

VII. Significance of Risk

The proposed single sample and plan verification rules prevent respirable coal mine dust overexposures by identifying them and then requiring corrective actions. As discussed in the Health Effects Section, CWP is a progressive disease that develops after many years of cumulative exposure to respirable coal mine dust, which may include quartz, and is associated with material impairment of health and pre-mature death (see Health Effects Section). The joint promulgation of the proposed single sample and plan verification rules would significantly reduce the risk of development of CWP over an occupational lifetime. The best available data were used to conduct the QRA.

(A) Through the "Benzene decision," the U.S. Supreme Court provided further guidance on determining and interpreting the significance of risks.

It is the Agency's responsibility to determine, in the first instance, what it considered to be a "significant" risk. Some risks are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it. Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as 'unsafe' (448 U.S. at 655).

The industry recognizes the health significance of maintaining exposures at or below the applicable dust standard. For example, at the August 16, 2000 public hearing, the National Mining Association's representative Mr. Watzman, stated " * * * (MSHA,) we don't want to see any miner overexposed. Our objective has been and will always be to maintain dust levels below the applicable dust standard." The United Mine Workers of America's written comments echoed the

importance of reducing overexposures, "Miners" exposure to unhealthy levels of coal mine dust leads to the disabling and life shortening "black lung" disease [CWP]."

The best estimates of reduction in risk for all categories of CWP, for miners who live to age 73, after a 45-year occupational exposure to respirable coal mine dust were: 2.3 per 1,000 affected non-designated occupation miners; 19.6 per 1,000 affected roofbolter designated areas miners; and, 24.4 per thousand affected designated occupation miners. These estimates quantitatively demonstrate MSHA's policy determination that there would be a significant reduction in risk of CWP as a consequence of the promulgation of these proposed rules.

(B) There are many elements that compile a QRA. For each element of a QRA, there may be multiple assumptions (*e.g.*, values of variables and sources of data) that could be applied. Various assumptions will differ in the extent to which they are less or more likely to occur (*i.e.*, be representative). Assumptions may also have relative degrees of impact on the risk estimate, either increasing or decreasing it. To the extent that miners experience conditions that differ from the assumptions in the QRA, their risk of developing CWP will consequently be higher or lower. A "conservative" assumption in the QRA is one that results in a higher estimate of risk than a less "conservative" assumption would. Estimated benefits (*i.e.*, the number of prevented cases of the outcome of concern, *e.g.*, CWP) are greater under QRA assumptions that are "conservative" in this sense.²⁹

The discussion below identifies various elements of the QRA and how these choices may have affected the estimates in reduction of risk.

i. The quantitative risk estimates are contingent on the representativeness of the exposure data in describing the exposures experienced by miners on all shifts. Currently, both operator and MSHA samples³⁰, may be taken on

production shifts that may not reflect production levels on the majority of non-sampled shifts.

Factors, such as mine ventilation and water sprays, mediate the amount of airborne respirable dust. Higher production is correlated with increased quantities of airborne respirable coal mine dust (Webster, *et al.*, 1990; Haney, *et al.*, 1993; O'Green, *et al.*, 1994). Some earlier commenters, in these proceedings and before the Dust Advisory Committee, have asserted that production is reduced and/or dust controls are increased on sampled shifts.

The estimates of risk reductions for affected miners are based on averages across those MMUs exhibiting a pattern of recurrent overexposures. In the QRA, the agency assumed representative operating conditions on those shifts sampled and extrapolated the results to all production shifts, including those that were not sampled. If there is diminished production and increased engineering controls on sampled shifts compared to the majority of non-sampled shifts, then this would mean that MSHA is underestimating the reduction(s) in risk to be expected from these proposed rules. (This is further discussed in the Benefits sections of the PREA and PV preamble).

ii. The QRA applies the traditional coal miner work schedule of 8-hours per day, 5-days per week, 48-weeks per year. Many of today's miners work longer hours per day, month, and year than the traditional work schedule. These longer work hours increase miners' cumulative exposure to respirable coal mine dust beyond what MSHA assumed in its risk estimates. Similarly, shorter work hours would decrease cumulative exposure below the values assumed in the QRA.

iii. In their comments on the 2000 proposed rules, the National Mining Association (NMA) criticized MSHA's use of a 45-year occupational lifetime, stating "the work experience of the vast majority of miners is far less than 45 years." Irrespective of the specific duration of a working lifetime of an individual worker or cohort of workers, health standards are promulgated to protect all workers from adverse health outcomes due to occupational exposure for an occupational lifetime. Under the Mine Act standards are set to protect miners for up to a full working lifetime (101 (a)(6)(A) (30 U.S.C. 811(a)(6)(A)):

must be taken on a normal production shift (*i.e.*, a production shift during which the amount of material produced in a MMU is at least 50 percent of the average production reported for the last set of five valid samples) (30 CFR 70.100 (k)(1)).

previous proposed rule, where lower bounds on the risk reduction were calculated. The calculations in the previous proposed rule defined

$$\Delta' = P_Y - P_X,$$

$$\text{where } Y' = y/x \text{ and } X' = e^{a_0 + a_1 \times \text{age}}$$

The previous method results in lower values than those shown in Table VI-1. For example, for "CWP 1+" among affected DO miners at age 73, applying the previous method to 2001 operator and MSHA data would have resulted in a calculated risk reduction of 16.3 per thousand instead of the 24.4 per thousand presented in Table VI-1. MSHA believes the method used in the current proposed rule more accurately represents the reduction in risk that can be expected if all individual shift overexposures are eliminated.

²⁹ For example, in a hypothetical QRA there is a reduction in risk estimate for CWP of 2.4 per 1,000 affected miners, based on a relatively conservative assumption for a particular element (holding all other assumptions constant). A reduction in the risk estimate for CWP based on an equally likely although less conservative assumption is 1.0 per 1,000 affected miners, holding all other assumptions constant. Assuming that the population of affected miners is 20,000. The more conservative assumption would result in an estimated 48 (2.4/1,000 * 20,000) prevented cases of CWP compared to the less conservative assumption's 20 prevented cases of CWP.

³⁰ Valid MSHA samples require production to be at least 60 percent of the average production for the last 30 days. Valid operator bimonthly samples