

were all significant predictors of irregular opacities. Irregular opacities were most common among miners who were older than 30, had bronchitis, and smoked, but exposure to coal mine dust was still a significant factor. Collins *et al.* (1988) found that the small irregular opacities were statistically significantly associated with both dust exposure and age in U.K. coal miners, but did not find a significant relationship with smoking. The exposure-response relationship was less steep for small irregular opacities than for small rounded opacities (Collins *et al.*, 1988). Therefore, the use of combined opacities rather than rounded opacities only may actually dampen the exposure-response relationship for pneumoconiosis (*e.g.*, in Attfield and Seixas, 1995), which is in contrast to the Nicolich and Gamble comment that the inclusion of irregular opacities would over-estimate the risk of pneumoconiosis. Nonetheless, the use of combined opacities is supported by the fact that statistically significant exposure-response relationships have been observed for both types of small opacities (rounded and irregular) in coal miners, and both types have been associated with adverse health effects.

Miners with small rounded opacities on their chest x-rays were more likely to report symptoms of chronic bronchitis (cough and phlegm) than were miners without small opacities (category 0/0) (Rae *et al.*, 1971). In Collins *et al.* (1988), both small rounded and small irregular opacities were associated with symptoms of chronic cough and phlegm, and breathlessness, compared to miners with no opacities observable on chest x-ray. Small irregular opacities have been associated with impaired lung function (Amandus *et al.*, 1976; Cockcroft *et al.*, 1982b,c; Collins *et al.*, 1988). As Nicolich and Gamble state in their comments, the lung function impairment reported by Collins *et al.* (1988) was in addition to that attributable to dust exposure. However, Collins *et al.* (1988) found that the observed pattern of lung function abnormalities was distinctly different from the pattern observed among smokers. Specifically, the mean FEV1 and mean FVC were significantly lower among miners with small irregular opacities compared to those with no observable opacities (*i.e.*, chest x-ray category 0/0), and this is the pattern of lung function abnormality typically associated with dust exposure in coal miners (Collins *et al.*, 1988). In contrast, smokers generally had more severe

reductions in FEV1 than in FVC (resulting in a reduction in the FEV1/FVC ratio). The authors suggest that the irregular opacities in coal miners may represent damage to the lungs that causes airways obstruction at different lung locations than that caused by cigarette smoke. Irregular opacities in coal miners may have also been associated with emphysema (Cockcroft *et al.*, 1982 b, c).

Because simple CWP represents an early stage of a progressive disease, miners who have had a chest x-ray classified as ILO category 1 or greater are more likely than those with a clear x-ray (category 0) to progress to the more severe stages of the disease, including the complicated form, PMF (categories A, B, or C) (Cochrane 1962; McLintock *et al.* 1971; Hurley *et al.* 1987; Morfeld *et al.*, 1992). PMF has been associated with impaired lung function, disability, and early death (Rasmussen *et al.*, 1968; Parkes *et al.*, 1983; Miller and Jacobsen, 1985), and miners with PMF qualify as totally disabled due to pneumoconiosis under the Department of Labor's Standards for Determining Coal Miners' Total Disability or Death Due to Pneumoconiosis under the criteria set forth at (20 CFR 718.304(a)). Miners with simple CWP were also found to have an increased risk of dying from pneumoconiosis (as the underlying or a contributing cause on the death certificate), and this risk tended to increase with increasing radiographic category (Kuempel *et al.*, 1995). Nicolich and Gamble are incorrect in stating that an implication of that study is "no increased mortality associated with exposure". Instead, Kuempel *et al.* (1995) showed a statistically significant exposure-response relationship for cumulative exposure to respirable coal mine dust and pneumoconiosis mortality.

After due consideration of the questions posed by Nicolich and Gamble, we have concluded that the development of CWP, as detected on chest x-ray as rounded and/or irregular opacities, poses a significant health risk to miners. Miners who have developed simple CWP have a materially altered risk status, which is a medically and scientifically reasonable measure of material impairment. Miners who have a chest x-ray with small opacities (rounded and/or irregular) are also more likely to report respiratory symptoms and/or to have lung function decrements. The use of radiographic

evidence of pneumoconiosis (combined opacities), both by Attfield and Seixas (1995) and in MSHA's risk assessment, is appropriate for assessing the risk that coal miners will suffer material impairment of health or functional capacity as a result of their respirable dust exposures accumulated over a working lifetime.

Appendix VI.1 DO Overexposure Patterns

In 1998, MSHA attempted to enforce compliance on individual shifts. Therefore, to compare the 2001 pattern of excess exposures on individual shifts to that of previous years, MSHA examined the regular bimonthly DO sample data submitted by mine operators in the 10 years from 1990 through 1997 and 1999–2000. The same three parameters were considered as discussed above for 2001: (1) The percentage of MMUs exhibiting a pattern of recurrent overexposures, as indicated by at least two of the valid measurements being above the applicable dust standard in a given year; (2) for those and only those MMUs exhibiting recurrent overexposures, the overall percentage of production shifts on which the DO was overexposed, as estimated by the percentage of valid measurements above the applicable dust standard; and (3) for the MMUs identified as exhibiting recurrent overexposures, the mean excess above the applicable dust standard, as calculated for just those valid measurements that exceeded the applicable dust standard in a given year.

Although MSHA found minor differences between individual years, there was no statistically significant upward or downward trend in any of these three parameters over the 1990–1997 time period (see Table VI–2). Beginning in 1999, however, there was a significant and persistent decrease in the average excess above the applicable dust standard (Parameter #3) for MMUs exhibiting recurrent overexposures. MSHA attributes this decrease to two important changes in the Agency's inspection program, beginning near the end of 1998. These changes, which both resulted in increased MSHA personnel presence, were: (1) An increase in the frequency of MSHA dust sampling at underground coal mines; and (2) initiation of monthly spot inspections at mines that were experiencing difficulty in maintaining consistent compliance with the applicable dust standard.