

premature mortality from COPD. For example, a diminished forced expiratory volume in one second (FEV₁) or a diminished ratio of the FEV₁ to the forced vital capacity¹⁶ (FVC) (*i.e.*, FEV₁/FVC) upon medical examination was associated with a significantly increased standardized mortality ratio (SMR) for COPD (322 and 212, respectively). In other words, miners with diminished lung capacity based on FEV₁ were two to three times more likely to die prematurely due to COPD than miners who had normal lung function. In contrast, SMRs for COPD were not significantly increased in miners with normal lung volumes and capacities. These data support prior conclusions of Seixas, *et al.* (1992, 1993) and Attfield and Hodous (1992) based on morbidity studies.

VI. Quantitative Risk Assessment

Having reviewed the reported health effects associated with exposure to respirable coal mine dust, MSHA has evaluated the evidence to determine whether the current regulatory strategy can be improved. The criteria for this evaluation are established by section 101(a)(6)(A) (30 U.S.C. 811(a)(6)(A)) of the Mine Act, which states that:

The Secretary, in promulgating mandatory standards dealing with toxic materials or harmful physical agents under this subsection, shall set standards which most adequately assure 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 dealt with by such standard for the period of his working life.

Based on Court interpretations of similar language under the Occupational Safety and Health Act, there are three questions that must be addressed: (1) Whether health effects associated with the current pattern of overexposures on individual shifts constitute a material impairment to miner health or functional capacity; (2) whether the current pattern of overexposures on individual shifts places miners at a significant risk of incurring any of these material impairments; and (3) whether the proposed rules will substantially reduce those risks.

The statutory criteria for evaluating the health effects evidence do not require absolute certainty. Under section 101(a)(6)(A) of the Mine Act, MSHA is required to proceed according to the "best available evidence" (30

U.S.C. 811(a)(6)(A)). Furthermore, the need to evaluate risk does not mean that an agency is placed into a "mathematical straightjacket." In *Industrial Union Department, AFL-CIO v. American Petroleum Institute* (448 U.S.), otherwise known as the "Benzene" decision, the court ruled that:

So long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions in interpreting the data * * * risking error on the side of overprotection rather than underprotection. (448 U.S. 607, 100 S.Ct 2844 (1980) at 656)

As explained earlier, MSHA's objective in strengthening the requirements for verifying the effectiveness of dust control plans, and in enforcing effective plans through the new enforcement policy proposed, is to ensure that no miner is exposed to an excessive concentration of respirable dust on any individual shift (*i.e.*, a concentration in excess of the applicable dust standard). MSHA's samples, combined with the more frequent bimonthly operator samples reveal recent overexposures on individual shifts in many mines. Furthermore, these dust samples demonstrate that, in many mines, dust concentrations exceed the applicable dust standard on a substantial percentage of the production shifts. This pattern has persisted for many years; and, since the existing program permits individual shift excursions above the applicable dust standard, a similar pattern can be expected to continue over the working lifetime of affected miners—unless an effort is made to eliminate excessive exposures on individual shifts.

In this quantitative risk assessment (QRA), MSHA will demonstrate that reducing respirable coal mine dust concentrations to no more than the applicable dust standard on each and every shift would, over a 45-year occupational lifetime, significantly bring down the cumulative exposure to respirable coal mine dust, thereby significantly reducing the risk of both simple CWP and PMF among miners. This reduction in risk would result from reducing concentrations on just that percentage of shifts currently showing an excess.

MSHA has estimated health benefits of the two rules based on eliminating excessive exposures at only those MMUs and roofbolter designated areas (RB-DAs) currently exhibiting a pattern of recurrent overexposures on individual shifts. In the previous proposed rule, MSHA used operator sampling data from the year 1999 to

identify and characterize such MMUs. In the current proposed rule, MSHA has updated the analysis to 2001, included MSHA DO sampling data in addition to operator data, and expanded the quantitative analysis to include the reduction in risk expected for certain miners not previously considered (*i.e.*, miners working in RB-DAs). As a result, MSHA believes it has now more comprehensively quantified the reduction in risk expected for the most highly exposed miners currently subject to recurrent overexposures.

By "exhibiting a pattern of recurrent overexposures," MSHA means that, for the same DO or RB-DA, at least two valid MSHA or bimonthly operator samples have exceeded the applicable dust standard during a year. MMUs exhibiting such a pattern are highly likely to have experienced excessive exposures on at least six shifts during the year under consideration.¹⁷

Based on 2001 MSHA and operator data, there were 716 MMUs (out of 1,256 total) at which dust concentrations for the DO exceeded the applicable dust standard on at least two of the sampling shifts (MSHA, datafile: DO_2001.ZIP). MSHA considers these 716 MMUs, representing 57 percent of all MMUs and more than one-half of all underground coal miners working in production areas, to have exhibited a pattern of recurrent overexposures. Valid DO samples were collected on a total of 20,905 shifts at these 716 MMUs, and the applicable dust standard was exceeded on 4,028 of these shifts, or 19.3 percent. For this 19.3 percent, the mean excess above the standard, as measured for the DO only, was 1.04 mg/m³.

These results are based on a large number of shifts (an average of nearly 30 at each of the 716 MMUs). Therefore, assuming representative operating conditions on these shifts, the results can be extrapolated to all production

¹⁷ MSHA estimates a MMU average of 384 production shifts per year. At MMUs exhibiting a pattern of recurrent overexposures in 2001, valid DO samples were obtained on an average of about 30 of these 384 production shifts. If dust concentrations on two or more of the sampled shifts exceed the standard, then it follows, at a 95-percent confidence level, that the standard is exceeded on at least six shifts over the full year.

If a different definition of "exhibiting a recurrent pattern of overexposures" had been used in the QRA, the estimate of the reduction in risk and associated benefits would have been different. For example, if the criterion were that four or more bimonthly DO exposure measurements exceeded the applicable dust standard then overexposures would be expected, with 95% confidence, to occur on at least 20 shifts in a year of 384 shifts. Using more than two recorded overexposures as the criterion would arbitrarily reduce the population for which MSHA is estimating benefits and decrease the estimated number of prevented cases.

¹⁶ Forced vital capacity (FVC) is the total volume of gas that can be exhaled with a forced expiration after a full inspiration; The vital capacity measured with a FVC may be less than that measured with a slower exhalation (West, 1992).