excess disease risk has been observed at cumulative exposures at or below those permitted by the existing OSHA 8-hour permissible exposure limit of 2 f/cc. In addition, OSHA has made risk estimates of the excess mortality from lung cancer, mesothelioma, gastrointestinal cancer, and the incidence of asbestosis using mathematical models that describe the data observed in epidemiologic studies conducted in various industrial populations.

In many cases, the elevated risks seen in worker populations reflect past exposures that were higher than those permitted today. OSHA's quantitative risk assessment entails using the directly observed risks from these past exposures to estimate risk at lower exposure levels. OSHA believes this is a scientifically appropriate and valid procedure. In some instances, OSHA estimated risks using studies which actually observed risks at or below cumulative exposures permitted by the existing standard. The range of studies used by OSHA covers many different work situations and exposure levels. Where possible, OSHA has quantified the ranges of uncertainties in the estimates. These numerical estimates, as well as those risks observed at low exposures, were evaluated to determine the significance of the risk and to determine whether the new standards will lead to a substantial reduction in risk.

OSHA's critical evaluation of all relevant animal and epidemiological studies resulted in the selection of eight studies that contain good data for the calculation of the dose-response relationship for lung cancer for this final rule [Selikoff et al., 1979, Ex. 84-90; Seidman, 1984, Ex. 261-A; Henderson and Enterline, 1979, Ex. 84-48; Weill et al., 1979, Ex. 84-206; Finkelstein, 1983, Ex. 84-240; Peto, 1980, Ex. 84-169; Dement et al., 1982, Ex. 84-35; Berry and Newhouse, 1983, Ex. 84-21] and six for mesothelioma [Selikoff et al., 1979, Ex. 84-90; Seidman et al., 1984, Ex 261-A; Finkelstein, 1983, Ex. 84-240; Peto, 1980, Ex. 84-169; Weill et al., 1979, Ex. 84-206; and Dement et al., 1982, Ex. 84-35]. In general, studies of human cohorts in the workplace should provide a better basis for quantitative risk assessment than studies of experimental animals because of the similarities in the populations at risk and the populations from which the risk estimates are derived. As Dr. Hans Weill, testifying on behalf of OSHA, noted:

> The greatest public confidence in decision-making to reduce an environmental or occupational risk results when the data used are the product of well designed and conducted studies of relevant human populations. . . . When an occupational hazard has been identified, useful epidemiologic study results will determine the quantitative relationship between the dose of exposure to the causative agent and the risk of the adverse health response in the exposed population. The product is the exposure-response relationship, which together with a valid estimate of the size of the exposed population, the extent of that exposure and accurate indicators of the disease outcome, give characterization of the risk [Ex. 99, p. 8].

The potency coefficients for lung cancer and mesothelioma (K_L and K_M, respectively) used to define the dose-response relationship were calculated for each study so that cancer mortality was estimated for various exposure levels and exposure durations. A number of well-conducted and high quality epidemiologic studies were available that contained sufficient information on which to base a quantitative risk assessment. Some of these studies did not contain exposure data, but could be coupled with exposure information from other sources in order to obtain an estimate of K_L and K_M.

OSHA chose not to use animal studies to predict quantitative estimates of risk from asbestos exposure because of the many high quality human studies available that were conducted in actual workplace situations. As is often the case with animal studies, laboratory conditions may not precisely parallel actual worksite exposures. In the case of asbestos, for example, is it not clear in all instances whether laboratory animals have been exposed to fiber size distributions similar to those found in workplaces. In addition, asbestos appears to multiply the underlying lung cancer risk of smoking and nonsmoking workers; laboratory animals generally do not have any underlying risk of lung cancer. Instead of relying on the animal studies to estimate risk, OSHA has supplemented the human data with results from animal studies when evaluating the health information and determining the significance of the risk; OSHA believes that the animal studies can provide valuable qualitative information on asbestos-related disease. For example, the animal studies show that all commercial asbestos types can cause cancer and pulmonary fibrosis. Animal studies also indicate that longer, thinner fibers may have greater carcinogenic potency than short, coarse fibers.

The paragraphs below provide a synopsis of OSHA's quantitative risk estimates derived from mathematical models and a discussion of the comments and testimony submitted regarding the quantitative assessment of risk for asbestos. OSHA's proposed estimates of risk may be found in Ex. 84-392, the emergency temporary standard ["the November proposal", 48 FR 51086], and in the April proposal [49 FR 14116].

I. Estimates of Risk for Lung Cancer

A. *The Model.* As discussed in the November proposal, OSHA chose a linear model to describe the relationship between the excess relative risk of lung cancer and asbestos exposure (dose). Relative risk is defined as the ratio of the mortality rate of exposed persons to the mortality rate of equivalent non-exposed persons. Relative risk is frequently approximated by the standardized mortality ratio (SMR), which is the observed number of deaths in the exposed population divided by the number of deaths that would be expected in the exposed population. The number of expected deaths is usually derived from the specific age, sex, and calendar year mortality rates in the comparison population.

Asbestos exposure is generally measured in terms of total or cumulative dose. Total dose, also referred to as cumulative exposure or cumulative dose, is a measure of the amount of asbestos inhaled; it is the product of the duration of exposure (in years [y]) and the intensity of exposure (which is workplace air concentration in millions of particles per cubic foot [mppcf] or fibers per cubic centimeter [f/cc]). Under this definition of exposure, a person exposed to airborne asbestos at 2 f/cc for 20 years [40 fiber-years/cc [f-y/cc]) has the same total dose as a person who is exposed to asbestos at 4 f/cc for 10 years (40 f-y/cc).

The relative risk model used by OSHA in assessing the risk of developing lung cancer from asbestos exposure is described by the following equation:

$$R_L = R_E[1 + (K_L \times f \times d_{(t-10)})] \qquad \text{(Eq. 1)}$$

where R_L is the lung cancer mortality resulting from the asbestos exposure, R_E is the expected mortality in the absence of exposure, f is the intensity of exposure in fibers/cc, d is the duration of exposure in years, t is the time from the onset of asbestos exposure in years (minus 10 years to allow for a minimum latent period) and K_L is the proportionality constant that is a measure of the carcinogenic potency of the asbestos exposure (slope of the dose-response curve).

The equation can be rewritten as