

## CLIENT ALERT

### Diesel After DEMS: Regulatory Developments on the Horizon for Mining

Summer 2015

Diesel exhaust exposure for underground miners has been regulated since the Mine Safety and Health Administration (MSHA) issued Diesel Particulate Matter (DPM) rules for underground coal miners and underground metal and nonmetal miners in 2001. In a related effort, beginning in 1992, the National Cancer Institute (NCI) and the National Institute for Occupational Safety and Health (NIOSH) conducted a study of the effects of DPM on miners in eight nonmetal mines, seeking to determine whether a link existed between lung cancer mortality in the miners in those mines and exposure to DPM. That study, known as the Diesel Exhaust in Miners Study or "DEMS," extended over a 21-year period and is a major contributor to the prospect of revised (and more stringent) diesel regulations in the mining industry. As scientists begin to build on the work done by DEMS, agencies are taking preliminary steps that may prove to be the building blocks for future diesel regulation. This article explores what regulatory developments inspired by DEMS may be on the horizon for the mining industry.

#### MSHA's Current DPM Regulations

On January 19, 2001, MSHA issued DPM rules addressing the health hazards to underground metal and nonmetal miners and underground coal miners from exposure to DPM. The preambles to these rules contained a comprehensive risk assessment<sup>1</sup> in which MSHA had determined that diesel particulate matter puts underground miners at increased risk for heart and lung disease, including lung cancer.<sup>2</sup> In metal and nonmetal mines, MSHA imposed permissible exposure limits (PELs) for underground miners of 160 micrograms of total carbon per cubic meter of air measured as an eight-hour equivalent shift concentration with staggered effective dates for implementation of that limit. Mine operators were required to achieve concentrations at or below the PEL by installing and maintaining feasible engineering and administrative controls. If not feasible, mine operators had to use engineering controls to achieve as low a level as feasible and then provide supplemental respiratory protection for the exposed miners. The rules imposed other requirements ranging from fueling practices, maintenance standards, training, exposure monitoring, and record-keeping requirements.

Protracted litigation over the metal/nonmetal DPM rule followed, culminating in a 2007 D.C. Circuit case upholding the legality of the DPM rules in their entirety.<sup>3</sup>

#### Diesel Exhaust in Miners Study (DEMS) and Reanalysis Efforts

Between 1992 and 2012, NCI and NIOSH undertook a major retrospective cohort lung cancer mortality and nested case-control study of 12,315 surface and underground workers at eight non-metal mines (trona, potash, salt, and limestone). The agencies collected data at those mines from 1992 through 1997. Because there is no means for assessing the toxicity of diesel exhaust when examined in its totality, the study used respirable elemental carbon (a component of diesel exhaust) as the primary surrogate for diesel exhaust. The study also used historical measurements to estimate, retrospectively, the exposure of each worker in the study.

That study culminated with the publication of seven peer-reviewed papers.<sup>4</sup> The final nested case-control study and cohort mortality study papers were published in 2012.<sup>5</sup> The DEMS authors concluded that exposure to diesel exhaust caused a statistically significant increased risk of death from lung cancer in excess of that otherwise predicted from cigarette smoking and the natural occurrence rate.

DEMS is widely considered to be the most significant epidemiological study to date due to its size and the agencies' use of respirable elemental carbon as a quantitative marker of exposure to diesel exhaust. As one commenter put it, "[t]hese papers are expected to have considerable impact on the evaluation of the carcinogenic potential of diesel exhaust and, furthermore, on occupational and environmental limit value discussions related to diesel motor emissions and particle exposures."<sup>6</sup>

DEMS is, however, a backwards-looking study that does not measure the impacts of exposure to today's improved diesel engines or diesel fuel. Furthermore, DEMS is not without its critics – and scientists attempting to replicate its findings have reached different conclusions than did the NCI and NIOSH authors. Specifically, after no small effort over a number of years, an industry coalition led by the Truck & Engine Manufacturers Association (EMA) obtained access, albeit somewhat limited access, to the DEMS data so that it could be reanalyzed by an independent team of epidemiologists and biostatisticians.<sup>7</sup>

The EMA independent team of researchers also examined the role of temporal factors in modifying the estimated effects of exposure to diesel engine exhaust on lung cancer mortality and characterized risk by mine type in the DEMS cohort.<sup>8</sup> They found that the respirable elemental carbon-associated risk of lung cancer mortality in DEMS was driven by the DEMS limestone mine. No significant exposure-response relationship existed after removal of the limestone mine workers from DEMS. They also explored the importance of temporal factors in determining the risk of lung cancer mortality and opined that the modifying impact of temporal factors and effect modification by age should be addressed in any quantitative risk assessment of diesel exhaust exposure.

The EMA team also conducted a reanalysis of the DEMS case-control data to evaluate its suitability for quantitative risk assessment, adjusting for radon exposure and including alternative estimates of diesel engine exhaust exposure.<sup>9</sup> Without adjusting for radon, their results were similar to those in the original DEMS analysis, but when exposure to radon was adjusted, the reanalysis team found that the evidence for an effect from exposure to diesel exhaust was greatly diminished. In addition, no consistent evidence of an effect from exposure to diesel exhaust was found for miners who worked only underground.

DEMS, therefore, remains an important study, but it is no longer the final scientific word on the effects of diesel exhaust exposure in surface and underground miners. Agencies have, nevertheless, been inspired to action by DEMS, as described below.

### **Regulation of Diesel After DEMS: What's On the Horizon for Mining?**

DEMS likely will be used by agencies to conduct revised health risk assessments and to justify more onerous regulation of diesel exhaust. The DEMS-inspired developments that loom large on the horizon for the mining industry are summarized below.

**IARC Reclassification.** DEMS had an almost immediate impact when the International Agency for Research on Cancer (IARC), which is part of the World Health Organization, revised its classification of diesel engine exhaust in the summer of 2012 from *probably carcinogenic to humans* to *carcinogenic to humans*.<sup>10</sup> Based largely on the DEMS results, IARC determined that there

was sufficient evidence that exposure to diesel exhaust is associated with an increased risk for lung cancer. The New York Times also reported that experts had identified diesel fumes as more carcinogenic than secondhand cigarette smoke.<sup>11</sup>

IARC's reclassification of diesel exhaust is significant because IARC has historically had enormous influence on cancer research and standard-setting.

**MSHA/OSHA Hazard Alert.** Also in 2012, MSHA and the Occupational Safety and Health Administration (OSHA) issued a diesel exhaust hazard alert informing workers that "[p]rolonged DE/DPM exposure can increase the risk of cardiovascular, cardiopulmonary and respiratory disease and lung cancer."<sup>12</sup> In that alert, the agencies highlighted IARC's diesel classification.

**NIOSH.** In 2014, NIOSH announced at a Health Effects Institute (HEI) workshop on "Diesel Exhaust, Lung Cancer and Quantitative Risk Assessment" that it will use DEMS as a basis for a new quantitative risk assessment of health effects of diesel exhaust. The starting date for that project is uncertain.

**MSHA Request for Information.** In response to two informal "petitions for rulemaking" received from the United Mine Workers of America and a group of public health academics, and in light of IARC's reclassification and the DEMS results, MSHA announced in its Fall 2014 regulatory agenda that it would publish a request for information (RFI) on "approaches that would improve control of DPM and diesel exhaust."<sup>13</sup> The RFI was projected to be published in April, but that did not occur. Instead, the Spring 2015 regulatory agenda has advanced the date to December 2015.<sup>14</sup>

Experience teaches that a date like this is a soft projection. MSHA rulemaking action, therefore, will almost certainly be time-bound by the lame duck Obama Administration. Even if this RFI were published in December, insufficient time will likely exist in the presidential election year of 2016 even to propose new rules, let alone promulgate them in final form. But depending on which party wins the next election, the RFI could eventually lead to new MSHA diesel rules. Unlike the current DPM rules (which apply to underground miners only), any new rulemaking also could extend to both underground and surface miners, as DEMS studied both types of mine workers. On this important point, it is noteworthy that MSHA already concluded in 2001 that "surface miners are entitled to the same level of protection as other miners; and the Agency's risk assessment indicates that even short-term exposure to concentrations of [diesel particulate matter] like those observed may result in serious health problems."<sup>15</sup>

**EPA and HEI.** In 2002, the U.S. Environmental Protection Agency (EPA) published its "Health Assessment Document for Diesel Engine Exhaust," which concluded that long-term exposure to diesel exhaust was likely to pose a lung cancer hazard as well as other types of damage to the lungs depending on exposure.<sup>16</sup> EPA may choose to revise that assessment based on forthcoming recommendations on whether DEMS will support a quantitative assessment from HEI, a public-private partnership between EPA and industry.

In 2012, HEI conducted an Advanced Collaborative Emissions Study (ACES) to attempt to distinguish between traditional diesel exhaust and new technology diesel exhaust. ACES found no evidence of gene-damaging effects in the rats and mice studied from exposure to new technology diesel engines and only a few mild effects on the lungs.<sup>17</sup> That study is the only new technology diesel study to date.

HEI has been charged by EPA to review recent epidemiologic studies including DEMS and the reanalysis papers to advise EPA on whether the agency should conduct a revised health assessment for diesel. At its annual conference in May 2015, the HEI Diesel

Epidemiology Panel presented its preliminary findings in advance of issuing a formal report later this year.<sup>18</sup> Although HEI's report is not final, it appears that the panel is inclined to deem DEMS an appropriate study to be used in a future quantitative risk assessment. Many stakeholders believe, however, that the HEI panel has not yet given equal consideration to the EMA-commissioned DEMS reanalysis papers in its work.

Because the HEI Diesel Epidemiology Panel's work is ongoing, it is too early to speculate on a final outcome, which we expect before the end of 2015. Whatever the outcome, the Panel's work should be closely watched by the mining industry because it could serve as the driver for a future EPA quantitative risk assessment and as yet another step on the path to increased regulation of diesel use at mines.

## Conclusion

In sum, diesel exhaust exposure for miners promises to be a continued focus for scientists and regulatory agencies alike. The next few years may see new MSHA rulemaking in this area, or at least MSHA, NIOSH, and EPA gathering additional information and making quantitative health assessments that could (and likely will) later be used to support downward revised exposure limits for mine workers.

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<sup>1</sup> 66 Fed. Reg. 5,526 (Jan. 19, 2001) (DPM rules for underground coal miners); *id.* at 5,706 (DPM rules for metal and nonmetal mines). The DPM rules are found at 30 C.F.R. §§ 57.5060 through 57.5075. The risk assessment was published at 66 Fed. Reg. 5,752-855, and as corrected at 66 Fed. Reg. 53,518-520.

<sup>2</sup> 66 Fed. Reg. at 5,637-39.

<sup>3</sup> *Kennecott Greens Creek Mining Co. v. MSHA*, 476 F.3d 946 (D.C. Cir. 2007). For more information on the metal/nonmetal mine litigation, see L. Joseph Ferrara, *MSHA's Diesel Particulate Matter (DPM) Rulemaking for Metal/Non-Metal Mines: What Have We Learned?*, 24 Energy & Min. L. Inst. ch. 7 (2004), [available here](#).

<sup>4</sup> For links to the study publications and more information on DEMS, see [National Cancer Institute, Division of Cancer Epidemiology & Genetics, Diesel Exhaust in Miners Study \(DEMS\)](#), (last visited May 16, 2015).

<sup>5</sup> Publication was delayed by Federal Advisory Committee Act litigation brought by the Methane Awareness Resources Group (MARG).

<sup>6</sup> Peter Morfield, *Diesel exhaust in miners study: how to understand the findings?*, *J. of Occupational Medicine and Toxicology* 2012, 7:10, [available here](#).

<sup>7</sup> See, e.g., Association of Equipment Manufacturers, Advisor Newsletter, [AEM Joins Coalition Seeking Review of 'Diesel Exhaust in Miners Study' Data](#) (Dec. 5, 2013). EMA was informed that, by data use agreement, the data cannot be linked and had to be viewed in a secure data facility.

<sup>8</sup> See Suresh H. Moolgavkar, et al., *Diesel Engine Exhaust and Lung Cancer Mortality: Time-Related Factors in Exposure and Risk*, *Risk Analysis*, [available here](#).

<sup>9</sup> See Kenny S. Crump et al., *Reanalysis of the DEMS Nested Case-Control Study of Lung Cancer and Diesel Exhaust: Suitability for Quantitative Risk Assessment*, Risk Analysis (published online Apr. 10, 2015), [available here](#).

<sup>10</sup> See IARC Press Release, *IARC: Diesel Engine Exhaust Carcinogenic* (June 12, 2012).

<sup>11</sup> Donald G. McNeil, Jr., *W.H.O. Declares Diesel Fumes Cause Cancer*, N.Y. Times (June 12, 2012), [available here](#).

<sup>12</sup> OSHA/MSHA Hazard Alert, Diesel Exhaust/Diesel Particulate Matter at 1, [available here](#).

<sup>13</sup> See Office of Information and Regulatory Affairs, Office of Management and Budget, DOL/MSHA RIN 1219-AB86.

<sup>14</sup> See Office of Information and Regulatory Affairs, Office of Management and Budget, DOL/MSHA RIN 1219-AB86.

<sup>15</sup> 66 Fed. Reg. at 5,531, 5,708.

<sup>16</sup> EPA, Health Assessment Document for Diesel Engine Exhaust (May 2002).

<sup>17</sup> See Jacob D. McDonald et al. (Part 1), Jeffrey C. Bemis et al. (Part 2), Lance M. Hallberg et al. (Part 3) and Daniel J Conklin and Maiying Kong (Part 4), *Advanced Collaborative Emissions Study (ACES) Subchronic Exposure Results: Biologic Responses in Rats and Mice and Assessment of Genotoxicity*, [available for download here](#); see also Press Release, *Study Finds Few Health Effects From New Technology Diesel Engines* (Apr. 12, 2012).

<sup>18</sup> See HEI Diesel Epidemiology Project (Sept. 2012); Katherine Walker, Health Effects Institute, Draft Report of the HEI Diesel Epidemiology Panel (Part II): Diesel Epidemiology and Lung Cancer. Those slides are drafts and we point to them only to demonstrate HEI's ongoing work on diesel.

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#### Other Articles in This Issue:

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