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
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By

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On behalf of
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Bituminous Coal Operators' Association
Bridger Coal Company

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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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