenic to humans, (2b) possibly carcinogenic to humans, (3) not classifiable as to carcinogenicity in humans, and (4) probably not carcinogenic to humans. Those kinds of hazard identifications are qualitative in nature – IARC does not make quantitative estimates of the potency of the agents for causing cancer.

Risk, on the other hand, is a *quantitative* concept and is defined as the probability that a consequence, occurrence of cancer, will occur as a result of a specific exposure (duration and concentration at a particular time in life) to an agent identified as being capable of causing cancer, i.e. has a carcinogenic hazard. The calculation of the probability of occurrence of a particular disease occurring as a result of a specific exposure requires knowledge of both the exposure *and* the potency of the hazardous agent for causing cancer at a particular exposure level and duration. The U.S. Environmental Protection Agency (USEPA) and NIOSH have developed quantitative estimates of cancer-causing potency for only a very modest number of agents.

Neither EPA nor NIOSH have formally developed quantitative estimates of the cancer causing potential of diesel exhaust exposure. I note, however, that development of a quantitative estimate of cancer causing potency for an agent is not necessarily required for regulatory action to limit exposure to the agent. For example, EPA's extensive regulations for diesel engines are not based on a quantitative estimate of cancer risk.

The HEI Epidemiological Panel concluded that both DEMS and the Truckers Study were sufficiently robust to be used in a future quantitative risk assessment, concluding they "were well designed and carefully conducted embodying the attributes of epidemiological studies that are considered important for risk assessment."[5] However, there is more to the HEI Panel's conclusion than the RFI acknowledges. The HEI Panel concluded that the DEMS and Trucker Study provided a useful basis for quantitative risk assessment of exposure *to older diesel engine exhaust*. The DEMS investigators found that the most influential exposure resulting in an increase in lung cancer risk were for 1982 and earlier. The investigators did not measure exposures to newer diesel engine emissions and thus did not take into account the dramatic changes in technology in diesel engines and diesel fuel. The HEI Panel also acknowledged that both studies had significant uncertainties and cautioned that those uncertainties must be factored into any attempt to derive an exposure response relationship for diesel exhaust particulate matter in a quantitative risk assessment. The RFI does not acknowledge those important qualifications, but MSHA's prospective work should do so.

I do extend my compliments to the investigators who conducted DEMS, to NIOSH and NCI for sponsoring it and to the operators and employees of the eight mines that participated in DEMS. The database available from DEMS is remarkable and is still being analyzed and

[5] 81 Fed. Reg. at 36,829 (quoting HEI Press Release, "New Report Examines Latest Studies of Lung Cancer Risk in Workers Exposed to Exhaust from Older Diesel Engines," Nov. 24, 2015).

interpreted. In my opinion, what has occurred with the DEMS data and the multiple analyses will ultimately be recognized as a landmark set of epidemiological analyses. It is extraordinarily rare that a large and complex data set such as that from DEMS is shared and used by multiple investigators beyond the team that collected the data and conducted the initial analyses. It was possible in this case because the DEMS data set was acquired by U.S. government scientists and, thus, the data are the property of the U.S. government. Moreover, the independent scientific analysts were able to obtain funding from a coalition of sources led by the Engine Manufacturers Association that were willing to financially support conduct of the analyses without controlling the analytic process or being allowed to review the results of the analyses before they were published in the peer-reviewed literature. This is a great example of the way science should work, especially when the science is going to be used to inform important public policy decisions.

As those analysts learned, there are substantial uncertainties in the DEMS' estimates of Respirable Elemental Carbon (REC) exposure, used as a surrogate measure for diesel exhaust, and the association between diesel exhaust exposure and lung cancer made by the original NIOSH/NCI investigators and those of the independent analysts using alternative estimates of REC exposure, central for radon exposure, and alternative REC-response models. In the DEMS project, Respirable Elemental Carbon (REC) was used as the metric for diesel exhaust exposure. However, it is important to recognize that *REC was not directly measured for any of the DEMS workers* in the eight mines from the beginning of dieselization (as early as 1947) through December 31, 1997 (the end of follow-up for all enrollees). In the absence of measured REC concentrations *all of the REC exposures used in the analysis of the DEMS data are estimates.* This includes the exposure estimates developed by the original investigators (Attfield et al, 20123 and Silverman et al, 2012) and reported in five papers by NIOSH/NCI investigators that were not cited in the RFI (Stewart et al, 2010; Coble et al., 2010; Vermeulen et al, 2010a,2010b; Stewart et al, 2012). The exposure estimates developed by later analysts (Crump and Van Landingham, 2012; Moolgavkar et al, 2015; Crump et al, 2015; and Crump, Van Landingham and McClellan, 2016) were also estimates of REC. Going forward, MSHA must recognize this serious limitation in any analyses of the DEMS data.

MSHA also must give due consideration to the papers reporting the results of analyses conducted by independent analysts (Moolgavkar et al, 2015; Crump et al, 2012; and Crump, Van Landingham and McClellan, 2016). These papers are not cited in the RFI. Using the DEMS data, the independent analysts' first replicated the analyses of the original investigators verifying that they were using the same DEMS data. Most importantly, in another step, the analysts extended the analyses using alternative models, alternative exposure estimates and controlling for radon exposure.

At the request of the IMA-NA, I have prepared a "Critique of the Health Effects Institute Special Report 19, "Diesel Emissions and Lung Cancer: An Evaluation of Recent Epidemiological Evidence for Quantitative Risk Assessment" (November 2015) (McClellan, 2015) [Attachment B]. In reviewing the HEI report, I drew on my four decades of experience following the literature and conducting research on the health hazards of diesel exhaust exposure, my participation as a member of the IARC Panel that reviewed the carcinogenic hazard of diesel exhaust in 1988, my personal attendance as an observer to the 2012 IARC review and personal participation in conducting extended analyses using the DEMS data.

I have attached a copy of my critique for the record. Let me briefly summarize my critique with emphasis on the multiple analyses of the DEMS data.

(1) The DEMS data set has been analyzed by multiple analysts with widely varying results that emphasize serious uncertainties in the underlying data that should be acknowledged when the results are used to inform policy decisions.

(2) It is important to recognize there are substantial differences among the eight mines studied in DEMS as can be seen by reviewing Table 1. There are meaningful differences in the (a) mode of operation from conventional mining with truck haulage to continuous long wall mining operations with conveyer belt movement of ore, (b) ventilation varying from natural ventilation with limited air movement to very substantial ventilation (1,630 thousand ft^3/min), and (c) wide differences in diesel equipment usage from 638 to 6,892 Adjusted Horse Power. Moreover, the mines are located in four different states (Ohio, Missouri, Wyoming and New Mexico) with very different cultural, economic and work environments. It is important to recognize that these differences are such that it is challenging to control for all potential variables in the epidemiological analyses and treat all the workers as being drawn from a single population.

(3) The worker population in the eight facilities were engaged in very different work activities and, hence, differences in exposure to diesel exhaust. Approximately one-third of the workers always worked on the surface (4008 workers and < 81 lung cancers), another one-third always worked underground (4080 workers and 82 lung cancers) and the other one-third spent some time working on the surface and sometime underground (4227 workers and < 44 lung cancers). Note the crude incidence for the latter group is only half of the other two groups, i.e. < 44 lung cancers in 4,227 ever-underground workers versus < 81 lung cancers in 4,008 surface workers and 82 lung cancers in 4,008 always-underground workers..

(4) The HEI Epidemiology Panel, individually and collectively, had limited professional knowledge of underground mining operations and use of diesel equipment in such operations. One member of the Panel is internationally recognized as an expert on diesel engine emissions. However, the other panel members had limited professional knowledge of diesel technology. The HEI Panel was invited to visit at least one of the mines included in DEMS, but declined the invitation.

(5) The most serious uncertainty in the DEMS data set and any epidemiological analyses based on it is the total lack of any measurements of Respirable Elemental Carbon (REC). As I have mentioned, all analyses are based on *estimated REC*. The estimates of REC developed by the original NCI/NIOSH investigators (using an extrapolation from CO measurements) are for some mines markedly different than the more straightforward REC estimates developed by the independent analysts using aggregate diesel equipment horse power (HP) and total mine ventilation (see Figure 2). The differences in the REC estimates are most substantial for the limestone and salt facilities which used substantial diesel HP and had less ventilation compared to the other mines (Table 1). The limestone and salt mines also had the highest portion of radon measurements above the limit of detection.

(6) It is important to recognize differences in the several metrics used for diesel exhaust exposure. As noted, the DEMS uses REC. This is different than Diesel Particulate Matter (DPM) metric used by MSHA for the Permissible Exposure Level. The DPM metric is based on Total Carbon, including both elemental carbon and organic carbon.

(7) A major strength of the DEMS data set is the availability of smoking history data in the case-control study for 198 lung cancer cases and 562 incidence density-sampled control subjects. Smoking information was not, however, available for the larger cohort.

(8) Both the original NCI/NIOSH investigators and the independent analysts observed that smoking status (never, former, or current smoker) and smoking intensity (former smoker of ≥ 2 packs per day to never smoker: Odds Ratio (OR) = 5.40 (95% CI = 2.23 to 13.06; current smoker of ≥ 2 packs per day versus never smoker: OR = 12.41, 95% CI of 5.57 to 2.66) was strongly associated with increased lung cancer. The original investigators found that among never smokers, ever-underground workers and surface workers had a similar OR suggesting that the lung cancer risk by surface only workers was mainly due to smoking.

(9) The original investigators found the lung cancer risk was substantially higher for surface-only workers than those who ever worked underground for both current and former smokers. For current smokers of 1 to less than 2 packs/day compared to never smoker the surface only workers had an OR = 13.34, 95% CI of 4.50 to 39.53 compared with an OR = 4.51, 95% CI of 1.5 to 13.58 for the ever underground workers. This unusual and unexpected finding was not adequately explained and suggests that a strong degree of caution should be exercised in using a group that combines individuals who spent some time working on the surface and some time working underground *and* always underground workers as done in the analyses conducted by the original investigators in creating an ever-underground group.

(10) The analyses of the original investigators and the analyses of the independent analysts both identify strong differences in lung cancer hazard associated with REC exposure among the different mine populations. The greatest lung cancer risk was in the limestone workers, with lower lung cancer risk associated with REC exposure in the potash and trona workers. Indeed, the OR for the potash workers was statistically significant at only the highest quartile of cumulative REC. Moreover, for trona workers the ORs for neither average REC intensity nor for cumulative REC were statistically significant.

(11) The HEI Report, building on work of independent analysts developing alternative REC exposure estimates, in detailed Appendix F, encouraged the development of an alternative REC exposure estimate based on mine diesel equipment HP and ventilation (CFM) (see Figure 1). In my opinion, this REC exposure estimate is the most defensible REC exposure estimate among those developed by the original investigators and the independent analysts.

(12) Using the HP-CFM based REC exposure estimates, none of the trend slopes for the OR were statistically significant ($p > 0.05$). Moreover, these trend slopes were smaller by roughly factors of five without control for radon exposure and factors of 12 with control for radon exposure, a well-recognized carcinogenic hazard, compared to those estimated in the original DEMS analysis. Also, the 95% confidence intervals for these trend slopes had only minimal overlap with those for the slopes in the original DEMS analyses (Table 2).

(13) In my opinion, the results of the original analyses of the DEMS data and those of the independent analysts in aggregate are probably adequate for evaluating the carcinogenic hazard of exposure to traditional diesel exhaust characteristic of diesel engines and high sulfur content fuels used in the 1980s and earlier. As the HEI Panel recognized, DEMS did not investigate exposure to newer diesel engines or fuel.

(14) In my opinion, the uncertainties in the results from analyses of the DEMS data are so substantial that extraordinary caution should be exercised in moving beyond their use in hazard characterization to using any single analytical result based on the DEMS population for quantitative risk assessment. Indeed, our quantitative understanding of the lung cancer risks of diesel exhaust exposure may be no better today than existed when MSHA made policy judgments to publish a final rule on May 18, 2006 phasing in a final Diesel Particulate Matter Permissible Exposure Limit of 160 micrograms of TC per cubic meter of air (160_{TC} $\mu g/m^3$).

(15) NIOSH has already initiated preparation of a Diesel Exhaust Risk Assessment (DERA) which will be available to MSHA and OSHA for use in regulatory decision making. I am eager to share my critique with the NIOSH scientists developing the DERA so they can be fully informed about the serious limitations in the original analyses conducted by the NIOSH/NCI investigators and the need to consider the later results published by independent analysts. Recognizing that any DERA developed by NIOSH will have potential for use by MSHA in regulatory rule making, it is important that MSHA encourage NIOSH to make public that agency's risk assessment protocol and related activities for public review and comment at an early date.

I will be pleased to engage in scientific dialogue with MSHA as you move forward with this important review of the science on the health hazards of exposure to diesel exhaust and evaluation of the adequacy of current MSHA regulations. To truly provide an adequate scientific basis for a review of "the effectiveness of the existing standards in controlling miners' exposure to diesel exhaust"[6] and "to preserve miners' health,"[7] MSHA must give due consideration to *all* of the currently available science in this area. If MSHA's review does not account for all of the relevant science, it is possible that estimates of the potential cancer hazards of miner's exposure to diesel exhaust may not be accurately characterized. This, in turn, could lead to inappropriate revision of the present regulations and misdirected actions to limit exposure of miners to diesel exhaust.

Thank you again for the opportunity to speak today.

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[6] 81 Fed. Reg. at 36,829.

[7] *Id.*

Attachment A: Roger O. McClellan Biography

Attachment B: Critique of Health Effects Institute Special Report 19, "Diesel Emissions and Lung Cancer: An Evaluation of Recent Epidemiological Evidence for Quantitative Risk Assessment"

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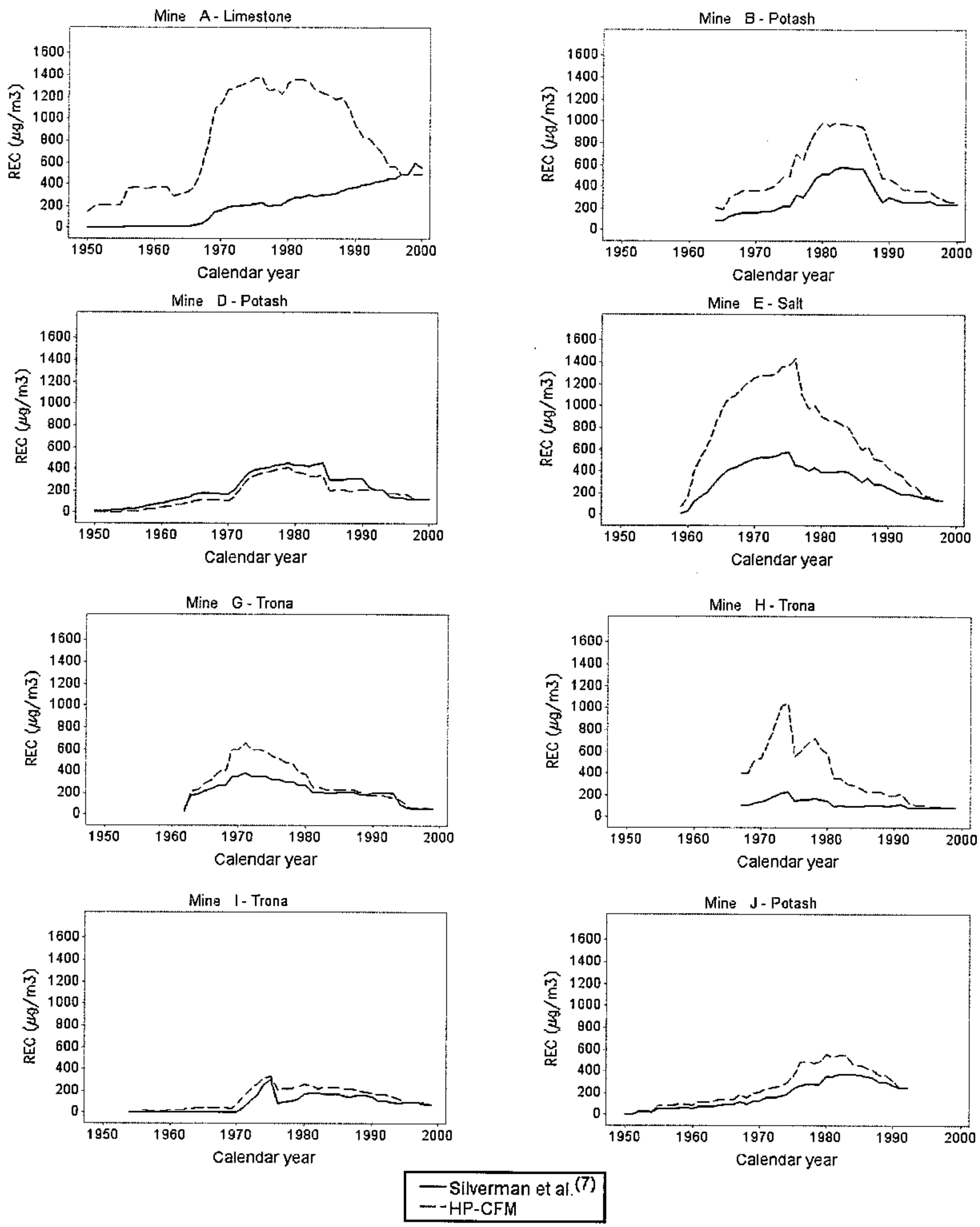

Figure 1: Alternative Respirable Elemental Carbon Metrics Using CO (red), developed by the original investigators versus HP-CFM (blue) Developed by Crump et al (2016).

Table 1: Characteristics of the Mines in the Diesel Exhaust in Miners Study (DEMS) (From Crump et al, 2016)

Mine	State	Ore	Ventilation	Year of First Diesel Use	Primary Mode of Operation	All Years CO # samples	CO % > LOD	Radon # samples	Radon % > LOD	1982 Activity CFM f^3/min (in thousands)	Diesel (Adj HP)
A	Missouri	Limestone	Natural	1947	Cv/H	248	70	37	84	--	6,862
B	New Mexico	Potash	Mechanical	1964	Cv/Con, Ct	447	62	18	44	250	892
D	New Mexico	Potash	Mechanical	1950	Cv/H, Cv/Con, Ct	323	54	61	39	360	2,326
J	New Mexico	Potash	Mechanical	1952	Cv/H, Cv/Con, Ct	178	52	13	38	240	1,421
E	Ohio	Salt	Mechanical	1959	Cv/H	207	66	39	70	233	2,804
G	Wyoming	Trona	Mechanical	1962	Cv/Con, Ct	276	50	17	24	450	638
H	Wyoming	Trona	Mechanical	1967	Cv/Con, LW, Ct	2361	39	40	15	950	1,110
I	Wyoming	Trona	Mechanical	1956	Cv/Con, Ct, LW	2000	54	54	20	1,630	1,493
Total						6040	50	279	42		

The above data were compiled from the Stewart et al.[1] and the substantial DEMS data files. Primary Mode of Operation: Cv/H – conventional with truck haulage, Cv/Con – conventional with conveyor belts, Ct – Continuous with conveyor belts, and LW – long wall with conveyor belts. Specific data for ventilation rates and HP are shown for 1982 for illustrative purposes, as 1982 was the last year of effective exposure for workers, assuming a 15 year-lag, as follow-up ended in 1997.

Table 2: Comparison of Conditional Original Logistic Regression Resulted (Silverman et al, 2012) with Results of Similar Analyses except based on New REC Estimates Defined Using HP and CFM (From Crump et al, 2016)

Analysis	Quartiles of cumulative REC, lagged 15 years (μg/m³-y)	Cases	Controls	OR (95% CI)	p_{trend}	Slope $(\mu g/m^3\text{-}y)^{-1}$ 95% CI
All Subjects						
Silverman et al.[7]	0 to < 3	49	158	1.0 (referent)	0.001	0.00073*
	3 to < 72	50	228	0.74 (0.40 to 1.38)		(0.00028,0.0012)*
	72 to < 536	49	157	1.54 (0.74 to 3.20)		
	≥ 536	50	123	2.83 (1.28 to 6.26)		
REC estimates from	0 to < 3	49	158	1.0 (referent)	0.0006	0.00082
Silverman et al.[7]	3 to < 72	50	228	0.79 (0.41 to 1.52)		(0.00035,0.0013)
and "without	72 to < 536	49	157	1.62 (0.75 to 3.49)		
radon" controls[12]	≥ 536	50	123	3.24 (1.40 to 7.55)		
HP-CFM REC	0 to < 6.6	49	172	1.0 (referent)	0.06	0.00016
estimates and	6.6 to < 129	50	191	1.05 (0.58 to 1.93)		(-0.000012,0.0003)
"without radon"	129 to < 891	49	168	1.60 (0.79 to 3.24)		
controls	≥ 891	50	135	2.37 (1.02 to 5.50)		
HP-CFM REC	0 to < 6.6	49	172	1.0 (referent)	0.63	0.00005
estimates and	6.6 to < 129	50	191	1.02 (0.55 to 1.90)		(-0.00016,0.00026)
"with radon"	129 to < 891	49	168	1.20 (0.56 to 2.56)		
controls	≥ 891	50	135	1.37 (0.5 to 3.77)		
All Subjects Who Ever Worked Underground						
Silverman et al.[7]	0 to < 81	29	92	1.0 (referent)	0.004	0.00065*
	81 to < 325	29	52	2.46 (1.01 to 6.01)		(0.00020,0.0011)*
	325 to < 878	29	69	2.41 (1.00 to 5.82)		
	≥ 878	29	51	5.10 (1.88 to 13.87)		
REC estimates from	0 to < 97	31	158	1.0 (referent)	0.01	0.00073
Silverman et al.[7]	97 to < 384	31	90	1.90 (0.78 to 4.63)		(0.00022,0.0012)
and "without	384 to < 903	31	80	2.73 (1.08 to 6.88)		
radon" controls[12]	≥ 903	31	84	5.04 (1.77 to 14.30)		
HP-CFM REC	0 to < 130	31	144	1.0 (referent)	0.16	0.00014
estimates and	130 to < 531	31	99	2.03 (0.83 to 4.96)		(-0.000062,0.0003)
"without radon"	531 to < 2149	31	99	3.45 (1.27 to 9.41)		
controls	≥ 2149	31	70	3.84 (1.07 to 13.74)		
HP-CFM REC	0 to < 130	31	144	1.0 (referent)	0.69	0.00005
estimates and	130 to < 531	31	99	1.83 (0.73 to 4.61)		(-0.00020,0.00030)
"with radon"	531 to < 2149	31	99	2.47 (0.79 to 7.73)		
controls	≥ 2149	31	70	2.5 (0.49 to 12.79)		
All Subjects Who Only Worked Underground						
HP-CFM REC	0 to < 106	14	26	1.0 (referent)	0.27	0.00024
estimates and	106 to < 410	15	28	1.89 (0.4 to 9.07)		(-0.000179,0.0007)
"without radon"	410 to < 1486	14	17	3.15 (0.47 to 21.05)		
controls	≥ 1486	15	26	4.73 (0.58 to 38.84)		
HP-CFM REC	0 to < 106	14	26	1.0 (referent)	0.36	0.00027
estimates and	106 to < 410	15	28	1.91 (0.38 to 9.75)		(-0.000316,0.0009)
"with radon"	410 to < 1486	14	17	5.61 (0.61 to 51.33)		
controls	≥ 1486	15	26	9.39 (0.47 to 187.84)		

*Calculated by us after reproducing Silverman et al results

Critique of

Health Effects Institute Special Report 19, "Diesel Emissions and Lung Cancer: An Evaluation of Recent Epidemiological Evidence for Quantitative Risk Assessment"

(November 2015)

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I. Abstract

The International Agency for Research on Cancer (IARC) in 2012 upgraded its cancer hazard classification of diesel engine exhaust exposure to Category 1 of "carcinogenic to humans" based on what IARC asserted was adequate or sufficient epidemiological evidence.[1] Its 1988 classification of "probably carcinogenic to humans" was based on limited epidemiological evidence.[2]

The new epidemiological evidence of an association between diesel exhaust exposure and lung cancer viewed as sufficient epidemiological evidence in the 2012 IARC review came primarily from a diesel exhaust in miners study (DEMS) published in 2012 by investigators from the National Institute for Occupational Safety and Health (NIOSH) and the National Cancer Institute (NCI). The DEMS investigation followed 12,315 workers in eight nonmetal mining operations (one limestone, one salt, three potash and three trona) from the beginning of dieselization (as early as 1947 in the limestone mine) through December 31, 1997 by which time there were 2,185 deaths in the study population with 198 lung cancers. IARC also relied on new evidence from a study published in 2012 of 31,135 U.S. truckers using diesel-powered trucks followed from 1985 through December 31, 2000, (the U.S. Truckers' Study), which included 4,306 deaths with 779 lung cancers.

Neither study actually measured diesel exhaust exposures for the individuals that were studied, resulting in the need to retrospectively estimate exposures to diesel exhaust. In the U.S. Truckers' study, the original investigators used Submicron Elemental Carbon (SEC), particles below one micron in aerodynamic diameter, as the exposure metric for diesel exhaust.

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[1] *See* IARC Monographs, Diesel and Gasoline Engine Exhausts and Some Nitroarenes (Vol. 105 2013), *available at* http://monographs.iarc.fr/ENG/Monographs/vol105/mono105.pdf.

[2] Epidemiology is the study of the distribution and determinants of health related status or events, including overt disease and related problems. Each epidemiological study may be viewed as analogous to a three-legged stool. The three legs being: (1) a defined population and related vital health data for the population such as morbidity (sickness) and mortality (deaths by cancer) for a defined period of time; (2) the exposure assessment for members of the population being studied, including the agent of interest (in this case, diesel engine exhaust) and any other agents such as cigarette smoke, radon, asbestos, etc. that may also cause the endpoint of interest; and (3) the analytical methods used to analyze for a relationship between exposure, in this case to diesel exhaust, and health outcome, in this case, lung cancer deaths. The overall strength of a study is dependent on the strengths and weaknesses of each component. Uncertainties in one component, such as in the exposure assessment or assessment of vital statistics, cannot be offset by superior quality or certainty of other components.

Estimates of SEC exposure were projected retrospectively from measurements made near the end of the study. In the DEMS investigations, Respirable Elemental Carbon (REC) was used as the metric for diesel exhaust exposure. REC is characterized with a sampling technique that collects particles less than 3.5 microns in aerodynamic size. The original NCI/NIOSH investigators retrospectively estimated REC using knowledge of diesel equipment horsepower (HP), mine ventilation in cubic feet per minute (CFM), past measurements of CO and assumed relationships among HP, CO and REC pre-1998 and measurements made in 1998-2000. This approach assumed that CO emissions and CO mine concentrations were reasonable surrogates for REC.

Following publication of DEMS, independent investigators used DEMS data to develop alternative REC estimates using CO as a surrogate for REC and most importantly, estimate REC based on HP-CFM, without using CO as a surrogate for REC.[3]

The initial analyses of the entire DEMS cohort, including both surface and underground workers, did not show a clear association between diesel exhaust exposure and lung cancer. However, analyses conducted with workers grouped as only (a) surface workers versus (b) ever-underground workers, (about one-half of the ever-underground workers had always worked underground and the other half of the ever-underground workers had spent time both on the surface and underground) revealed a modest increase in the standardized mortality rate ratio for diesel exhaust exposure (1.26, 95% Confidence Interval of 1.09 to 1.44) when adjustment was made for worker location. This standard mortality rate ratio translates to an attributable risk for diesel exhaust exposure of 0.21. Thus, the majority of the lung cancer deaths were attributable to other risk factors, including cigarette smoking, the dominant cause of lung cancer in the United States.

A group of independent investigators, funded by a coalition of private industry organizations organized by the Engine Manufacturers Association were provided access (under carefully controlled conditions) to the DEMS data via NIOSH/NCI and other official channels of the Department of Health and Human Services. The independent investigators replicated the original NIOSH/NCI investigators' analyses demonstrating that the independent investigators were using the same basic DEMS data sets. However, the independent investigators, using an alternative biologically based model found a somewhat reduced association between diesel

[3] As an aside, neither the REC metric in the DEMS or SEC metric exactly coincide with the Diesel Particulate Matter (DPM) metric used in the current Mine Safety and Health Administration regulations for diesel exhaust which is based on total carbon, including both elemental carbon and organic carbon.

exposure and lung cancer, and, most importantly, identified a strong influence from the workers in one mining operation, the limestone mine.

The original NIOSH/NCI investigators also conducted a nested lung cancer case-control study in which they obtained smoking data on the 198 lung cancer cases and 562 incidence density-sampled control subjects. As expected, they found a very strong association between cigarette smoking and lung cancer. This included an unexplained markedly stronger association between smoking and lung cancer for surface-only workers versus ever-underground workers. The original investigators observed a statistically significant increasing trend in lung cancer risk with increasing cumulative REC and average REC Intensity. They also observed an interaction between smoking and cumulative REC such that the effects of each of those exposures was attenuated in the presence of high levels of the other, an unexpected and not explained finding.

The independent investigators' analyses of the DEMS nested case-control data replicated the results of the original investigators. However, when the independent analysts used REC exposure estimates based on HP-CFM (without assuming CO was a surrogate for REC), none of the trend slopes for (a) all subjects, (b) all subjects who ever worked underground, or (c) subjects who worked only underground were statistically significant. Moreover, these trend slopes calculated using the new REC estimates based on HP-CFM were smaller by a factor of five without control for radon, and a factor of 12 smaller with control for radon exposure compared to those reported in the original DEMS analysis. Also, the 95% confidence intervals for the trend slopes with the HP-CFM based REC had minimal overlap with those for the slopes in the original analyses.

The original analysis of the U.S. Truckers' Study cohort data revealed a weak association between SEC and lung cancer and, even then, only when mechanics were excluded from the analyses. There have apparently been no analyses of the U.S. Truckers data set other than those published by the original investigators. One published paper has joined the U.S. Truckers' study results with the DEMS results in an attempt to show consistency between the results of studies of the two populations.

The Health Effects Institute (HEI), at the request of HEI's sponsors (both the U.S. Environmental Protection Agency and the engine manufacturers), convened an independent panel (HEI Epidemiology Panel) of nine scientists to evaluate use of the results of the U.S. Truckers' study and DEMS whether those studies could provide the basis for a future quantitative risk assessment. Most of the Panel members were experienced in epidemiology, biostatistics, and/or industrial hygiene. One member is well known for his expertise in diesel engine technology. None of the Panel members were experienced in underground mining operations using diesel equipment. The HEI Epidemiology Panel declined an invitation to visit one of the mines that was studied in DEMS.

Such a quantitative risk assessment, if conducted, could establish a quantitative estimate of the potency of diesel exhaust exposure for causing lung cancer. Such potency estimates could be used to estimate, for a specified level of exposure, the estimated excess risk of lung cancer attributable to measured or estimated levels of diesel exposure. The results of such calculations are frequently reported as avoidable deaths and these numerical estimates used as evidence of the need for more stringent regulation.

In Special Report 19: Diesel Emissions and Lung Cancer: An Evaluation of Recent Epidemiological Evidence for Quantitative Risk Assessment (Nov. 2015) (HEI Report), the HEI Panel concluded, "the DEMS and the Truckers' Study provided results and data that provide a useful basis for quantitative risk assessment of exposure in particular to older diesel engine exhaust."[4] "However, "the uncertainties within each study should be considered in any attempt to derive an exposure response relationship" for diesel exhaust particulate matter."[5]

In my opinion, even this qualified endorsement of the two studies is not consistent with the substantial uncertainties in estimates of REC exposure and the association between diesel exhaust exposure and lung cancer made by the original NIOSH/NCI investigators and those of the independent analysts using alternative estimates of REC exposure, control for radon exposure, and alternative REC exposure-response models.

As expected, analysis of the DEMS nested case-control data reveals a strong influence of cigarette smoking on lung cancer, an influence that makes it challenging to tease out the effects of other risk factors, including diesel exhaust exposure and radon exposure. The new analyses of the DEMS data by independent analysts using new estimates of REC exposure based on HP-CFM showed a reduced risk of REC-associated lung cancer compared to those of the original investigators. Moreover, the new analyses using limited radon measurement in the mines show a clear influence of radon exposure. Based on all of the analyses conducted to date by either the original investigators or independent analysts, it is likely that any estimates of the potency of diesel exhaust from old traditional technology diesel engines (pre-1990) will be bounded on the upper bound by the results of the original analyses of the DEMS nested case-

[4] HEI Report at 1 (*available at* http://pubs.healtheffects.org/view.php?id=446).

[5] *Id.* at 7.

control data and on the lower bound by limited excess risk, as revealed by the independent analyses using the HP-CFM based REC estimates and control for radon exposure.

The multiple analyses performed to date using the DEMS data set serve as an example of the value of making epidemiological data sets available for replicative and new extended analyses by multiple teams of scientific investigators. Moreover, the results of the multiple analyses emphasize the importance of considering the complete constellation of results to inform public policy decisions on the risks of exposure to diesel exhaust without excessive reliance on the original analyses.

Any use of the DEMS results for either cancer hazard characterization or quantitative risk assessment also needs to recognize the results of such assessments are most relevant to old traditional diesel technology (pre-1990). This is especially the case since the strongest influence of REC on the relationship between REC and excess lung cancer was found when a 15 year lag was used in the models. With mortality followed through December 31, 1997, this meant the exposures of greatest influence occurred in 1982 and earlier. Substantial changes in diesel technology (engine technology, exhaust after-treatment and ultra-low sulfur fuel) have been made in recent decades such that new technology diesel engines have extraordinarily low emissions of particulate matter and nitrogen oxides. The results of the analyses of DEMS data based on exposure to exhaust from old technology engines have limited relevance to evaluating the health risks of exhaust from the new technology diesel engines.

The cancer hazard findings from analysis of the DEMS data, even if uncertain, underscore the value of past and continuing efforts to reduce the exposure of workers to exhaust from traditional diesel engines. Moreover, the results emphasize the benefits of shifting to new technology diesel engines using ultra-low sulfur fuel with low emissions of particulate matter and oxides of nitrogen.

II. Introduction

This critique of the Health Effects Institute Special Report 19 – "Diesel Emissions and Lung Cancer: An Evaluation of Recent Epidemiological Evidence for Quantitative Risk Assessment" (HEI, 2015) addresses an issue of substantial importance to many different audiences, including the mining industry. It is also a topic with a rich history. The author of this critique, Roger O. McClellan, has over four decades of experience investigating the potential health effects of diesel exhaust as detailed in Section XIV.

To provide context, this critique starts with a brief review of concerns for the health effects of exposure to diesel engine exhaust emphasizing lung cancer as the primary health endpoint of concern. It then proceeds to provide a brief description of the Health Effects Institute and its 35-year history of involvement in the broad issue of diesel engine exhaust exposure and potential health effects.

The critique then describes the DEMS and U.S. Truckers' studies of the association between diesel exhaust exposure and excess risk of death from lung cancer. This section starts with a discussion of the design of the epidemiological studies and proceeds to a discussion of the findings published by the original NIOSH/NCI investigators, and then the findings obtained by a group of independent analysts funded by a coalition of private industry organizations organized by the Engine Manufacturer's Association (EMA).

The evaluation conducted by the HEI Epidemiology Panel, the authors of HEI Special Report 19, is then discussed.

The critique concludes with summary conclusions on the utility of the range of findings, especially those from analyses using the DEMS data, for conducting quantitative risk assessment of the lung cancer risk to miners from exposure to diesel exhaust.

This critique is not intended to address the broader issue of the applicability of the findings of the DEMS and U.S. Truckers' Study for evaluating the lung cancer risks to the general population of exposure to ambient $PM_{2.5}$ containing diesel exhaust particulate matter. Obviously, many of the issues raised in this critique are also applicable to any use of results of analyses of the DEMS data, irrespective of the population under consideration.

III. Historical Concerns for Potential Health Effects of Exposure to Diesel Engine Emissions

Diesel compression ignition engines named for the inventor, Rudolph Diesel, were introduced into commerce in the early 20^{th} century and soon became the major power source used in a wide range of industrial settings and in transportation. The power, durability and fuel efficiency of diesel engines have made them attractive in heavy duty applications such as trucks, buses, construction, farming and mining equipment, locomotives and in marine shipping. The low emission rate of carbon monoxide from diesel engines, as contrasted with emissions from gasoline-fueled spark ignition engines, has been viewed as a plus for many applications, including use of diesel engines in mines. Early in the commercialization and use of diesel engines, concerns developed for their conspicuous black carbon soot emissions and the odor of diesel exhaust. Concern for the emissions initially focused on their impact on visibility. With increasing use of diesel-powered equipment, concern developed for the potential impact of exposure to diesel exhaust emissions on lung disease and especially lung cancer in workers and the general population.

In the 1960s and 1970s, numerous new techniques were developed and introduced for evaluating the function of living cells in humans and laboratory animals, including the development of tests for evaluating the potential for a range of agents to cause genetic alterations, i.e., mutation in cells. One of the most popular of these tests, utilizing special strains of bacteria, was developed by Professor Bruce Ames of the University of California, Berkeley, and used to test a wide range of agents for mutagenicity. The use of the Ames test was based on the presumption that detection of mutagenic potential served as a surrogate measure of the potential of the agent to cause cancer in humans. This presumptive evidence of human carcinogenic potential could then be used to limit exposure to the mutagenic agent even in the absence of laboratory animal or epidemiological evidence of carcinogenic potential for the agent.

It is not surprising that soon after the Ames test was developed and introduced for widespread use, the test was used by EPA scientists and others to test organic solvent extracts of diesel exhaust soot particles (McClellan, et al., 2012). As an aside, the organic solvent extracts were already presumed to be carcinogenic since the extracts contained high concentrations of polycyclic aromatic hydrocarbons and nitroarenes. Some of these compounds had already been identified individually as having cancer-causing potential. The results of the Ames tests of the organic solvent extracts of diesel soot particles were clearly positive, immediately resulting in heightened concern for exposure to diesel engine exhaust causing cancer and, especially, lung cancer. Ironically, decades earlier scientists had collected large samples of airborne particles near freeways in Los Angeles and demonstrated that organic extracts of the collected particles applied to the skin of mice caused skin tumors.

The positive mutagenicity findings with organic solvent extracts of diesel exhaust particles also served as a stimulus for additional research on the potential health effects of exposure to diesel exhaust. This included the conduct of new epidemiological studies of workers previously exposed to diesel exhaust. In addition, in four countries around the globe, controlled exposure studies were initiated using laboratory animals. In these studies, multiple species of laboratory animals were exposed, in many studies over their lifetime, to various low dilutions (and thus, high concentrations) of whole diesel engine exhaust. Other research studies sought to characterize the fate of inhaled diesel soot particles and their organic constituents and identify the mechanisms by which cancer might presumably be produced by exposure to diesel exhaust.

To some extent, concern over the new findings on the potential cancer hazard of diesel exhaust exposures served to stimulate the creation of a new non-profit entity, the Health Effects Institute (HEI). HEI was created in 1981 as a "good intentions" approach to meeting the requirements of the Clean Air Act that required combustion engine manufacturers to "certify" that over and above meeting all applicable health-related regulation, use of the engines did not pose any health risks. Moreover, the Act required the EPA Administrator to certify that the manufacturers' certification was correct. Creation of HEI to conduct research on the health effects of engine emissions, with joint funding from the engine manufacturers and the EPA, was viewed as an alternative to the impossible to meet "certification requirements."

By the late 1980s, a substantial body of scientific information had been developed indicating that protracted exposure to high concentrations of diesel soot particles could cause lung cancer in rats at incidences over and above the background rate. The primary studies in the United States were conducted by Mauderly, et al. (1987) at the Lovelace Institute in Albuquerque, NM with support from the U.S. Department of Energy. A typical study involved exposures of 7,000 µg diesel exhaust particles/ m^3 for 7 hours/day for 5 days/week for up to 2½ years. To provide perspective, these exposures represented about a 1 to 10 dilution of whole exhaust from diesel engines typical of the 1980s. Similar results were obtained in studies conducted in laboratories in Germany, Switzerland, and Japan. Ironically, mice exposed under identical conditions at the Lovelace Institute did not develop an increased incidence of lung cancers (Mauderly et al., 1996).

During this same time period, it was discovered that exposure of rats to the high concentrations of other poorly soluble particles, such as titanium dioxide, over their lifespan caused an increased incidence of lung cancer (Lee, et al., 1985). This raised the possibility that the association between long-term high concentration exposure to diesel exhaust and lung cancer in rats might be due to the carbonaceous diesel soot particles alone or in combination with organic constituents. A paper by Wolff, et al. (1987), now viewed as a classic, revealed that the rats exposed to the highest concentrations of diesel particulate matter had impaired lung clearance and lung burdens of particles that were disproportionately higher than at low concentration exposures. Later it would be demonstrated that prolonged high concentration exposure of rats to pure carbon black particles, absent any organic compounds, would cause an increase in lung cancer (Nikula, et. al., 1995). These findings supported the view that the findings of lung cancer in diesel exhaust exposed rats were a species-specific, high exposure phenomena that was not relevant to assessing human risks.

Debate over the relevance of the findings in cell assays and laboratory animal bioassays for predicting human cancer causation placed even more emphasis on the need to conduct epidemiological studies of diesel exhaust exposed workers. This included studies on worker populations using diesel-powered equipment, including bus drivers, railroad workers, truckers and underground miners. The results of the epidemiological studies were viewed, and continue to be viewed, as the "gold standard" for evaluation of the human carcinogenic hazard of specific chemicals and occupational and environmental exposure circumstances. A major challenge in all of the epidemiological studies has been uncertainties in the estimates of diesel exhaust exposure.

IV. The Risk Assessment Paradigm

The dominant paradigm for evaluating the safety of drugs, food additives, work place exposures and other situations pre-World War II, was to assume that any adverse health effects observed with long duration, high concentration exposure could be reduced and, indeed, eliminated if the exposure duration and concentration were reduced below some threshold concentration. In short, there were thresholds above which health effects were observed and below which exposures were considered to be safe. This approach began to be questioned in the 1930s as concern increased for genetic effects and cancer being caused by exposure to radiation and other agents. Debate began, and continues today, over whether exposure-response relations for particular agents and a range of health endpoints are best described by (a) an exposure-response function with a threshold, or (b) a linear, no threshold exposure-response function.

A new paradigm for evaluating and regulating safety began to emerge during World War II and intensified in the 1950s and 1960s (McClellan, 1999). This new paradigm was clearly evident in new legislation and organization of new regulatory agencies in the 1970s. This was the era of the influential book – "Silent Spring," the passage of the Clean Air Act Amendments of 1970 and the creation of numerous new environmental and occupational health agencies such as the EPA, NIOSH, the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA).

The new paradigm that emerged was multi-faceted (McClellan, 1999; NRC, 1983, 1993, 1994, 1996, 2009). The paradigm recognized that exposure-response relationships for some agents might show thresholds but also assumed that for some agents and health endpoints such as cancer, the relationship may be linear and not have a threshold.

The basic risk or, conversely, safety paradigm that emerged in the 1960s and 1970s is illustrated in Figure 1. This figure summarizes the basic paradigm as advocated by the National Research Council (2014) and used by the EPA and most federal agencies. The paradigm has four components: (a) hazard identification (Does an agent have potential to produce and adverse outcome such as cancer?); (b) exposure characterization (What are the exposures encountered or estimated to be encountered?) (c) exposure-response characterization (What are the observed or estimated exposure-response relationships?); and (d) risk characterization (What is the estimated or predicted outcome when the exposure and potency are both taken into account?). The history of development of the risk assessment paradigm and its application has been reviewed by McClellan (1999).

It may be noted that in Figure 1, the phrase, dose-response, is used. For consistency it should have been exposure-response. However, the two words, exposure and dose, are often used interchangeably although they have very different meanings. Exposure refers to the concentration present in the air, water or food and available for intake. Dose is a more restrictive term relating to the quantity of an agent that enters the body and may reach various organs and tissues. Two other words, hazard and risk, deserve comment. Within this paradigm, the word hazard is used as a descriptor of potential harm without consideration of the level of exposure or dose required to produce an effect, such as cancer. Risk, on the other hand, takes account of the likelihood of a hazardous agent causing harm, i.e. its potency <u>and</u> the level of exposure or dose to yield a probability that harm can occur, i.e. cancer incidence, over and above that arising from other factors.

The hazard identification component of this paradigm soon gave rise to development of qualitative assessments of causality for specific agents. This approach under-girds the IARC monograph program initiated in the early 1970s that has evaluated over 1000 agents or exposure circumstances with regard to human carcinogenic hazard, i.e., does the agent or exposure have the potential to cause cancer. The IARC program conducts periodic reviews utilizing expert panels that place agents in five categories: 1 – human carcinogens; 2a – likely human carcinogens; 2b – possible human carcinogens 3 – not likely to be a human carcinogen; and 4 – insufficient information for classification. Decisions on which cancer hazard characterization is appropriate are made by a panel of some 20 scientific experts and consideration of three types of data: (a) epidemiological; (b) animal; and (c) mechanistic evidence. The IARC Monograph Reports also contain information on sources of the agent and exposure circumstances. The EPA and the National Toxicology Program (NTP) in the United States have developed and used similar schemes. More recently, this approach has been extended by multiple agencies to other health endpoints, including non-cancer effects. It is important to note that IARC and the NTP only address whether the agent or exposure pose a carcinogenic hazard, they do not provide estimates of carcinogenic potency.

As public concern increased for the exhaust emissions of diesel engines, a number of U.S. and International agencies conducted reviews of the health hazards of exposure to diesel exhaust with an emphasis on human carcinogenic hazard (Table 1). Not shown in Table 1 is an independent review of emissions, exposures, and health effects of diesel exhaust conducted by HEI (1995). The table includes columns summarizing the conclusion drawn based on animal data and human data. As discussed earlier, interpretation of the animal evidence, especially the results of lifespan studies of diesel exhaust exposure with lung cancer as a health outcome in rats, has been complicated by questions as to the relevance of the findings in laboratory animals to humans.

The same situation exists with regard to interpreting the relevance of mechanistic findings from studies conducted with *in vitro* systems or animals injected with diesel soot particles typically at high concentrations. Alternatively, particles can be collected, extracted with a strong organic solvent and the extracts containing organic constituents of the particles studied. Findings from such studies have been published in more than a thousand papers in the peer-reviewed literature (Hesterberg, et al., 2005, 2006, 2012). It is noteworthy that diesel soot particles are relatively easy to collect and study in cell assays or by injection into laboratory animals. Thus, the studies are relatively easy and inexpensive to conduct with a wide array of different assay systems. In this reviewer's opinion, these results are of limited value in most cases for better understanding the human hazards of exposure to diesel exhaust because of the substantial uncertainties in extrapolating from: (a) cells to intact mammalian organisms; (b) laboratory animal species to humans; (c) extraordinarily high exposures *in vitro* to *in vivo*; and (d) the use of non-physiological modes of exposure, such as intra-tracheal injection, to inhalation exposure. Nonetheless, the results of these assays continue to heighten the concern of scientists and, in turn, concern by the public for the health hazards of diesel exhaust emissions and a multitude of other materials.

The last entry in Table 1 shows the IARC 2012 categorization of exposure to diesel exhaust as "carcinogenic to humans (Group 1)" based on sufficient evidence from epidemiological studies (Benbrahim-Talla, et al., 2012; IARC, 2013). That landmark decision was followed the next year by IARC categorizing "ambient air pollution" and "particulate matter in ambient air" as "carcinogenic to humans" (Loomis, et al., 2013; IARC, 2015). In view of the significance of these findings, the background to these decisions is reviewed in the next section of this critique.

V. History of Assessing Carcinogenic Hazards of Diesel Technology

All of the assessment reviews in Table 1 have been comprehensive, utilizing scientific evidence from epidemiological studies on occupationally exposed populations, a small number of controlled exposure studies conducted with human volunteers, long-term inhalation bioassays of diluted diesel exhaust conducted with laboratory animals, and a broad array of studies with cells and laboratory animals directed toward understanding mechanisms by which diesel exhaust could potentially cause cancer and other diseases. It is generally recognized that diesel exhaust is among the most studied agents that human populations routinely encounter.

It is also noteworthy that of the assessments shown in Table 1, only the assessment conducted by the California EPA in 1998 included quantitative characterizations of the cancer risk of exposure to diesel exhaust based on human data (Dawson and Alexeeff, 2001). That quantitative assessment was based on an epidemiological study of railroad workers (Garshick, et al., 1988). As an aside, in 1999 an HEI Panel had recommended against the use of the 1988 railroad workers study results for quantitative risk assessment (HEI, 1999).

IARC first qualitatively evaluated the carcinogenic hazard potential of exposure to diesel exhaust in 1988 (reported in IARC, 1989). This review was updated in 2012 (Benbrahim-TL, et al., 2012; IARC, 2013). The 1988 evaluation concluded that data from chronic exposure studies with diesel exhaust conducted in rats provided "sufficient" positive evidence of lung cancer induction. Ironically, as noted earlier, later studies would reveal that the same effects were produced by chronic exposure to pure carbon black particles and other poorly soluble particles such as TiO_2. Pure carbon black particles do not contain polycyclic aromatic hydrocarbons that are found as components of exhaust particles from traditional diesel technology engines and are known to be carcinogenic. In the 1980s, it was commonly assumed that carbonaceous diesel soot particles containing polycyclic aromatic hydrocarbons, when inhaled, could initiate the carcinogenic process. Thus, the findings of lung cancer in the diesel exposed rats were expected. However, by the mid-1990s, the picture had changed and it was generally accepted that the lung cancers observed in rats exposed in lifespan studies to high concentrations of poorly soluble particles such as diesel soot, titanium dioxide, and carbon black resulted from a species-specific, prolonged high concentration exposure mode of action that did not involve the hydrocarbons. This led to the conclusion that these findings should not be used as evidence of a cancer causing potential for humans, especially at the modest air concentrations found in ambient air or most work place environments.

A key finding in the 1988 IARC evaluation was that the human epidemiological evidence for diesel exhaust exposure causing cancer in humans was judged to be "limited." This IARC evaluation included consideration of the data from the Garshick, et al. (1987) study on railroad workers used by CARB to develop quantitative estimates of the potency of exhaust from old technology diesel engines to cause lung cancer. A major criticism of the Garshick, et al. (1987) railroad workers study was the uncertainty in the retrospective exposure assessment.

Not shown in Table 1 is an evaluation conducted by HEI (1999), noted earlier, which concluded that the epidemiological findings available at that time were not suitable for qualitative risk assessments.

In the early 1990s, the EPA, anticipating development of regulations for diesel engine exhaust emissions and diesel fuel quality, initiated a comprehensive assessment of the health effects of exposure to diesel exhaust. This review, as is customary within EPA, was conducted by the EPA's Office of Research and Development as part of its risk assessment activities. It was anticipated that this assessment would inform the EPA's regulatory decisions on diesel technology developed and issued by EPA's Office of Air and Radiation. Ultimately, the EPA evaluation would involve preparation and external review of five draft reports before a report was finally endorsed by the external advisory committee, a panel of the EPA Clean Air Scientific Advisory Committee on which this author served in 2002 (EPA, 2002).

The major contentious issue that delayed preparation and endorsement of the final report on the health effects of diesel exhaust was whether either the epidemiological or animal evidence were sufficient for conducting a quantitative cancer risk assessment. The final report published in 2002 concluded that exposure to diesel exhaust posed a health hazard; however, the data were not sufficient for developing a quantitative cancer risk assessment. As it turned out, EPA in 1998 (while development of the health hazard report was still underway) set very stringent exhaust emission regulations for diesel engines and the sulfur content of diesel fuel. These regulations were based on the qualitative assessment of hazards for cancer and other health endpoints reviewed in the earlier draft reports. This is an excellent example illustrating that quantitative assessments of cancer risk or other health endpoints are not always essential for regulatory agencies to take action.

It is noteworthy that the controversy in the late 1980s and early 1990s over the adequacy of the epidemiological evidence for diesel exhaust causing cancer served as a major impetus for the conduct of new epidemiological studies. A key consideration in the design of the new studies was increased attention to developing quantitative estimates of historical exposure to diesel exhaust (HEI, 1999, 2002). That issue will be considered in detail later in this critique.

Two of the new studies initiated in the 1990s yielded results that were evaluated by IARC in 2012 and were the focus of the HEI evaluation (HEI, 2015) and this critique: the U.S. Truckers' Study and the Diesel Exhaust in Miners Study (DEMS). These studies will be reviewed in detail later in this critique.

For now, it is sufficient to note that the 2012 IARC evaluation of diesel exhaust exposure concluded diesel engine exhaust exposure should be placed in Category 1, "carcinogenic to humans." That conclusion was based on a key finding of "sufficient" epidemiological evidence largely based on the positive findings reported for the original analysis of the DEMS data set by Attfield. et al. (2012) and Silverman, et al. (2012) and, to a lesser extent, the results of the U.S. Truckers' Study (Garshick, et al., 2012a). A review by Gamble, et al. (2012) provides an independent perspective on the literature used in the 2012 IARC review on occupational exposures to diesel exhaust and lung cancer.[6]

In 2013, another IARC Panel (Loomis, et al., 2013; IARC, 2015) concluded that exposure to (a) outdoor air pollution, and (b) particulate matter in outdoor air pollution is "carcinogenic to humans." Both evaluations made reference to the earlier IARC (2012) conclusion that diesel exhaust particulate matter was carcinogenic to humans and was an important component of ambient air pollution and of particulate matter in ambient air. Thus, the conclusions rather automatically followed that "outdoor air pollution" and "ambient particulate matter in outdoor air" were carcinogenic to humans (IARC, 2015).

[6] As an aside, both the 1988 and 2012 IARC Panels also evaluated gasoline engine exhaust and concluded in both reviews that it was "possibly carcinogenic to humans." The finding for gasoline engine exhaust deserves comment. It was based on much more limited experimental and epidemiological research. Diesel exhaust is much easier to study than is exhaust from gasoline-fueled spark ignition engines and the epidemiological findings were characterized as "limited evidence" of human carcinogenicity. Moreover, by the 1980s major changes had been made in gasoline engines and fuels, including removal of lead from gasoline enabling the use of catalyst-based exhaust treatment systems resulting in reduced emissions of hydrocarbons, CO and NO_x.

EPA officials have regularly referred to removal of lead from gasoline as a major success story for the Agency. More recently, senior EPA officials have commented on development of clean diesels as a success story.

IARC's classifications in 2012 and 2013 seem to have motivated EPA to ask HEI to determine whether the new epidemiological studies could be used in a quantitative risk assessment. Motivation for EPA to develop an updated cancer risk assessment for exposure to diesel exhaust could also have come from the Mobile Source Office within the EPA's Office of Air and Radiation Programs that issued EPA's previous diesel engine emission and diesel fuel regulations. A quantitative cancer risk assessment for diesel exhaust would strengthen the evidence used to justify past actions and also lay the groundwork for more aggressively replacing old technology diesel engines with new technology diesel engines. The EPA already has in place a very popular, but modestly funded, program to subsidize the purchase of new technology diesel equipment by state and local agencies. In considering this myriad of options, it is important to recognize EPA is not a monolithic agency, it has multiple offices competing for resources and attention,

At an early stage in its evaluation process, the HEI Epidemiology Panel held a workshop on "Diesel Exhaust, Lung Cancer and Quantitative Risk Assessment" on March 6, 2014 for multiple interested parties. At that workshop, one of the participants, Robert Park from NIOSH, announced the intention of his agency to develop a quantitative risk assessment on diesel exhaust. That work is apparently proceeding, as evidenced by Park submitting an abstract on his preliminary work with the DEMS data for presentation at an international exposure assessment and occupational epidemiology meeting in Barcelona, Spain in September 2016. Encouragement to complete the NIOSH quantitative risk assessment on diesel exhaust could come from NIOSH's partner agencies, OSHA and MSHA, which would use a NIOSH prepared risk assessment to under-gird any new regulations related to diesel exhaust emissions. This would include any updates to the MSHA 2005 regulations (DOL/MSHA, 2005).

It is important to recognize that any future regulatory actions on occupational exposure to diesel exhaust particulate matter as well as occupational exposure to other kinds of airborne particulate matter will occur within a broader arena than just occupational exposures to the agents. It is my opinion that the boundaries between different kinds of particulate matter exposures in the work place will become less distinct. Moreover, the scientific and policy boundaries between occupational and environmental health are becoming increasingly blurred, as are the boundaries between air quality and climate change.

VI. Epidemiological Studies

Epidemiology is the study of the distribution and determinants of health-related status or events, including overt disease and related problems. An epidemiological study may be viewed as analogous to a three-legged stool. The three legs being: (1) a defined population and related vital health data for the population such as morbidity (sickness) and mortality (deaths by causes) for a defined period of time; (2) the exposure assessment for the population being studied, including the agent of interest (in this case, diesel engine exhaust) and other agents such as cigarette smoke, asbestos, radon, etc.; and (3) the analytical methods used to analyze relationships between exposure and health outcome, for example, lung cancer. Today, these analytical procedures routinely include complex computer-based statistical programs that typically use conditional logistic regression models to evaluate the risk of dying of disease, in this case, lung cancer, from the putative carcinogenic agent, in this case, diesel exhaust exposure, relative to a base line situation without exposure to the putative agent, diesel exhaust. A well-conducted epidemiological study is dependent on all three components of the study being solid. Uncertainties in one component, such as the exposure assessment or the assessment of vital statistics cannot be offset by the superior quality or certainty of other components. In my opinion, the weakest component of DEMS is the retrospective exposure assessment.

As already noted, the original NIOSH/NCI DEMS investigators used Respirable Elemental Carbon (REC) concentrations as the metric for diesel exhaust exposure. However, REC measurements do not exist for any of the workers from the beginning of dieselization of the mines through December 31,1997; the end of the mortality follow up for the DEMS workers. Hence, all REC concentrations used in the original epidemiological analyses (Attfield, et al., 2012; Silverman, et al., 2012) were developed from an elaborate retrospective exposure assessment. That original DEMS exposure assessment was done largely by NCI personnel and was reported in a series of peer-reviewed publications (Stewart, 2010, 2012; Coble, et al., 2010; Vermeulen, et al., 2010a, 2010b).[7] The follow-up epidemiological analyses by the independent investigators (Moolgavkar,et al., 2015; Crump, et al., 2015; Crump, et al., 2016;

[7] As an aside, the leader of the DEMS exposure assessment was Patricia Stewart, a long time NCI employee who is now retired and works as a private consultant. A second lead in the DEMS exposure assessment effort was Roel Vermeulen, a citizen of The Netherlands, who has since returned to Utrecht University and remains very active in the exposure assessment and occupational epidemiology fields.

Neophytou, et al., 2016) also used the estimates of REC exposure developed by the original DEMS team.

The independent investigators also developed alternative estimates of REC exposure. The first set were developed based on the analysis in Crump and Van Landingham (2012) and used in the Crump, et al (2015) extended analysis of the lung cancer case-control DEMS data. Another alternative REC exposure estimate followed the lead suggested in Appendix F of the HEI Report (2015) and was based on HP and CFM in each mine each year beginning with dieselization through 1997. This REC estimate based on HP-CFM was used in analyses reported by Crump, et al. (2016).

Thus, various methods of extrapolation have been used to estimate the exposure of miners to REC from the times the mines dieselized (as early as 1947 for the limestone mine) and extending through December 31, 1997. All of these REC estimates have substantial uncertainty, especially recognizing that some of the estimated REC exposures extend back 45 years to as early as 1947.

One special feature of many epidemiological studies, especially those involving cancer as a health endpoint, is the evaluation of various lag periods between when exposures occur and deaths from the health endpoint, in this case, cancer occurs. The use of various lag periods, typically 5, 10, or 15 years, recognizes that the development of cancer is complex and cancers typically occur years after an extended period of exposure. Indeed, the cancer may occur years after the exposure has been discontinued, recognizing that most lung cancers occur relatively late in life. While the time of death from cancer is precisely known, the time of various events in the initiation and progression of the cancer, including specific exposures such as diesel exhaust are not known with certainty. This becomes a matter of statistical estimation. In the analyses of the DEMS data, the use of a 15-year lag yielded the most consistent results. Hence, for a DEMS worker dying in 1997, the exposures of interest were those that occurred 15 years previously and earlier, i.e., in 1982 and earlier.

VII. Overview of U.S. Truckers' Study and Summary of Results

An overview of the U.S. Truckers' Study as developed by the HEI Panel is provided in Table 2. The original cohort included 58,326 unionized trucking industry workers who worked one day or more in 1985 and were followed through 2000. The original analysis of this cohort was reported by Laden, et al. (2007) and included 769 lung cancer cases. The Standardized

Mortality Rate Ratio for lung cancer was SMR = 1.04, 95% CI = 0.97-1.12. This indicates a very weak signal for diesel-related lung cancer, a signal that was not statistically significant.

Garshick et al. (2008, 2012a) reported a more detailed analysis of the Trucker cohort using an elaborate retrospective exposure assessment based on Submicron Environmental Carbon (SEC), elemental carbon less than 1.0 micron in diameter (Davis et al., 2007, 2009). Over 4,000 personal and area monitoring measurements were made in 2001-2006 and retrospectively modeled to earlier time periods (Davis, et al., 2006, 2011; Smith, et al., 2006).[8]

A total of 31,135 male workers who were over 40 years of age in 1985 with at least one year of work were included in Garshick, et al. (2008, 2012a,b). The workers were followed through 2000, by which time 4,306 deaths with 779 lung cancers had occurred. The 18% crude incidence of lung cancer is quite high and, is no doubt reflective of the smoking history of the population although the actual smoking history of the population was not ascertained. Thus, none of the analyses of the U.S. Truckers cohort could rigorously control for smoking despite strong evidence that smoking was the major cause of lung cancer in the cohort.

Key analyses reported by Garshick, et al. (2012a), excluding mechanics, yielded statistically significant elevated Hazard Ratios (HRs) for a 5-year lag, for example, HR = 1.48, CI = 1.05 – 2.10, for a cumulative SEC of ≥ 1803 μg/m^3–months. For comparison purposes, this is equal to 150 μg/m^3–years. The results without a lag and for a 10-year lag were not statistically significant nor were analyses of the mechanics alone. There were no results presented for a 15-year lag; it is not known if such analyses were or were not done. It is not known if any analysts, other than the Garshick team, have analyzed the U.S. Truckers' Study data. Vermeulen, et al. (2014b) did use the U.S. Truckers' results in an aggregate analysis that also included the DEMS findings. Crump (2014) has noted the shortcomings of that analysis using the results of several studies with a mix of different lag periods. Morfeld and Spallek (2015) have also noted serious reservations with the approach of Vermeulen, et al. (2014a), especially for estimating lung cancer risks at low exposure levels, below 150 μg/m^3-years and Vermeulen, et al. (2014b) has responded.

The IARC Panel (Benbrahim-Talla, et al., 2012; IARC 2013), in concluding that diesel exhaust exposure was carcinogenic to humans, relied most heavily on the DEMS results.

[8] As an aside, the SEC metric is different than the Diesel Particulate Matter (DPM) metric used by Mine Safety and Health Administration (MSHA) in controlling exposures to DPM. The MSHA permissible Exposure Limit (PEL) of 100 μg/m^3 is based on Total Carbon which includes both EC and Organic Carbon (OC).

However, the U.S. Truckers' Study results were also used as supporting evidence along with results from a number of other less conclusive studies.

The HEI Special Report 19 contains a brief review of the U.S. Truckers' Study; however, like IARC, the HEI evaluation focused primarily on the DEMS study. In my opinion, the HEI Panel's evaluation of the U.S. Truckers' Study was rather superficial. It could have explored in greater depth the weaknesses in the U.S. Truckers' Study related to: (a) the retrospective exposure assessment; (b) the need to exclude mechanics to obtain positive results; and (c) the lack of smoking histories on any members of the cohort. In this reviewer's opinion, findings from the U.S. Truckers' Study, as reported to date, are not likely to be used as a primary source of information in any quantitative risk assessment, an opinion also shared by the HEI Epidemiology Panel. It is not apparent that the findings reported to date from the U.S. Truckers' Study provide any unique insights into the potential lung cancer hazards of diesel exhaust exposure of underground miners.

VIII. Overview of Diesel Exhaust in Miners Study (DEMS)

As noted earlier, the 1988 IARC evaluation published in 1989 concluded that exposure to diesel engine exhaust was "probably carcinogenic to humans," a conclusion largely driven by the characterization of the animal evidence as being "sufficient" tempered by the human epidemiological evidence at that time being viewed as "limited." This uncertain characterization in 1988 of the epidemiological evidence and the overall classification served as a major stimulus for the design and conduct of epidemiological studies with improved design and statistical power for detecting a carcinogenic hazard.

In the United States, NIOSH has the primary federal government responsibility for developing information on occupationally related diseases, including lung cancer. In this role, NIOSH serves as an advisor to MSHA and OSHA for the regulations those agencies develop. NCI is the primary U.S. federal agency responsible for funding and conducting research on the etiology, diagnosis, and treatment of cancer. Thus, it was natural for these two agencies, NIOSH and NCI, to jointly fund, design and conduct the DEMS project, initiated in 1992. The non-metal mining industry was selected for study because monitoring reports indicated this industry had high levels and a wider range of diesel exhaust (DE) exposure than other industries (NCI/NIOSH 1997; Stewart, et al., 2010)

A summary overview of the DEMS project as developed by the HEI Panel is provided in Table 3. Some important details for each of the mining operations are given in Table 4. Table 5 provides a summary of the data available for estimating REC exposure. Note that very limited

REC data are available except for post-1997 and the relative abundant CO data, especially from MSHA Mine Information Data System (MIDAS) historical area CO compliance data (1976-2001). This was a key factor in the NIOSH/NCI decision to use CO as a surrogate for REC. Summary data on the populations studied are provided in Table 6.

After an extensive feasibility effort, 10 mining facilities in the USA [four potash in New Mexico, three trona (trisodium hydrogen dicarbonate dehydrate) in Wyoming, two rock salt mines in Ohio and Louisiana, and one limestone mine in Missouri] were selected for further evaluation. These particular mining operations were selected because they had a long history of using diesel-powered equipment underground and were thought to have low concentrations of other potential airborne agents, such as radon, silica and asbestos known to cause lung cancer. (NCI/NIOSH, 1997) Two of the 10 facilities, a potash facility in New Mexico and a salt mine in Louisiana, were later excluded from the DEMS due to incomplete personnel records. One of the potash mines in New Mexico closed before the DEMS research was concluded. Thus, for exposure assessment purposes one of the other potash mines in New Mexico served as a surrogate for the closed mine located in the same area.

The mines selected had started using diesel equipment in 1947 through 1967, dependent upon the mine (Table 4). Ultimately, 12,315 workers in all eight mining and associated operations would be studied through December 31, 1997, by which time 2,185 deaths had occurred among the study population with 193 lung cancers.

The first actual air contaminant monitoring measurements made specifically for DEMS were not made until 1998-2001 (Table 5). Thus, it was necessary to retrospectively estimate the DE exposures using REC as the exposure metric for the DEMS participants from the dieselization of each mine through December 31, 1997. Recall that mortality of the participants in DEMS was followed through December 31, 1997. The DEMS exposure assessment process has been documented in five detailed peer-reviewed papers: Stewart, et al., 2010; Coble, et al., 2010; Vermeulen, et al., 2010a; Vermeulen, et al., 2010b; and Stewart, et al., 2012.

At the core of the DEMS exposure assessment process was the decision to use Respirable Elemental Carbon (REC) as the indicator for DE exposure. REC is characterized with a sampling technique that collects airborne particles less than 3.5 microns in size. This size cut off is slightly above the 2.5 micron cut off used for the NAAQS $PM_{2.5}$ standard. The REC metric is different than the DPM metric used by MSHA to regulate and control exposures to diesel exhaust. MSHA uses a PEL of 160 $\mu m/m^3$. In the absence of measurements of REC, another diesel exhaust constituent, carbon monoxide (CO), was selected for use in DEMS as a surrogate for REC. This was done because it was one of the airborne agents for which there were measurements available dating to 1976 (Table 5). It is noteworthy that for all mines for all years, approximately 50 percent of the CO measurements used were below the limits of detection. In the absence of measured CO concentrations, the CO values used in the exposure assessments had to be imputed. This added uncertainty for estimating CO concentrations and, most importantly, also added to the uncertainty to the REC estimates that were retrospectively estimated from the CO concentrations.

The basic approach of the DEMS team to retrospectively estimate REC involved measurement of REC on personal monitoring samples collected on individual workers in seven of the eight DEMS mines in 1998-2001. Recall one potash mine had closed in 1993 and, thus, was not available. Arithmetic means of the DEMS REC measurements in 1998-2001 were considered to be reference values. Temporal trends in CO measurements based primarily on MSHA Mine Information Data System (MIDAS) historical area CO compliance data were modeled using diesel exhaust related determinants, i.e., diesel engine horse power (HP) and ventilation rates (CFM). The modeled trends in CO concentrations were then used to adjust the 1998-2001 REC reference values to obtain historic annual REC concentrations for each job in each prior year in each mine. Central to this approach is the assumption that CO is a suitable surrogate for REC.

The estimated primary REC concentrations used by Attfield, et al. (2012) and Silverman, et al. (2012) to conduct their epidemiological analyses are shown graphically in Figure 2. As discussed in Crump, et al. (2015), the NIOSH/NCI investigators also developed three other REC estimates.

A total of 12,315 workers, with 2,185 deaths, in the eight mining operations were included in DEMS (Table 6). This included all workers who were employed in blue-collar jobs for at least one year after dieselization of the study facilities. Individuals who held only administrative or management positions during their employment were excluded. Mortality of the workers was followed through December 31, 1997. The cohort was matched with the National Death Index (NDI-plus) and Social Security Death files to identify individuals who died and the cause of death (Attfield, et al., 2012).

Within the DEMS cohort, 207 deaths were identified as being caused by lung cancer (Attfield, et al., 2012). For a variety of reasons, nine cases were excluded from the nested lung cancer case-control study (Silverman, et al., 2012). The remaining 198 lung cancer case deaths were matched with 562 incidence density-sampled control subjects. As an aside, about 10% of the deaths in the DEMS cohort were associated with lung cancer, substantially less than the 18% reported for the U.S. Truckers' Study. This substantial difference could be related to many factors, including the age distribution of the population and differences in smoking history in the population.

The epidemiological analyses of the total DEMS cohort directed at identifying an association between exposure to diesel exhaust using REC as the metric were reported in Attfield, et al. (2012). Those analyses did not consider cigarette smoking since it was not possible to ascertain the smoking history of all 12,315 individuals in this cohort or even the 2,185 individuals who died prior to December 31, 1997.

To ascertain, and potentially to adjust for, the effects of cigarette smoking, a nested lung cancer case-control study was conducted as part of DEMS (Silverman, et al., 2012). In this study, information on cigarette smoking was ascertained from next-of-kin interviews for the 198 lung cancer cases and for the 562 incidence density-sampled control subjects.

It is noteworthy that in the analyses conducted by Attfield, et al. (2012) and Silverman, et al. (2012), workers were categorized in binary fashion either as *surface-only workers* or as *ever-underground workers* (Table 6). The ever-underground category includes both (a) underground-only workers, and (b) individuals who, at different times, worked on the surface and underground. From Table 6 it is apparent that about one third (approximately 4000 workers) of the total cohort is included in each of the three subgroups, the surface-only, underground only, and mixed (sometimes underground and sometimes on the surface). The number of lung cancer cases is not proportional to the population sizes, presumably related to differences in the age distribution of the individuals in each group and, most importantly, their smoking history. The older the population studied, the higher the incidence of lung cancer and the higher the portion of the population smoking, the higher the incidence of lung cancer.

IX. Results for DEMS Data Analysis

The primary results of the analysis of the DEMS data by the original NIOSH/NCI investigators have been summarized by the HEI Panel and are shown in Table 3. As noted earlier, the DEMS cohort study did not include collection of smoking history data. Attfield, et al. (2012) did a Standardized Mortality Rate (SMR) ratio analysis with rates externally standardized to state-, age-, gender- and ethnic group-, specific death rates for each mine. This was necessary because rates vary substantially for different populations, especially state specific death rates. Recall the mines were located in four different states. They found statistically significant effects for the (a) complete cohort – SMR = 1.26, CI = 1.09-1.44; (b) ever-underground – SMR = 1.21, CI = 1.01=1.45; and (c) surface-only – SMR = 1.33, CI = 1.06-1.66.

These results can be interpreted as indicating about 21% of the lung cancers in the DEMS cohort are attributable to diesel exhaust exposure or a closely correlated risk factor such as radon exposure. A key consideration in interpreting these findings is that the cigarette smoking history of the workers is assumed to be similar to that of the populations of the states in which the mines are located. The results can be interpreted as indicating that for the DEMS population, just as for the general population, the vast majority of the lung cancers are attributable to smoking.

Attfield, et al. (2012) also reported Cox Proportional Hazard (CPH) analyses for the cohort. The initial CPH analysis conducted for the total cohort did not yield statistically significant results. It was only when the ever-underground workers (122 lung cancers in 8,307 workers) were analyzed separately from the surface-only workers (78 lung cancers in 4,008 workers) that a statistically significant effect was found in the ever-underground workers. The HR was not elevated in surface-only workers who had low REC exposure. The HR was elevated for ever-underground workers in a cumulative REC exposure-related manner with a statistically significant increase in the HR for the two highest quantities of exposure, 445 to < 946 $\mu g/m^3$ –years, HR = 2.17, CI = 1.21-3.88 and > 946 $\mu g/m^3$-year, HR = 2.21, CI = 1.19-4.09. It is noteworthy that the REC effect on lung cancer was strongly influenced by excluding the most heavily exposed workers, >1870 $\mu g/m^3$ –years. The basis for these findings was not discussed.

It is noteworthy that Attfield, et al. (2012) did briefly comment on analysis of a radon exposure effect. They noted that "among ever-underground workers, there was some evidence of a cumulative radon exposure effect (P=0.037)," although detailed results were not shown. They went on to note this effect was absent in seven of the mines, and in the eighth mine (Mine A, the limestone mine) the radon effect was driven by workers aged 40 years or older employed before 1947. The cumulative radon effects on lung cancer were large and statistically significant in some analyses. They noted that removing the early older workers from the analysis removed the radon effect both for the facility and the total DEMS cohort.

In my opinion, the most significant DEMS results are those that were reported for the nested lung cancer case-control study in which cigarette smoking histories were ascertained from next of kin interviews for 198 lung cancer cases and 562 incidence density–sampled control subjects. (Silverman, et al., 2012) The Cox Proportional Hazard analysis odds ratios for subjects with cumulative REC over 536 $\mu g/m^3$ –years was 2.38 (CI = 1.28-6.26), a statistically significant finding.

It is commendable that the original investigators (Silverman, et al., 2012) explored the role of cigarette smoking in some detail and reported all of the results even though some of the findings as related below could not be fully explained. As expected, these analyses showed the overwhelming influence of cigarette smoking on lung cancer in this cohort. Indeed, Silverman, et al. (2012) concluded that the lung cancer risk experienced by surface-only workers who had quite low exposures to diesel exhaust was mainly due to smoking. This finding seems to be at odds with the observation of Attfield et al. (2012) who found the highest SMR in the surface-only workers.

For both surface workers and ever-underground workers combined, not unexpectedly, the risk of lung cancer was statistically significantly associated with both (a) smoking status (never, former, current smokers), and (b) smoking intensities. For example, for former smoker of ≥ 2 packs per day versus never smokers; OR = 5.40, CI = 2.23-13.06; current smoker of ≥ 2 packs/day versus never smoker; OR = 12.41, CI = 5.57-27.66. These results were certainly not unexpected and show the clear value of smokers quitting. The original investigators' analyses yielded an anomalous finding, a substantially greater lung cancer risk for workers who only worked on the surface vs. those who ever-worked underground. For example, the OR for current smokers of one to less than two packs per day who only worked on the surface was 13.34 (CI = 4.50-39.53) compared with an OR of 4.51 (CI = 1.50-13.58) for those who ever-worked underground. This unexplained difference is of special interest because, as noted earlier, the ever-underground workers group included two sub-groups: (a) individuals who always worked underground (4,080 workers and 82 lung cancers), and (b) individuals who had worked both on the surface and at other times underground (4,229 workers and < 44 lung cancers). In short, the crude incidence of lung cancer for the two groups differed by a factor of about 2.

The nested case-control Cox Proportional Hazard (CPH) analysis yielded a statistically significant REC effect on the odds ratio for the quartile with > 536 $\mu g/m^3$ –years, having an OR – 2.38, CI = 1.28-6.26. The trend test across all four quartiles was statistically significant. It is clear there is a strong, statistically significant signal from this original analysis of DEMS that exposure to diesel exhaust at some concentrations and durations of exposure elevates the lung cancer risk. This was the driver for the 2012 IARC characterizing diesel exhaust exposure as a human carcinogen. Moving beyond hazard characterization, the question now is whether the analyses of DEMS data are sufficiently robust for use in quantitative risk assessment.

X. Replication and Extended Analyses of DEMS Data

As noted earlier, NIOSH and NCI have allowed other investigators, beyond the original investigators, to have access to the DEMS data under carefully prescribed and controlled conditions. This critique will focus on the analyses conducted by the independent analysts funded by a coalition of private organizations coordinated by the Engine Manufacturers Association (EMA). The results of that substantial body of work have been reported in three papers published in the peer-reviewed literature (Moolgavkar, et al., 2015; Crump, et al., 2015, 2016). Other analyses are still in progress.

One of the teams of independent analysts, Moolgavkar, et al. (2015), reported analyses of the DEMs cohort data set originally analyzed on and reported by Attfield, et al. (2012). The re-analysis team was provided three de-identified data files with demographic, occupational and death outcome data. By the end of mortality follow-up, December 31, 1997, a total of 2,185 deaths and 200 lung cancer deaths had been ascertained. All of the analyses conducted by the independent analysts initially used the same REC exposure estimates developed and used by the original investigators. The independent team replicated the findings of Attfield, et al. (2012) using Standardized Mortality Rates (SMR) analyses and Cox Proportional Hazard Regressions. This step was crucial in that it verified the re-analysis team was using the same basic data set as the original investigators. While this replication lends confidence to the conduct of the original analyses, the replication of the results should not be taken as a blank endorsement of either the original analytical approach or the interpretation of those findings by the original DEMS investigators.

At the next step, the independent investigators conducted extended analyses using parametric functions based on the concepts of multistage carcinogens to estimate lung cancer hazard functions focusing on the role of temporal factors and mine type. The multistage models used were similar to those used by Dawson and Alexeeff (2001) who estimated units risk for diesel engine exhaust-associated lung cancer in a cohort of railroad workers (Garshick, 1987) using the now classical multistage model of carcinogenesis of Armitage and Doll (1954). The quantitative lung cancer risk assessment results of the Dawson and Alexeeff work were used by the California Air Resources Board as a basis for its early and stringent diesel emission regulations using a report of the California Environmental Protection Agency (CEPA, 1998).

The extended analysis of the DEMS cohort data set by Moolgavkar, et al. (2015) using the biologically-based model revealed a statistically significant association between REC and lung cancer for the entire cohort with a substantial influence related to the workers employed in the limestone mining operation. Further, the REC-lung cancer association was observed in ever-underground workers and not observed in surface-only workers. The analyses showed a strong influence of time-related factors, i.e., when exposures occurred, exposure intensity and age. It is important to know that Moolgavkar, et al. (2015) could not control for radon in their analyses because the data sets they were originally given did not contain accurate radon data. The Moolgavkar team is now in the process of repeating some of their analyses having recently been given access to the radon data.

The next set of replication and re-analyses were conducted by Crump, et al. (2015) using the nested case-control DEMS data originally evaluated by Silverman, et al. (2012). By the time these analyses were conducted NIOSH/NCI had barred the independent analysts from using the DEMS data set except under closely controlled conditions. Thus, the Crump team analyses utilized DEMS data assembled and made available at the National Center for Health Statistics (NCHS) Research Data Center (RDC) in Hyattsville, Maryland. The Crump, et al. (2015) paper focused on evaluating alternative REC metrics developed by Crump and Van Landingham (2012) to evaluate the influence of changes in the REC metrics on the REC-lung cancer association. All of the REC exposure metrics evaluated had been developed assuming CO in the mines was a suitable surrogate for REC, the same approach as used by the original DEMS team. Without adjusting for radon exposure, the results were similar to those of Silverman, et al. (2012) with eight of nine REC exposure metrics showing an association between REC exposure and lung cancer mortality with trend slopes differing by only a factor of two. When exposure to radon was adjusted, the evidence for a REC effect was greatly diminished but still present in analyses that utilized the three original DEMS REC exposure estimates. When the six alternative REC exposure metrics developed by Crump were used and radon was controlled no REC effect on lung cancer mortality was observed in miners who only worked underground. The NIOSH/NCI investigators reported analyses on ever-underground workers and never reported any analyses for always underground workers. The finding of Crump et al. (2015) are of special interest since always underground miners are the individuals whose estimated exposure to diesel exhaust was likely to be the most certain.

In a third set of analyses, Crump, et al. (2016) extended the evaluation of alternative REC exposure estimates using the case-control DEMS data. As noted earlier, all four REC estimates developed and used by the original NIOSH and NCI team relied upon using CO as a surrogate for REC. There are serious shortcomings both with the use of CO as a surrogate and the CO data themselves. Recall from Table 4 that 50% of the CO measurements used by the original investigators in developing REC estimates were below the limits of detection varying from 30% below the limits of detection in the limestone mine to 61% in one of the trona mines. Because of the substantial portion of CO measurements below the limits of detection it was necessary to impute (statistically assign) CO concentrations when detectable concentration values were not available.

A key concern with the REC estimates developed by the original investigators was this strong dependence on the relationship between engine HP and CO emissions. Figure 3 is a graph of data from Yanowitz, et al. (2000) showing the highly uncertain relationship of emissions of CO to HP for individual engines. This illustrates the uncertainty involved in assuming there is a constant quantitative relationship between CO and HP as assumed in the REC estimates of the original NIOSH/NCI team.

An alternative approach to more directly estimate REC exposure is based on yearly diesel equipment usage expressed in HP and ventilation rates as CFM for each mine, based on historical records for each year assembled by the original DEMS team. The records were made available to the independent analysts in response to a Freedom of Information Act request filed with NCI by the EMA. Further, adjustments in total PM emission per brake HP were made for the interval between 1975 and 1995 when major reductions in PM emissions occurred with improvements in diesel technology (Figure 4), data included in the Health Assessment Document prepared by EPA (2002). Particulate matter emissions per brake HP-hour were assumed to be constant pre-1975 and post-1995. This approach built on the earlier work of Crump and Van Landingham (2012) and Crump, et al. (2015). Most importantly, this HP-CFM approach was consistent with an approach suggested in the HEI Special Report 19, Appendix F, largely authored by Professor David Foster, the only expert on diesel technology who was a member of the HEI Epidemiology Panel.

The REC estimates based on HP-CFM developed by Crump, et al. (2016) are shown in Figure 2 for ease of comparison with the REC estimates developed by the original DEMS investigators using CO as a surrogate for REC. As may be noted, the most substantial differences are for the limestone mine and salt mine, both of which made substantial use of high HP diesel-powered equipment to haul ore (See Table 4). Recall also that limestone mine A was naturally ventilated.

The results of using the REC exposure estimates based on HP-CFM compared to the original analyses for REC exposure response analysis to evaluate the association between REC and excess lung cancer risk are shown in Table 7. This is a complex table that may be challenging to follow. The table includes analyses on three sets of subjects; (a) all subjects at the top of the table; (b) all subjects ever underground in the middle section of the table; and (c) all subjects who only worked underground in the lower section of the table. The ever underground grouping is consistent with the grouping of the original DEMS investigators. The only worked underground group was developed by the independent analysts using the original DEMS data.

The results of Silverman, et al. (2012) analysis are shown at the top for all subjects and ever underground workers and were taken directly from the Silverman, et al. paper. Results for the first set of analyses below the original findings were a replication analysis performed by Crump, et al. (2016). These analyses verify that as closely as possible the original analyses were duplicated and, thus, the data sets used and reported in Crump et al. (2016) must be very similar to those used by Silverman, et al. (2012). These analyses were done without control for radon because Silverman, et al. did not control for radon. The next set of analyses for each of the three groups use the HP-CFM based REC exposure estimates without and then shown below with control for radon.

Going from left to right in the table, the columns are; (a) analysis; (b) quartiles of cumulative REC; (c) number of cases; (d) number of controls; (e) the Odds Ratio (with Confidence Interval); (f) the P trend value; and (g) the slope expressed as cases per $\mu g/m^3$ – year. The smaller the value, the shallower the slope. All of the results in Table 7 are based on use of a 15-year lag.

It may be noted that the initial analyses performed using the REC estimates as Silverman, et al. (2012) without control for radon yielded results that were almost identical to those of Silverman, et al. (2012) verifying that the same basic DEMS data are being analyzed by the original investigators and the Crump team. When these analyses were repeated using the REC estimates based on HP-CFM, the findings were reduced in statistical significance and the slopes were shallower without control for radon. With control for radon, the statistical significance was further reduced and the slopes were even more shallow. When the analyses were conducted for all subjects who only worked underground (58 lung cancer cases and 97 controls), there was a further reduction in statistical significance.

In summary, none of the trend slopes calculated using the REC estimates based on HP-CFM were statistically significant ($p > 0.05$). Moreover, these trend slopes were smaller by roughly factors of five without control for radon exposure and factors of 12 smaller with control for radon exposure compared to those estimated in the original DEMS analyses reported by Silverman, et al. (2012). In my opinion, several factors influence the results. One factor relates to the generally higher estimates of REC concentrations based on HP-CFM compared to the original REC concentration estimates. The higher the REC concentration in the denominator of the slope the shallower the slope since the number of lung cancer cases remains constant in the analyses. Most importantly, the analyses of Crump, et al. (2015, 2016) show an influence of radon. This is not surprising since radon is well recognized as a cause of lung cancer in humans (Moolgavkar, et al., 1993; IARC, 1998). In my opinion, if radon is not controlled for in the analyses even with low exposures to radon the estimates of the potency of REC will be exaggerated. It is scientifically inappropriate to focus on analyzing the risk factor of current concern, in this case, diesel exhaust, and ignore other well-known risk factors such as radon.

The results reported by Crump, et al. (2016) using the HP-CFM based REC exposure estimates and control for radon compared to the results of Silverman, et al. (2012) emphasize how sensitive the results of analysis of the DEMS data are to choice of the exposure metric and control for the low level radon exposures. In my opinion, the HP-CFM based REC estimate metric is superior to the REC estimates developed by the original investigators because of uncertainties associated with using CO as a surrogate for REC have been removed. Recalling the analogy to the three-legged stool discussed earlier, the exposure leg of the stool for any analysis of the DEMS data is highly uncertain.

The re-analyses of the DEMS cohort data conducted by Moolgavkar, et al. (2015) using the same REC estimates used by the original investigators and without control for radon are now being extended to include the HP-CFM based REC exposure metric and control for radon. This is being done by accessing the DEMS data at the NCHS-RDC in Hyattsville, MD. The results of those analyses should be available in the near future.

XI. HEI Epidemiology Panel Evaluation

The HEI in November 2015 published Special Report 19 – "Diesel Emissions and Lung Cancer: An Evaluation of Recent Epidemiological Evidence for Quantitative Risk Assessment," authored by the HEI Diesel Epidemiology Panel that consisted of nine scientists (Table 8). In the interest of completeness, the Peer Reviewers of Special Report 19 are also shown in the table.

The HEI Epidemiology Panel *primarily focused* on evaluating the findings of the Diesel Exhaust in Miners Study (DEMS) as reported in papers authored by scientists from NIOSH and NCI, the two federal agencies that funded and conducted DEMS. The HEI Panel Report concludes "that the DEMS and the Truckers Study provided results and data that provide a useful basis for quantitative risk assessments of exposures in particular to older diesel engine exhaust."[9] The report goes on to note -- "The uncertainties within each study should be considered in any attempts to derive an exposure-response relationship" for diesel exhaust particulate matter.[10]

In my opinion, the HEI Panel gave *secondary consideration* to analyses conducted by the independent scientists funded by a coalition of private sector entities organized by the Engine Manufacturers Association (EMA). The independent scientists encountered substantial difficulty in gaining access to the basic DEMS data sets assembled by the U.S. government scientists which delayed the conduct of their analyses. Ultimately, access to the DEMS data sets was given to the independent scientists to conduct analyses under carefully defined conditions, ostensibly to protect the identity and privacy of individuals enrolled in DEMS. The various delays in allowing access to the DEMS data resulted in the results of the independent analyses becoming available late in the HEI Panel's evaluation process. Indeed, some of the results of the extended analyses the independent analysts conducted were not available until after the HEI gave a preliminary report at the May 2015 HEI Annual Conference. At this HEI conference, one of the HEI Epidemiology Panelists noted that he intentionally gave secondary attention to the independent analyses because they were funded by industry.

By failing to consider *all* of the analyses of the DEMS data set in a more even-handed manner, the HEI Panel missed an opportunity to advocate for more open access and extended analyses of important epidemiological data sets, such as DEMS, assembled by either government or private sector funded scientists. This should be "the way of the future" and encouraged, i.e., open access to data, replication of results and extended analyses by multiple investigators. The HEI Panel ignored this opportunity and provides no guidance in its report as to how the interests of the original investigators (and subjects in the epidemiological studies) can be protected yet the broader interests of Society also better served by access to data and conduct of alternative analyses.[11]

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[9] HEI Report at 1.

[10] *Id.* at 7.

[11] The topic of more open access to data has received a great deal of attention during the last decade. This has included concern for access to epidemiological data such as that undergirding the setting of National Ambient Air Quality Standards for the criteria pollutants and especially the standards for $PM_{2.5}$. HEI is quite familiar with this controversy having sponsored the re-analysis of two data sets, one using data from the American Cancer Society (ACS) and the other data from the Harvard Six Cities study. HEI arranged to obtain restricted access to these data and sponsored re-analysis of the data. Ironically, Professor Daniel Krewski, who chaired the HEI Epidemiology Panel, had a lead role in conducting the earlier re-analyses of the ACS and Harvard data. The National Research Council (NRC, 2016) has recently published a

In the opinion of this reviewer, the construct of the HEI Report is biased toward support of the conclusions reported by the original DEMS investigators. The HEI Report does identify uncertainties in the DEMS original analyses, frequently noting these will pose "challenges" in the conduct of future quantitative risk assessments using DEMS.[12] However, in identifying issues that create uncertainties, the HEI Panel and their Report carefully avoids providing a roadmap or plan for conducting future quantitative risk assessments. This approach is understandable. However, the Panel had considerable latitude it did not use to note how key uncertainties would impact on the conduct of any quantitative risk assessments.

Some of the key issues relating to use of the DEMS data set and interpretation of the results are discussed below.

- *Panel Members' Experience in Mines:* Neither the HEI Panel members, individually or collectively, nor HEI staff, visited any of the DEMS mines despite being specifically invited to visit one of the trona mines. Nor was any evidence provided of Panel members having prior knowledge of underground nonmetal mining operations of the kind used in the DEMS mines. Knowledge of how the mines are operated and, specifically, how diesel-powered equipment is used in mining operations such as in the mining operations included in DEMS would have provided valuable context for the Panel's evaluation.
- *Exposure Assessment*: The DEMS report fails to clearly note that all of the Respirable Elemental Carbon (REC) metrics used in the original analyses and subsequent analyses of DEMS are based on uncertain retrospective extrapolations. Actual measured REC concentrations are not available pre-December 31, 1997, when the study concluded. Further, the report does not emphasize that with use of a 15-year lag in the analyses, the extrapolated REC estimates of greatest interest are the estimates for 1982 and earlier. In addition, the report does not make clear that CO measurements from the MIDAS data set were only available for 1976 and later. Despite these major short-comings, the overall tone of the HEI report is to laud the exposure assessment done by the original DEMS investigators and relegate key aspects of the Panel's valuation of the exposure assessment to Appendix F to the report.

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report summarizing a conference sponsored by the NRC on issues associated with more open access to data. The title of the NRC report – "Principles and Obstacles for Sharing Data for Environmental Health Research," in part indicates the difficulties of achieving wider "open access" of data.

[12] HEI Report at 7.

- *Work Location*: The original investigators conducted analyses on: (a) the total cohort; (b) surface only workers; and (c) ever underground workers. The latter is a mixed group of individuals who had worked sometimes on the surface and sometimes underground and those who always worked underground. The independent analysts subdivided the latter group and separately evaluated those who always worked underground from those who had mixed surface and underground work experience. The HEI Panel tended to dismiss this approach because the smaller size of this population of always underground workers reduced the statistical power of the analyses.
- *Lung Cancer Effect of Cigarette Smoking*: As expected, analyses of the DEMS nested lung cancer case-control data showed the overwhelming impact of cigarette smoking. Overall, for both surface-only and ever-underground workers combined, the risk of lung cancer was statistically significantly associated with (a) smoking status (never, former, current smokers) and (b) smoking intensity (former smoker of ≥ 2 packs per day vs. never smoker: OR = 5.40, 95% CI = 2.23 to 13.06; current smoker of ≥ 2 packs per day vs. never smoker: OR = 12.41, 95% CI = 5.57 to 27.66. The original investigators found that the lung cancer risks were substantially higher among workers who only worked on the surface in contrast to those who ever worked underground for both current and former smokers. For example, the OR for current smokers of one to less than two packs per day who worked only on the surface was 13.34 (95% CI = 4.50 to 39.53) compared with an OR of 4.51 (95% CI = 1.50 to 13.58) for those who worked ever underground. The HEI Panel did not explore this anomaly in any depth. This difference among surface-only and ever-underground workers is potentially very important because the original investigators grouped individuals together that had worked both on the surface and underground as an ever-underground group.

Retrospective Exposure Assessments

The HEI Report contains a series of useful Appendices. One of these is Appendix F, Technical Background and Further Evaluation of the DEMS Retrospective Exposure Model. This appendix, primarily authored by Professor David Foster of the University of Wisconsin, who was the Panel's only expert on diesel engines and their emissions, provides a thoughtful analysis of the DEMS retrospective exposure modeling activities. His analysis builds on previous criticisms of the exposure reassessment models used by the original investigators, criticisms that have largely gone unaddressed. Much attention is given in Appendix F to the issue of Horse Power (HP) – CO – REC relationships. Most importantly, Appendix F suggests a path forward that relies on use of engine horsepower and mine ventilation rates to estimate REC without the need to make any assumptions concerning CO as a surrogate for REC. That is the approach that undergirds the analyses published in Crump, et al. (2016) and shown in Table 7.

Population Studied

The DEMS population of 12,315 individuals worked both on the surface and underground. About one-third worked exclusively on the surface, one-third exclusively underground and one-third worked, at different times, on the surface and underground. The original DEMS analyses combined the latter two subgroups to create an ever-underground cohort. Recognizing that the original DEMS investigators found anomalous results for the association between cigarette smoking and lung cancer related to work location (greater potency for surface workers smoking versus ever underground workers) the independent investigators deemed it important to analyze the always underground miners as a separate group. The HEI report does not address this critical issue in depth. Instead the HEI Panel and Report dismisses analyses using the always-underground miners as lacking statistical power.

Radon Exposure

Radon is a well-known cause of lung cancer especially in underground miners (Moolgavkar, et al., 1993; IARC, 1998; NRC, 1999). This was recognized initially in selecting the nonmetal mines for study in DEMS since it is generally acknowledged that nonmetal mines have low concentrations of radon. The HEI Panel explored the possible role of radon in the DEMS population in considerable depth. However, the Panel's evaluation of radon appears to have focused on attempting to support the view of the original DEMS investigators – that radon did not need to be included in the analyses evaluating the role of REC as a causative agent. The independent investigators' analyses showing a clear impact of radon exposure was down-played by the HEI Epidemiology Panel. This was especially disappointing since Attfield, et al., (2012) had called attention to this issue, especially related to the limestone mine workers in their paper. Recall that the Moolgavkar et al. (2015) paper also pointed at the influence of the limestone miners.

There is a fundamental difference of scientific opinion between the HEI Panel and the independent analysts with regard to control for radon in the analyses. The Panel raises concern that the radon effects are likely low and the radon exposure measurements are uncertain and, thus, are not worthy of inclusion in the analyses. In contrast, the independent analysts note the radon values that are available are actual measurements, not extrapolations, and it is appropriate to conduct analyses both with and without control for radon. The Crump et al. (2015 and 2016) analyses clearly show the influence of radon.

Mine to Mine Differences

The HEI Panel gave scant attention to the remarkable difference in the nature of the mining activities across the eight different operations mining four different types of ore in four different states. As already noted, neither the Panel collectively or any of the individual Panel members visited any of the DEMS mines. They were extended an invitation to visit one of the trona mines. The differences among the mines are very substantial, especially in how ore is mined and moved, the horsepower of the diesel-powered equipment used, the presence (or absence) of methane, and ventilation controls. By failing to address mine-to-mine differences, or at least call them to the attention of readers, the original investigators and the HEI Panel imply that all the mines are the same. This is certainly not the case. The most notable differences are between the single limestone mine (which was naturally ventilated and used very large horsepower equipment to haul ore from the face to the surface on a level plane) and the operations in other mines. As already noted, the limestone mine was naturally ventilated in contrast to the variable use of mechanical ventilation in the other mines. Concern for buildup of explosive gases in some of the other mines, such as the trona mines, prompts the use of higher ventilation rates in those mines. In mines other than the limestone mine, the horsepower of the diesel equipment used is relatively low because ore is primarily moved by electrical powered conveyors (except in the salt mine studied) and then hoisted to the surface. The salt mine used diesel powered units to haul ore from the face to central locations for processing and hoisting to the surface. In my opinion, the HEI Report should have more directly addressed these issues in critiquing the DEMS data set, even if nothing can be done in analyzing the DEMS data because of the relatively low number of lung cancer cases in individual mines, and thus, the lack of statistical power for evaluating individual mines and sub-populations.

It is especially noteworthy that the HEI Panel did not pursue further mine-to-mine differences considering that both the Attfield, et al. (2012) and Silverman, et al. (2012) papers opened the door to this subject. As already noted, Attfield, et al. called attention to differences between mines when they discussed the role of radon as a major risk factor in the limestone mine. Silverman, et al. (2012) examined the 102 lung cancer cases in the potash mining operations and 51 lung cancer cases in the trona mining operations and noted that the association between REC exposure and lung cancer was more consistent in the potash workers than in the trona workers. It is remarkable that Silverman, et al. (2012) did not call attention to the lack of statistical significance of the association between REC exposure and lung cancer in the trona workers although it is apparent in the tabular material in the paper. It is also of interest that Silverman, et al. (2012) did not address directly potential differences in smoking history among the trona workers (in southwest Wyoming) versus potash workers (in New Mexico), recognizing that the southwest Wyoming population has many individuals of the Mormon faith, a which strongly discourages smoking. Indeed, it would have been of interest to learn if differences in smoking history were reflected in the next-of-kin interview data for the trona mines compared to other mines. Another issue relates to any work experience by DEMS participants in uranium mining with well-known exposure to high concentrations of radon and radon daughter products.

XII. Author's Conclusions

The HEI Report provides a blank endorsement of the use of the DEMS data set for quantitative risk assessment while noting the need to consider uncertainties in the data and their results. In this reviewer's opinion, the HEI Report does not adequately consider the implications of the results of the extended analyses conducted by the independent investigators. There is a stark contrast between the findings of Silverman, et al. (2012) and those of Crump, et al. (2016) based on analyses using the same DEMS data and different REC exposure metrics with and without control for radon. Silverman, et al. (2012) report a statistically significant association between exposure to REC and lung cancer for two groups: (a) all subjects; and (b) all subjects who ever worked underground. In contrast, Crump, et al. (2016) found reduced associations between REC and excess lung cancer with the HP-CFM based REC metric analyses conducted with and without control for radon. None of the trend slopes calculated using the new HP-CFM based REC estimates were statistically significant ($P > 0.05$). Moreover, these trend slopes were smaller by roughly factors of five without control for radon and factors of 12 with control for radon exposure compared to those of Silverman, et al. (2012). Also, the 95 percent confidence intervals for the newly derived trend slopes had only minimal overlap with those for the slopes in the original DEMS analyses.

It is the opinion of this reviewer that any quantitative risk assessment conducted using the DEMS data should consider the full range of potency for diesel exhaust particulate matter identified in the original and extended analyses. This should be the case whether developed to retrospectively to ascribe harm from diesel exhaust exposure to the worker population studied (or other populations with similar exposure) or prospectively to predict or estimate risk for other populations exposed to diesel exhaust.

Further, it should be noted that diesel engine technology, including the fuels used, has constantly changed over the past half century, resulting in continuous reductions in diesel exhaust particulate emissions, and more recently reduced NO_2, and the associated reduced exposure of underground workers. Diesel engines currently marketed with modern control technology have virtually no particulate emissions and very low NO_x emissions (Khalek, et al, 2011, 2015).

XIII. Path Forward

The saga of the health effects of exposure to diesel exhaust continues and is likely to continue for some time. In the near future it will be important to anticipate a number of activities as enumerated below:

1. As noted above, another set of analyses of the DEMS cohort data are in progress under the direction of Dr. Suresh Moolgavkar. This work involves analysis of the DEMS cohort data originally reported on by Attfield, et al. (2012) and includes the use of the HP-CFM based REC metric with and without control for radon using the Cox Proportional Hazard model that was also used by Attfield, et al. These results should be available in the near future. It would be advantageous if these analyses could also be extended using biologically-based models as reported in Moolgavkar, et al. (2015). Unfortunately, it is uncertain if the biologically-based models can be used under the constraints imposed by NIOSH and NCI for use of DEMS data at the secure NCHS-RDC IN Hyattsville, MD. It will also be useful to encourage other investigators to seek to gain access to the DEMS data for extended analyses. This includes interested parties from Europe.

2. It is important to continue to make the results of the independent analyses of DEMS known to as many individuals and organizations as possible. Indeed, the access to data, replicative analyses and extended analyses using the DEMS data should be championed as a case study in how large data sets from government-funded studies should be made available as a matter of routine, especially when the results of analysis of the data will influence major public policy decisions. This is a topic that has been of considerable interest to some members of Congress.

3. The activities of NIOSH, EPA and other agencies that may conduct quantitative risk assessments for diesel exhaust from traditional diesel engines (pre-1990) need to be carefully monitored. At some juncture, such efforts are likely to shift from scoping or research activities to activities that clearly have potential regulatory impact. It is my impression that at some point these activities become part of the regulatory agenda and must be publicly disclosed. This should include holding public meetings in which the plans and protocols for conducting quantitative risk assessments should be disclosed and the opportunity provided for public comment.

4. The results of the HEI Epidemiology Panel evaluation and the findings of the independent analysts should be conveyed to interested workers, especially to workers in the mining operations that participated in DEMS, as the NIOSH/NCI investigators' findings have already been conveyed to those workers. The results of analysis of the DEMS data by the original investigators and the independent analysts reveal again that the major cause of lung cancer in workers is cigarette smoking. This emphasizes the importance of smoking cessation programs for workers and their families.

5. The DEMS data set includes a valuable compilation of data on diesel equipment usage and ventilation in the eight DEMS mines through 1997. It is important that these records be updated for the mining operations included in DEMS and similar records developed for other mines. It will be especially important to establish and maintain records on diesel fuel usage underground (both quantity and quality) to complement the records on diesel equipment. The quantity of diesel fuel used underground provides a simple index of exhaust emissions. These data, along with ventilation data, provide a useful index of potential exposures. It will also be important to clearly document the emission characteristics of both old engines and new engines as operations transition to increased use of new "low emission" diesel technology. Efforts to maximize the efficient use of ventilation to minimize worker exposures should continue.

6. Both worker and area monitoring activities should be reviewed to ensure they are in compliance with applicable regulations and, moreover, meet "best practice" standards for the industry. Current and future worker monitoring activities should focus on Respirable Particulate Matter (less than $PM_{2.5}$ microns) and REC. However, it is important to know that some individuals have trumpeted the potential harm of nanoparticles (particles less than 0.1 micron) and the potential greater importance of particle number versus particulate mass concentrations as indicators of potential harm. These are topics of active debate relative to environmental ambient air exposures and there is already evidence of these concerns being transferred to the occupational arena.

7. It will be important to continue to cooperate with investigators from NIOSH, MSHA and other organizations interested in using private facilities for research. However, it will be important to request the opportunity for prior review and approval of research protocols before research is initiated in private facilities.

XIV. The Author, Roger O. McClellan

Roger O. McClellan is an internationally recognized expert on the health effects of exposure to diesel exhaust. He was responsible for developing and leading the extensive

Lovelace Research Institute's multi-faceted research program on diesel exhaust beginning in the 1980s and served in an advisory capacity to other research programs on diesel exhaust health hazards around the world. He served on the National Research Council's (NRC) Board on Environmental Studies and Toxicology that provided guidance for the first NRC report on the health impacts of diesel technology. He was a founding member (1981-1992) of the Health Effects Institute Research Committee that had a major focus on designing and overseeing studies on diesel exhaust from engines in use in the 1980s. Later, he would serve on the external oversight committee for HEI's research in the early 2000s to study new technology diesel exhaust. He served as chair of the U.S. EPA's Clean Air Scientific Committee (1987-1992) and served on the Committee that reviewed the EPA's 2002 Health Assessment for Diesel Exhaust. He chaired the Animal Evidence Panel for IARC's 1988 evaluation of the carcinogenic hazard of exposure to diesel exhaust. He served as a member of the Department of Labor Mine Safety and Health Administration's review (1985-1987) of the use of diesel equipment in underground mines. He attended, as an observer, the 2012 IARC review of diesel engine exhaust.

McClellan received a Doctor of Veterinary Medicine degree from Washington State University in 1960. His early research was concerned with the effects of internally-deposited radionuclides. He was the leader of the Lovelace Inhalation Toxicology Research Institute from 1966-1988 conducting studies to evaluate the health risks of a range of airborne agents, including emissions from nuclear facilities and accidents to vehicles to coal-fired power plants. From 1988-1999, he was the President of the Chemical Industry Institute of Toxicology directing research that improved the scientific basis for assessing health risks of chemicals. Since 1999, he has served as an independent advisor to public and private organizations. McClellan has served on over 100 major advisory committees to all of the major U.S. federal agencies concerned with environmental and occupational health issues as well as international agencies. He has testified multiple times to Committees of both the U.S. Senate and House of Representatives on human health risk assessment issues. He occasionally testifies as an Expert Witness in legal proceedings.

He is a Diplomate of the American Board of Veterinary Toxicology and American Board of Toxicology. He is a Fellow of the Academy of Toxicological Sciences, American Association for Aerosol Research, International Assembly for Aerosol Research, Society for Risk Analysis, Health Physics Society and American Association for Advancement of Science. He was elected to membership in the National Academy of Medicine in 1990. He has received numerous honors for his contributions to improving environmental and occupational health through the conduct of research at all levels of biological organization from cells to human populations and the application of the results to inform policy decisions impacting use of multiple technologies.

XV. Declaration of Interest

Roger O. McClellan prepared this critique as an independent contractor to the law firm of Crowell and Moring LLP, which in turn, was compensated by the Industrial Minerals Association – North America. The critique was prepared independently and the conclusions drawn and opinions expressed are exclusively those of the author.

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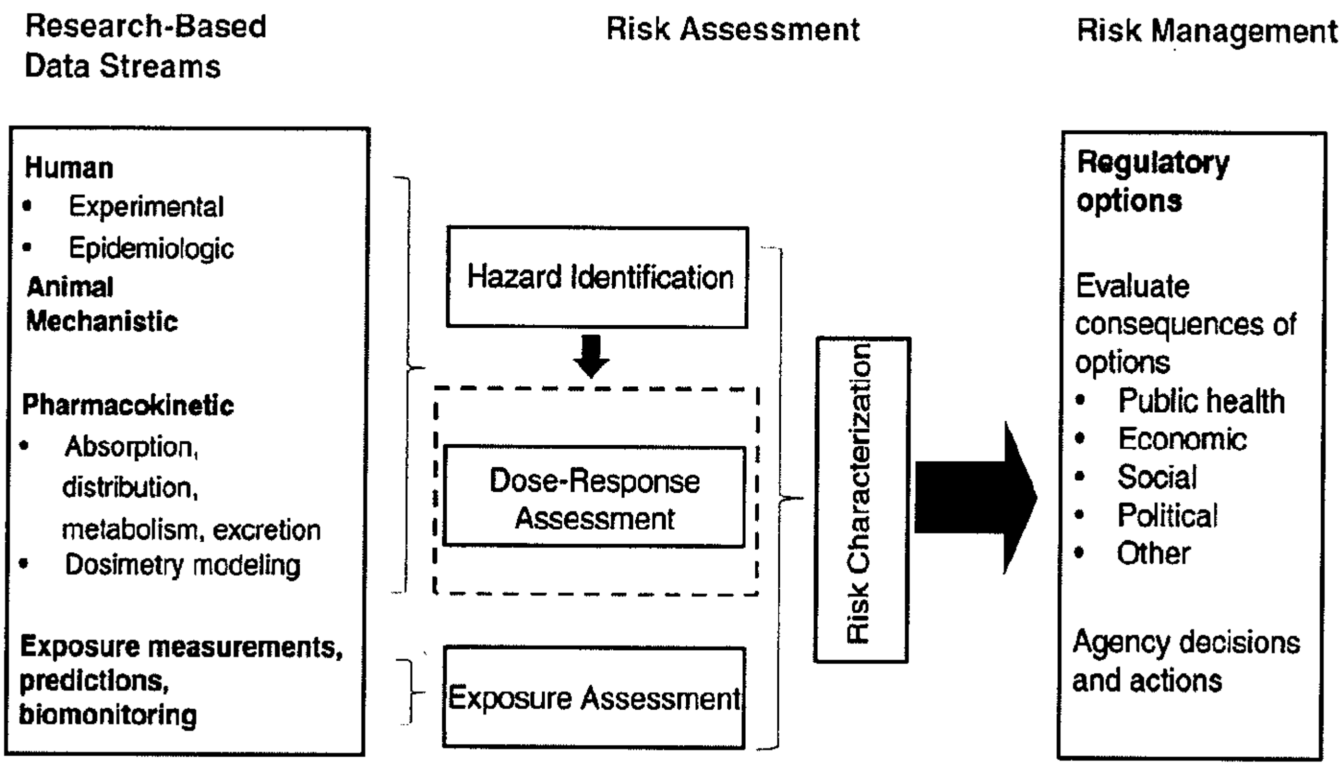

Figure 1: Risk Assessment Paradigm that emerged in the 1970s (National Research Council, 2014; from HEI, 2015).

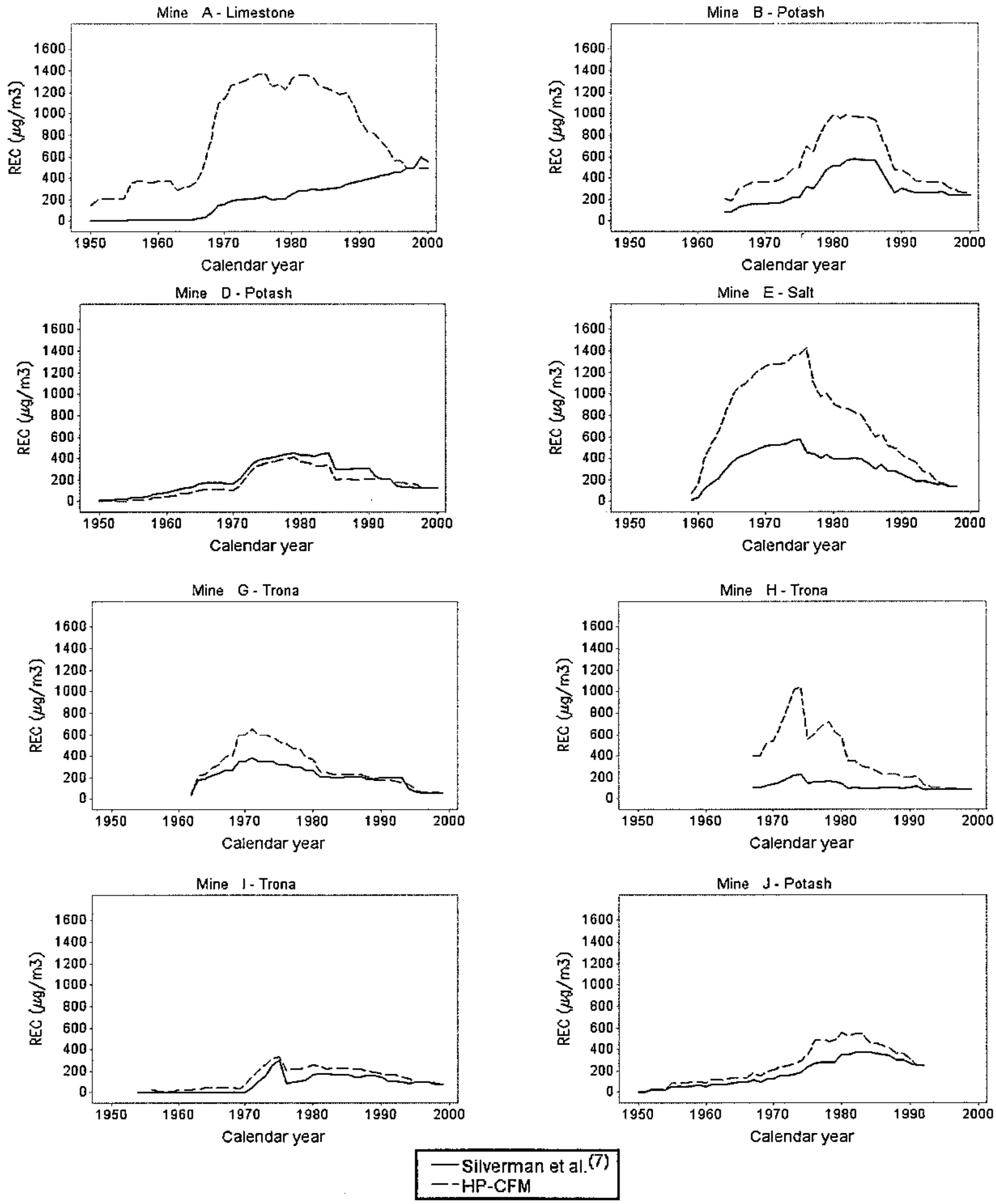

Figure 2: Alternative Respirable Elemental Carbon Metrics Using CO (red), the Original Investigators versus HP-CFM (blue) Developed by Crump et al (2016)

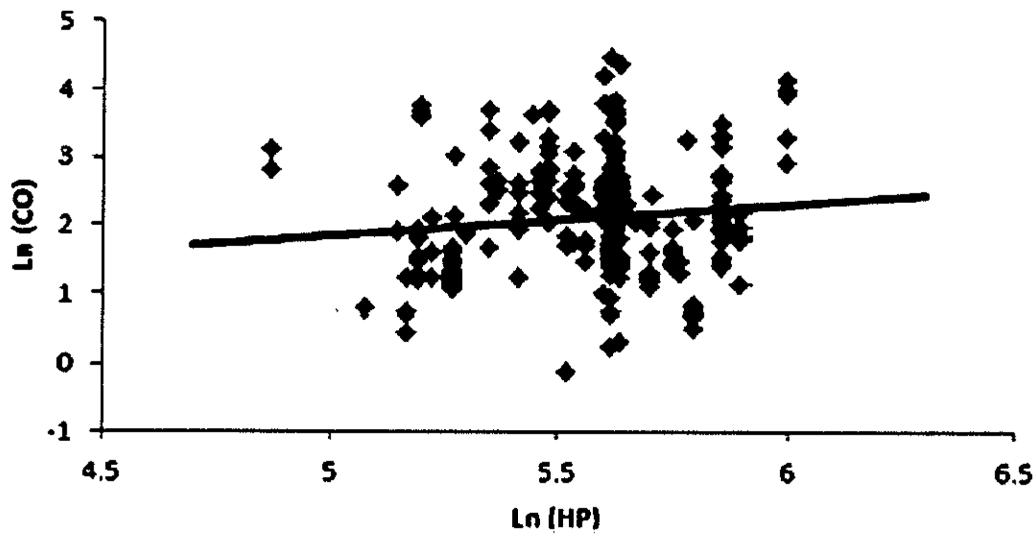

Figure 3: Poor Correlation Between HP and CO (Taken from Yanowitz et al, 2000 and reported in Crump and Van Landingham, 2012)

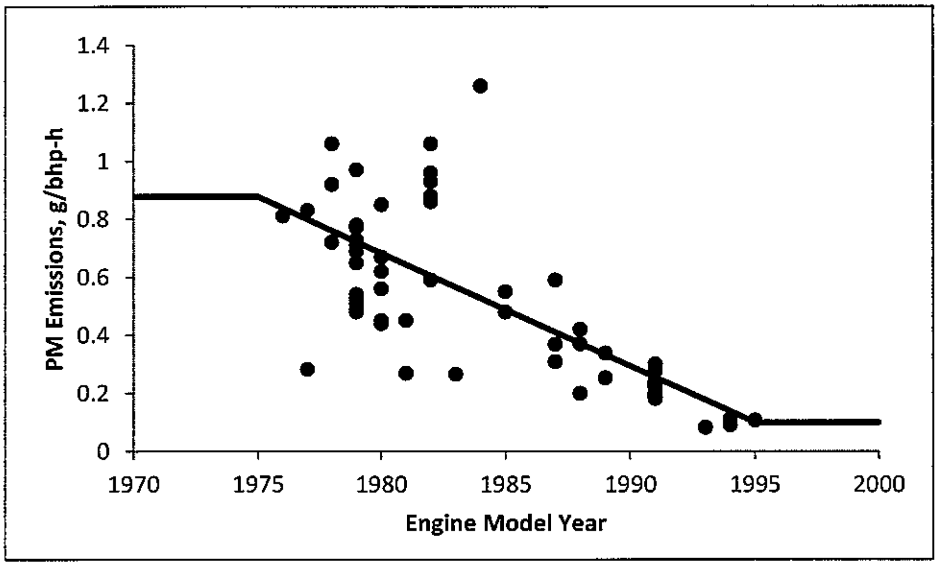

Figure 4: Reduced PM Emissions with Improved Diesel Technology (Reproduced from US EPA, 2002)

Table 1: Past Reviews of the human carcinogenic Hazard of Exposure to Diesel Exhaust (Taken from HEI Epidemiology Panel Report, 2015).

Organizational Reviews	Animal Data	Human Data	Classification	Quantitative Risk Assessment Conducted?
National Research Council (1981)	Negative	Not convincingly demonstrated	—	—
NIOSH (1988)	"Confirmatory"	"Limited"	"Potential occupational carcinogen"	None
IARC (1989)	"Sufficient" (rats)	"Limited"	"Probably carcinogenic to humans (Group 2A)"	None[a]
World Health Organization (1996)	Supportive (rats)	Suggest "probably carcinogenic"	—	Yes, based on rat data; epidemiologic data considered inadequate
Office of Environmental Health Hazard Assessment, California EPA (1998)	"Demonstrated" carcinogenicity (rats)	"Reasonable and likely"	"Toxic air contaminant"	Yes, based on epidemiologic data in railroad workers [cancer unit risk factor of 3×10^{-4} $(\mu g/m^3)^{-1}$]
U.S. EPA (2002)	"Adequate" (rats)	"Limited"	"Likely human carcinogen"	No; epidemiologic dose–response data inadequate
National Toxicology Program (2011)	"Supporting evidence"	"Limited evidence"	"Reasonably anticipated to be a human carcinogen"	None
IARC (2012, 2014)	"Sufficient evidence"	"Sufficient evidence"	"Carcinogenic to humans (Group 1)"	None[a]

[a] Note: IARC does not conduct quantitative risk assessments at this time for any chemicals.

Table 2: Summary of U.S. Truckers Study (from HEI, 2015).

Truckers Cohort	Exposure Assessment	Outcome Assessment	Analysis	Selected Results	
Original Cohort (Laden et al 2007): 58,326 unionized trucking industry workers (93% male) who worked 1 day or more in 1985	None	**All cause, and cause-specific mortality**	**Standardized mortality ratios** Expected numbers of all cause and cause-specific deaths calculated from person-years in each race, 10-year age- and calendar period-specific stratum, and national reference rates. SMRs = ratio observed/expected deaths.	**Standardized mortality ratios:** Ischemic heart disease (1133 cases) SMR = 1.41, 95% CI = 1.33–1.49) Lung cancer (769 cases) SMR = 1.04, 95% CI = 0.97–1.12	
Garshick 2008, 2012a Cohort: 31,135 male workers ≥ 40 years of age in 1985 with at least one year of work **Cohort description:** Ethnicity: 85% Caucasian, 9% Black, 6% Other/unknown Mean age in 1985: 49.1 years Mean total work: 21.6 years End of follow up: year 2000 Person-years of follow up: ≈106,000 for each quartile of exposure. **8 Job Groups:** *Drivers:* Long-haul, Pick-up & delivery / dockworker (combination), Hostler *Nondrivers:* dockworker, mechanic, clerks, other	**Metric:** Submicron ($PM_{1.0}$) Environmental carbon (SEC) in μg/m³ **Exposure model:** *Current Exposures:* From 2001–2006, over 4000 personal and area measurements were taken for cross-shift (8–12 hr) SEC at 36 large terminals randomly chosen to be representative of all terminals. Personal SEC exposures were calculated using Structural Equation Modeling as a function of job category, terminal characteristics, and background EC *Historical Exposures:* Ambient SEC levels were modeled based on the ratio of SEC: Coefficient of haze data available from 1971–2000. Comparison of 1988–1989 data to 2001–2006 data was used to calculate job-specific multipliers for 1971–1989 and extrapolated linearly for 1990–2000 *Personal Exposure:* Modeled current exposures were combined with the historical models, including job-specific multipliers, to extrapolate SEC exposures.	**Primary outcome:** Lung cancer, as indicated anywhere on death certificate **Total male deaths:** 4306 (779 lung cancer) **Ascertainment:** National Death Index (NDI-Plus) matched with Social Security Administration files, date of birth, and first, last, and middle names	**Internal cohort analysis:** Proportional hazard regression models, separate baseline hazards based on decade of hire, age in 1-year increments, exposure measured as cumulative SEC and average EC, lags of 0, 5, and 10 years as continuous, and in quartiles. **Adjustments:** age, lung cancer secular trends, calendar year, race, census region of residence, total years of employment (as a time-dependent covariate). There was no control for smoking. **Mechanic Workers:** Separate analyses also performed excluding workers present for ≥ 1 year as a mechanic (n = 1811) due to inconsistency in exposure modeling for mechanics.	**Cohort excluding mechanics, adjusted for duration of work (Garshick et al. 2012a)**	
				Cumulative SEC (μg/m³-months)	**HR (95% CI)**
				No lag < 530 530 to < 1061 1061 to < 2076 ≥ 2076	 1 1.25 (0.99–1.60) 1.30 (0.99–1.72) 1.24 (0.89–1.71)
				5-yr lag < 371 371 to < 860 860 to < 1803 ≥ 1803	 1 1.31 (1.01–1.71) 1.38 (1.02–1.87) 1.48 (1.05–2.10)
				10-yr lag < 167 167 to < 596 596 to < 1436 ≥ 1436	 1 1.17 (0.88–1.57) 1.26 (0.90–1.78) 1.41 (0.95–2.11)

Table 3: Summary of Diesel Exhaust in Miners Study (DEMS) (from HEI, 2015)

DEMS Cohort	Exposure Assessment	Outcome Assessment	Analysis	Selected Results
8 Nonmetal Mines 1 – limestone (Missouri) 3 – potash (New Mexico) 1 – salt (Ohio) 3 – trona (Wyoming) Year of dieselization in the mines: 1947–1967 Mean year of first exposure to DE: 1971 Mean underground tenure: 8.0 years **Cohort Population** 12,315 workers Sex: 96% male Ethnicity: 88% white, 2% black, 10% Hispanic Mean age at start of exposure: 29 years End of follow up: year 1997 278,041 person-years of follow up 2200 deaths at end of follow up 200 lung cancer deaths	**Metric:** Respirable elemental carbon (REC) in µg/m³ **Historical REC exposure reconstruction:** Models based on REC measurements, horsepower (HP), CO, ventilation (see details in report text). Individual-level annual and cumulative REC exposure assigned based on estimated historical REC levels and job history in the mines. **Confounding exposures measured:** Silica, asbestos, nonDE PAHs, radon, respirable dust. Mines selected for low levels of these contaminants.	**Primary:** Lung cancer defined as malignant neoplasm of the bronchus and lung, excluding tracheal cancer, as underlying cause of death. **Other:** all-cause mortality, other malignant neoplasms, and chronic diseases. **Ascertainment:** National Death Index (NDI-Plus) matched with Social Security Administration files.	**Cohort 'external' analysis:** Standardized mortality ratio analysis, externally standardized to state-, age-, gender-, and ethnic group-specific death rates for each mine. **Cohort 'internal' analysis:** Cox proportional hazards (CPH) models, quantiles of average and cumulative REC, unlagged and lagged 15 years. By work location (ever-underground, surface-only). Adjustments: race, birth year, sex, state Sensitivity analyses: exposure metric, tenure exclusion, continuous models, work location.	SMRs (95% CI): Lung Cancer (LC) Complete cohort: 1.26 (1.09–1.44) Ever-underground: 1.21 (1.01–1.45) Surface-only: 1.33 (1.06–1.66) Cohort CPH analysis: Hazard Ratios (95% CI) Cumulative REC (µg/m³-years), 15-yr lag Complete cohort (200 LC deaths) 0 to < 2.5 — 1.00 (referent) 2.5 to < 56 — 0.55 (0.35–0.85) 56 to < 583 — 1.03 (0.60–1.77) ≥ 583 — 1.39 (0.78–2.48) Ever-underground workers (122 LC deaths) 0 to < 108 — 1.00 (referent) 108 to < 445 — 1.50 (0.86–2.62) 445 to < 946 — 2.17 (1.21–3.88) ≥ 946 — 2.21 (1.19–4.09) Surface-only workers (78 LC deaths) 0 to < 0.70 — 1.00 (referent) 0.70 to < 4.6 — 1.28 (0.64–2.58) 4.6 to < 14 — 0.73 (0.35–1.53) ≥ 14 — 1.00 (0.44–2.28)
Nested Case–control: 198 lung cancer cases, 562 incidence density matched controls; matched on mine, sex, race/ethnicity, and birth year (Note that they had 666 controls for analysis purposes as some subjects served as controls for more than one case subject.)	**Nested Case–control: In addition to REC and confounding exposures above, individual questionnaire data collected on:** Smoking, medical history, occupational history, other personal risk factors		**Nested Case–control:** Conditional logistic regression: with quantiles of average and cumulative REC, unlagged and lagged 15 years, duration of exposure. Two-sided Wald test for linear trend. Various continuous models fit. Control for confounding: Smoking status and intensity, location (as a joint variable), history of high risk jobs. Sensitivity analyses: exposure metric, tenure exclusion, work location, continuous models, smoking metrics.	**Nested case-control CPH analysis: Odds Ratios (95% CI)** Cumulative REC (µg/m³-years), 15-yr lag 0 to < 3 — 1.00 (referent) 3 to < 72 — 0.74 (0.40–1.38) 72 to < 536 — 1.54 (0.74–3.20) ≥ 536 — 2.38 (1.28–6.26) $P_{trend} = 0.001$

Table 4: Characteristics of the Mines in the Diesel Exhaust in Miners Study (DEMS) (from Crump et al., 2016)

Mine	State	Ore	Ventilation	Year of First Diesel Use	Primary Mode of Operation	All Years: CO # samples	All Years: CO % > LOD	All Years: Radon # samples	All Years: Radon % > LOD	1982 Activity: CFM f^3/min (in thousands)	1982 Activity: Diesel (Adj HP)
A	Missouri	Limestone	Natural	1947	Cv/H	248	70	37	84	--	6,862
B	New Mexico	Potash	Mechanical	1964	Cv/Con, Ct	447	62	18	44	250	892
D	New Mexico	Potash	Mechanical	1950	Cv/H, Cv/Con, Ct	323	54	61	39	360	2,326
J	New Mexico	Potash	Mechanical	1952	Cv/H, Cv/Con, Ct	178	52	13	38	240	1,421
E	Ohio	Salt	Mechanical	1959	Cv/H	207	66	39	70	233	2,804
G	Wyoming	Trona	Mechanical	1962	Cv/Con, Ct	276	50	17	24	450	638
H	Wyoming	Trona	Mechanical	1967	Cv/Con, LW, Ct	2361	39	40	15	950	1,110
I	Wyoming	Trona	Mechanical	1956	Cv/Con, Ct, LW	2000	54	54	20	1,630	1,493
Total						6040	50	279	42		

The above data were compiled from the Stewart et al.[1] and the substantial DEMS data files. Primary Mode of Operation: Cv/H – conventional with truck haulage, Cv/Con – conventional with conveyor belts, Ct – Continuous with conveyor belts, and LW – long wall with conveyor belts. Specific data for ventilation rates and HP are shown for 1982 for illustrative purposes, as 1982 was the last year of effective exposure for workers, assuming a 15 year-lag, as follow-up ended in 1997.

Table 5: Table 2 of Stewart et al. (2010) Summarizing the Data Available for Constructing Estimates of REC Exposures at the Eight Mining Facilities

Table 2. Number of area and personal DE-related measurements by agent for the eight mining facilities

Agent	Survey[a]										All surveys		Total
	MIDAS 1976–2001		DEMS 1998–2001		MESA/BoM 1976–1977		Feasibility study 1994		Other 1954–1996				
	Area[b]	Personal[b]	Area	Personal	Area	Personal	Area	Personal	Area	Personal	Area	Personal	
CO	9746	46	208	0	1099	0	25	0	46	0	11 124	46	11 170
CO_2	8234	15	390	0	961	0	17	0	49	0	9651	15	9666
NO	45	0	381	995	24	0	42	69	9	0	501	1064	1565
NO_2	4288	38	387	1031	252	646	42	69	76	11	5045	1795	6840
TD	1	782	215	0	161	667	32	0	69	703	478	2152	2630
RD	0	324	209	2	99	0	31	0	158	178	497	504	1001
SD	0	0	121	0	0	0	69	0	20	0	210	0	210
TEC	0	0	224	0	0	0	0	0	0	0	224	0	224
REC	0	0	216	1156	0	0	0	69	12	4	228	1229	1457
SEC	0	0	209	0	0	0	0	0	0	0	209	0	209
TOC	0	0	224	0	0	0	0	0	0	0	224	0	224
ROC	0	0	221	1151	0	0	0	0	0	0	221	1151	1372
SOC	0	0	207	0	0	0	0	0	0	0	207	0	207
DPM/SCD	0	0	212	0	0	0	0	0	180	102	392	102	494
Total	22 314	1205	3424	4335	2596	1313	258	207	619	998	29 211	8058	37 269

DPM, diesel particulate matter; RD, respirable dust; ROC, respirable organic carbon; SCD, submicron combustible dust; SD, submicron dust; SEC, Submicron elemental carbon; SOC, submicron organic carbon; TD, total dust; TEC, total elemental carbon; TOC, total organic carbon.

[a]Surveys: the MSHA MIDAS (1976–2001); the DEMS (1998–2001) (Coble *et al.*, 2010; Vermeulen *et al.*, 2010*b*); the MESA/BoM (1976–1977) (Sutton *et al.*, 1979); the feasibility study for the DEMS in Facility B (1994) (Stanevich *et al.*, 1997); compliance visits by the State of New Mexico, MSHA hard copy reports, and the mining facilities (1954–1996).

[b]Area measurements; personal measurements. The number includes both full-shift and short-term measurements.

Table 6: Workers Studied in Diesel Exhaust in Miners Study (DEMS) (from Moolgavkar et al., 2014)

			Ever-Underground Workers					
	Surface-Only Workers		Underground-Only Workers		Surface and Underground Workers		Complete Cohort	
Mine Type	**Miners**	**Deaths**	**Miners**	**Deaths**	**Miners**	**Deaths**	**Miners**	**Deaths**
Limestone	730	15	123	12	823	10	1676	37
Potash	1293	38	1951	46	1327	18	4571	102
Salt	50	<5	208	9	289	<5	547	<19
Trona	1935	23	1798	15	1788	11	5521	49
Entire cohort	4008	<81	4080	82	4227	<44	12315	<207

Table 7: Comparison of Conditional Original Logistic Regression Resulted (Silverman et al, 2012) with Results of Similar Analyses except based on New REC Estimates Defined Using HP and CFM (from Crump et al., 2016)

Analysis	Quartiles of cumulative REC, lagged 15 years (µg/m³-y)	Cases	Controls	OR (95% CI)	p_{trend}	Slope $(\mu g/m^3\text{-}y)^{-1}$ 95% CI
All Subjects						
Silverman et al.[7]	0 to < 3	49	158	1.0 (referent)	0.001	0.00073*
	3 to < 72	50	228	0.74 (0.40 to 1.38)		(0.00028,0.0012)*
	72 to < 536	49	157	1.54 (0.74 to 3.20)		
	≥ 536	50	123	2.83 (1.28 to 6.26)		
REC estimates from Silverman et al.[7] and "without radon" controls[12]	0 to < 3	49	158	1.0 (referent)	0.0006	0.00082
	3 to < 72	50	228	0.79 (0.41 to 1.52)		(0.00035,0.0013)
	72 to < 536	49	157	1.62 (0.75 to 3.49)		
	≥ 536	50	123	3.24 (1.40 to 7.55)		
HP-CFM REC estimates and "without radon" controls	0 to < 6.6	49	172	1.0 (referent)	0.06	0.00016
	6.6 to < 129	50	191	1.05 (0.58 to 1.93)		(-0.000012,0.0003)
	129 to < 891	49	168	1.60 (0.79 to 3.24)		
	≥ 891	50	135	2.37 (1.02 to 5.50)		
HP-CFM REC estimates and "with radon" controls	0 to < 6.6	49	172	1.0 (referent)	0.63	0.00005
	6.6 to < 129	50	191	1.02 (0.55 to 1.90)		(-0.00016,0.00026)
	129 to < 891	49	168	1.20 (0.56 to 2.56)		
	≥ 891	50	135	1.37 (0.5 to 3.77)		
All Subjects Who Ever Worked Underground						
Silverman et al.[7]	0 to < 81	29	92	1.0 (referent)	0.004	0.00065*
	81 to < 325	29	52	2.46 (1.01 to 6.01)		(0.00020,0.0011)*
	325 to < 878	29	69	2.41 (1.00 to 5.82)		
	≥ 878	29	51	5.10 (1.88 to 13.87)		
REC estimates from Silverman et al.[7] and "without radon" controls[12]	0 to < 97	31	158	1.0 (referent)	0.01	0.00073
	97 to < 384	31	90	1.90 (0.78 to 4.63)		(0.00022,0.0012)
	384 to < 903	31	80	2.73 (1.08 to 6.88)		
	≥ 903	31	84	5.04 (1.77 to 14.30)		
HP-CFM REC estimates and "without radon" controls	0 to < 130	31	144	1.0 (referent)	0.16	0.00014
	130 to < 531	31	99	2.03 (0.83 to 4.96)		(-0.000062,0.0003)
	531 to < 2149	31	99	3.45 (1.27 to 9.41)		
	≥ 2149	31	70	3.84 (1.07 to 13.74)		
HP-CFM REC estimates and "with radon" controls	0 to < 130	31	144	1.0 (referent)	0.69	0.00005
	130 to < 531	31	99	1.83 (0.73 to 4.61)		(-0.00020,0.00030)
	531 to < 2149	31	99	2.47 (0.79 to 7.73)		
	≥ 2149	31	70	2.5 (0.49 to 12.79)		
All Subjects Who Only Worked Underground						
HP-CFM REC estimates and "without radon" controls	0 to < 106	14	26	1.0 (referent)	0.27	0.00024
	106 to < 410	15	28	1.89 (0.4 to 9.07)		(-0.000179,0.0007)
	410 to < 1486	14	17	3.15 (0.47 to 21.05)		
	≥ 1486	15	26	4.73 (0.58 to 38.84)		
HP-CFM REC estimates and "with radon" controls	0 to < 106	14	26	1.0 (referent)	0.36	0.00027
	106 to < 410	15	28	1.91 (0.38 to 9.75)		(-0.000316,0.0009)
	410 to < 1486	14	17	5.61 (0.61 to 51.33)		
	≥ 1486	15	26	9.39 (0.47 to 187.84)		

* Calculated by us after reproducing Silverman et al. results.

Table 8: Contributors

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† As a co-author with Eric Garshick on the 2012 study of trucking industry employees (Garshick et al. 2012a), Thomas Smith did not review Chapter 3.

statement
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Statement for July 26 Public Meeting on MSHA Request for Information on Diesel Exhaust
July 22, 2016

My name is Ed Green and I am here today to present a statement regarding MSHA's Request for Information on Exposure of Underground Miners to Diesel Exhaust (the "RFI"), as published in the Federal Register for June 8, 2016. 81 Fed. Reg. 36,826. Docket No, MSHA—2014—0033. My statement is offered on behalf of Murray Energy Corporation, the Bituminous Coal Operators' Association ("BCOA"), and Bridger Coal Company (the "Companies"). To begin, the Companies are pleased to provide MSHA with this Statement. We are reviewing the RFI with great interest and are of the preliminary view that it will help us and all stakeholders focus on a topic that is worthy of attention. At the very outset, however, we want to support and agree with the statements of the Industrial Minerals Association—North America ("IMA—NA") proposing that MSHA and NIOSH establish a Diesel Health Effects Partnership and that MSHA grant at least a 90-day extension of the comment period from the current deadline of September 6. Such an extension will allow stakeholders to benefit from what we expect will be learned from the first meeting of the Partnership.

This statement will briefly describe how MSHA currently regulates the exposure of underground coal miners to diesel exhaust, pointing out the fundamental difference between those regulations and the MSHA rules governing the exposure of underground metal/nonmetal miners to diesel exhaust. The statement will also briefly address the recent research identified in the RFI; and will introduce Dr. Roger McClellan to the MSHA Public Meeting Panel again, as he is an advisor to the Companies as well as to IMA-NA.

Finally, this statement will address our understanding of the true underlying basis for the initiation of this RFI and will remind MSHA that, at a time when the Companies are dealing with the greatest ever economic downturn of the entire US coal industry, MSHA must take into special account the economic feasibility of any regulatory steps MSHA may advance as a next step of the RFI.

From a personal perspective, I want the MSHA Panel to know that I have been working frequently on diesel safety and health issues since 1972 as: (1) a lawyer in the early days of the modern federal mine safety and health program; (2) the general counsel of the American Mining Congress (a precursor trade group to the National Mining Association); and (3) an attorney in the nationally recognized mining practice at the Washington, DC-based law firm of Crowell & Moring LLP.

Current MSHA Regulations Relating to the Exposure of Underground Coal Miners to Diesel Exhaust

Current MSHA regulations dealing with the exposure of underground coal miners to diesel exhaust are contained in:

- Subpart E of 30 C.F.R. Part 7—Diesel Engines Intended for Use in Underground Coal Mines;

- Subpart F of 30 C.F.R Part 7—Diesel Power Packages Intended for Use in Areas of Underground Coal Mines Where Permissible Electric Equipment is Required;

- 30 C.F.R. Part 36, Approval Requirements for Permissible Mobile Diesel-Powered Transportation Equipment;

- 30 C.F.R. Part 72, Health Standards for Coal Mines, Subpart D, Diesel Particulate Matter—Underground Areas of Underground Coal Mines; and

- 30 C.F.R. Part 75, Mandatory Safety Standards—Underground Coal Mines, Subpart T—Diesel-Powered Equipment.

Central to these coal rules are the provisions of Subpart D of Part 72. Sections 72.500, 72.501, and 72.502 set forth grams/hour emission limits of diesel particulate matter ("DPM") for permissible diesel-powered equipment (§72.500), nonpermissible heavy-duty diesel-powered equipment, generators, and compressors (§72.501), and nonpermissible light-duty diesel-powered equipment other than generators and compressors.

Importantly, although there are some exceptions, generally speaking, MSHA will determine compliance with these emission requirements by using the amount of DPM emitted by a particular engine during Part 7 engine approval testing. Of course what this means is that once deployed underground, the engine emission limits are not tested in real time. Real-time testing would be unworkable in an underground coal mine considering that the ambient atmosphere contains particles of carbon from the coal being mined, as well as the carbon contained in the coal itself.

This regulatory scheme for exposure of miners to diesel exhaust in underground coal mines is thus necessarily very different from that in underground metal and nonmetal mines, where miners' exposure is based on a measured real-time personal exposure limit ("PEL") of DPM expressed as total carbon, as set forth in 30 C.F.R. §57.5060.

Recent Research

The Companies note that the RFI identifies key recent research on which the RFI depends. You have already heard from Dr. Roger O. McClellan speaking for IMA—NA. Dr. McClellan is a consultant for the Companies too. As such, we not only endorse his presentation for the IMA—NA, but also, following my statement, Dr. McClellan will have some additional commentary to give you on our behalf. Of course, we want to remind the Panel that pursuant to section 101(a)(6)(A) of the Federal Mine Safety and Health Act of 1977 (the "Mine Act"), MSHA must consider all "of the latest scientific evidence in the field." The Companies also endorse Dr. McClellan's Critique of the HEI Report referenced in the RFI. And very importantly, the Companies strongly agree with the idea of establishing an MSHA-NIOSH Partnership with all the stakeholders to discuss in detail the questions MSHA has raised in the RFI. The Partnership, we earnestly believe, will lead to development of additional relevant science.

What is the True Underlying Basis for the RFI?

The Companies have read the introductory language in the RFI that precedes the questions asked. We also understand that at the public meetings last week in Salt Lake City, UT and Pittsburgh, PA (on July 19 and 21, respectively), MSHA has said the agency's mind is open at this juncture as to whether additional rules dealing with the exposure of underground miners to diesel exhaust are necessary.

The Companies are pleased to hear that; but, candidly, we wonder about its accuracy. We say that because we are aware of 2012 letters from the United Mine Workers' of America (the "UMWA") and a group of public health academicians appearing to petition MSHA to promulgate stricter DPM standards for both coal and metal/nonmetal mines than those currently in effect. The Companies also understand that, at the Pittsburgh public meeting, representatives of the UMWA and the United Steelworkers of America called upon MSHA for new and more stringent rules. We also want to say, categorically, that although we are not opposed to new rules, we want to make sure they are need- and science-based.

Feasibility

Thus, as I conclude before re-introducing Dr. McClellan to you for his specific comments on our behalf, please allow me to re-emphasize our support for his Critique of the HEI Report and our endorsement of the establishment with NIOSH and MSHA of a Diesel Exhaust Health Effects Partnership. Returning to Mine Act section 101(a)(6)(A), the Companies also wish to remind MSHA of its mandatory obligation to consider the feasibility of any new rules the agency may adopt. Feasibility not only includes technological feasibility (a difficult enough requirement), but also economic feasibility. In that regard, MSHA must take into account the fact that the US domestic coal mining industry is under severe stress, with several major coal producers undergoing Chapter 11 reorganization as we meet here today, and with prices down and environmental regulatory pressure up.

With this introduction in mind, please allow me to turn to Dr. McClellan so he may give you his additional comments. Thank you very much for your attention.