differentially, and most significantly for the lowest exposure group.

On the other hand, if the initial period of followup is ignored then the risk for workers with high exposure may be underestimated. In a study of lung cancer in asbestos cement factory workers Finkelstein (84–240) estimated the relative risk for workers in three exposure groups, starting 20 years after onset of exposure. The highest exposure group had the lowest risk. If a higher exposure causes a shorter disease latency, then proportionately more cases in the highest exposure group would have occurred prior to the beginning of the followup period, i.e., during the first 20 years since onset of exposure, and would have been missed.

It is often stated that cases of asbestosis are rarely seen within 15-20 years of first exposure; however, Berry et al. (Ex. 84–20) have shown that signs associated with interstitial fibrosis are seen less than 10 years from first exposure and clearly within 10–14 years of first exposure. In addition, Dement et al. (Ex. 84–35) have shown an excess mortality due to other non-malignant respiratory diseases within 10–19 years after initial employment. Selikoff et al. (Ex. 84–189) have reported on asbestosis death rates in a cohort with the longest period of followup. In this study, the mortality rate began to increase approximately 13 years after first exposure. A decline in the death rate from asbestosis occurred 45 years from first exposure. The authors suggested that competing causes of death, in part due to smoking, may have accounted for this decline. It is not possible, however, to tell whether the incidence of asbestosis, i.e., the occurrence of new cases, would also have begun to decline 45 years after first exposure.

Berry et al. (Ex. 84–20) studied textile factory workers. Two cohorts were defined: Workers first employed between January 1, 1933 and December 31, 1950 who were still employed as of June 30, 1956; and workers employed after June 30, 1966 who had completed at least 10 years of service up to December 31, 1972. The latter cohort is important because measures of dust or fiber levels were available beginning in 1951 and the exposure estimates for individuals in the study are likely to be more valid after that time. In addition, proportionately more of the latter cohort was exposed to a lower mean dust level than the former cohort. Although these dust levels are not equivalent to or below the level stipulated by the current PEL, they are closer to it than the mean fiber or dust levels incurred by the earlier cohort. The maximum number of years of followup, 24, was considerably less than the latency for late-onset cases of asbestosis. Among those first employed after 1950, Berry and his colleagues estimated a 1 percent prevalence of crepitations, "possible asbestosis," and "certified asbestosis" at 37, 46, and 63 f/cc-years, respectively, suggesting that an excess risk exists at levels below 100 f/cc-years. Since the average number of years of followup in this study was only 16 years, new cases will have accrued in the subsequent period. It is also noteworthy that when men who had left the factory prior to 1966 were included in the cohort in an effort to reduce the selection bias associated with the risk of asbestosis, the prevalence of signs associated with the disease increased. However, even in the more complete cohort studied, selection factors remained. The overall effect of these methodological problems is that the measures of prevalence in this study are underestimates.

Finkelstein (Ex. 84–44) studied the risk of asbestosis in 157 Ontario cement production workers first exposed to asbestos between 1948 and 1960 and employed for at least 15 years. Because of the nature of the cement production operation, some workers employed at this plant may not have been exposed to asbestos. Workers were followed up until death or up to October 1, 1980. The number of years since first exposure ranged from 18–33 years, with a median of 25 years, Cases were ascertained primarily through annual examinations or by means of death certificates. The author noted that "83 percent of the production workers received an examination for asbestosis within the 3 years prior to the cutoff date or within 3 years of their death" (Ex. 84–44). It is uncertain how the production workers who were lost to followup (17 percent) were handled in this analysis; OSHA assumes that only those person-years of observation up to the time of the last followup examination were included.

The Ontario criteria for certifying asbestosis, which results in an award of disability pensions, are not strictly defined but involve considerations of such factors as history of occupational exposure, dyspnea, crepitations, clubbing of fingers, radiographic signs of pulmonary fibrosis, and abnormal lung function. In general, it can be assumed that, despite the absence of definitive criteria, the certified asbestosis cases included in this study occurred at an advanced stage of the disease, in contrast to other studies that included possible cases of asbestosis in the analysis.

Only two cases in the Finkelstein study were certified before the 20th year after first exposure. A majority of the asbestosis cases were certified between 22 and 28 years of exposure; however, cases continued to accrue in the followup period, and there is no clear evidence that the incidence of asbestosis declined after more than 28 years since first exposure. Finkelstein calculated incidence as the number of new cases of certified asbestosis per 100 person-years at risk, i.e., the rate at which new cases of asbestosis develop in a given period of time, which results in a direct measure of the risk of developing of disease. The Finkelstein study found the incidence of asbestosis to be 0.5, 3.4, and 6.5 per 100 person-years of exposure for workers receiving 0–49, 50–99, and 100–149 f/cc-years of exposure, respectively, showing a positive dose-response relationship.

Using a life table method, Finkelstein also calculated the cumulative probability of developing a certified case of asbestosis after 32 years of followup and observed that men in the 0–49, 50–99, and 100–149 f/cc-years categories and 10 percent, 55 percent, and 70 percent probabilities, respectively. Although these estimates are somewhat uncertain because of the small number of subjects in each category, especially in the lowest exposure category, the data do indicate that, even for exposures below 50 f/cc-years, there is an excess risk of asbestosis morbidity. In addition, as noted above, there is no evidence to suggest that the risk of asbestosis declines after 32 years from first exposure.

Finkelstein (Ex. 84–044) notes that a selection bias may have been introduced by excluding workers with fewer than 15 years of employment from the cohort, resulting in an overestimation of risk at lower exposure levels. Typically, one assumes that the morbidity and mortality of the excluded group are the same as those of the group included in the study. Finkelstein suggests that if the excluded individuals had been considered, lower estimates of risk might have been obtained for the lower exposure category; however, this could only have occurred if the risk of asbestosis for the same cumulative exposure level among those excluded was less than that of the group studied. OSHA believes that it is not possible to determine the effect of such a selective exclusion.

Finkelstein estimated the cumulative exposure that would result in a 1 percent probability of developing asbestosis by extrapolating from his