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

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