

oncology. Only 9 percent of lung cancer patients survive for 5 or more years after diagnosis (American Cancer Society, Ex. 84-180). Asbestos exposure acts synergistically with cigarette smoking to multiply the risk of developing lung cancer.

Many studies have also shown conclusively that mesothelioma is associated with asbestos exposure. In some asbestos-exposed occupational groups, 10-18 percent of deaths have been attributable to malignant mesotheliomas. Malignant mesotheliomas of the pleura and peritoneum are extremely rare in persons not exposed to asbestos. Generally, a latency period of at least 25-30 years is required before mesotheliomas are observed in an occupational cohort, although some victims of mesothelioma have had latency periods exceeding 40 years (Craighead et al., Ex. 84-033). This form of cancer is rarely curable and is usually fatal within a year after diagnosis.

Some epidemiologic studies of asbestos-exposed persons have shown increases in esophageal, stomach, colorectal, kidney, laryngeal, pharyngeal, and buccal cavity cancers. Although the increased risk of incurring cancers at these sites is not as great as the increased risk of lung cancer and mesothelioma, the increase is of considerable importance because of the high background rates; and therefore the large number of victims, associated with some of these tumors in the general population. For example, a 50 percent increase in a common cancer such as colo-rectal cancer results in many more deaths than a 50 percent increase in a rare cancer.

Asbestosis is pulmonary fibrosis caused by the accumulation of asbestos fibers in the lungs. The adverse effects of asbestosis range from shortness of breath during exertion to cyanosis, effusions of serous fluid, respiratory failure, cardiac decompensation, and death. Asbestosis is often a progressive disease, even in the absence of continued exposure. The symptoms of the disease are shortness of breath, cough, fatigue, and vague feelings of sickness. When the fibrosis worsens, shortness of breath occurs even at rest. One clinical feature of early asbestosis as well as other lung diseases is end-inspiratory crackles (rales). Diagnosis of asbestosis is based on the presence of characteristic radiologic changes, symptoms, rales, other clinical features of fibrosing lung disease, and a history of exposure to asbestos.

Asbestos exposure can cause pleural and/or other pulmonary disease. Pleural plaques are one of the markers of

asbestos exposure and may develop within 10-20 years after the initial exposure. Plaques are opaque patches visible on chest X rays that consist of dense strands of collagen (connective tissue protein) lined by mesothelial cells. All commercially used types of asbestos induce plaques. Plaques can occur without fibrosis and do not seem to reflect the severity of pulmonary parenchymal disease. Pleural calcification is also commonly found in persons who have been exposed to asbestos (Craighead et al., Ex. 84-033).

The adverse effects of exposure to asbestos have been observed in workers involved in the manufacture of asbestos cement pipes and shingles (Enterline et al., Exs. 84-044, 84-122; Weill et al., Ex. 84-123; Finkelstein, Exs. 84-208, 84-240), asbestos mining and milling (Wagner et al., Ex. 2-21; Liddell et al., Ex. 84-059; McDonald et al., Ex. 84-085; Hobbs et al., Ex. 84-072; Nicholson et al., Ex. 84-088; Rubino et al., Ex. 84-086), asbestos textile manufacturing (Doll, Ex. 84-040; Peto et al., Ex. 84-169; Berry et al., Ex. 84-020; Dement et al., Ex. 84-037), insulation work (Selikoff et al., Ex. 84-109), shipbuilding (Selikoff et al., Ex. 84-091; Blot et al., Ex. 84-109; Tagnon et al., Ex. 84-182), talc mining and milling (Brown et al., Ex. 84-29) and in a variety of asbestos products manufacturing industries (Jones et al., Ex. 84-138; Henderson and Enterline, Ex. 84-048; McDonald and McDonald, Ex. 84-154; Seidman et al., Exs. 84-087, 261-A; Robinson et al., Ex. 84-082; Acheson et al., Ex. 84-103).

The conclusions just expressed are widely accepted both in the U.S. and abroad. The following agencies and organizations have reviewed the health data for asbestos: International Agency for Research on Cancer (IARC) (Ex. 84-321), Organization for Economic Cooperation and Development (OECD) (Ex. 84-337), NIOSH (Exs. 84-338 and 84-320), Advisory Committee of the Health and Safety Commission of the United Kingdom (Ex. 84-216), the Chronic Hazard Advisory Panel on Asbestos (CHAP) (Ex. 84-256), and the U.S. Environmental Protection Agency (Ex. 84-180). All of these groups have concluded that there is a causal relationship between asbestos exposure and the development of cancer and non-malignant respiratory disease. NIOSH recommended reducing the permissible exposure limit (PEL) for asbestos to 0.1 fiber per cubic centimeter (0.1 f/cc) in 1976. In 1980, a joint NIOSH-OSHA Asbestos Work Group stated that there was no level of exposure to asbestos below which clinical effects did not occur and recommended a PEL of 0.1 fiber per cubic centimeter (0.1 f/cc),

based on the limitations of current technologies for measuring airborne concentrations of asbestos. The 1979 report of the Advisory Committee of the Health and Safety Commission of the United Kingdom (hereafter referred to as the U.K. Committee) led to the reduction of the British standard for asbestos to 1 f/cc for chrysotile, 0.5 f/cc for amosite, and 0.2 f/cc for crocidolite.

The following sections describe the record evidence that demonstrates the causal relationship between asbestos exposure and increased risks of incurring lung cancer, mesothelioma, gastrointestinal cancer, and non-malignant respiratory diseases such as asbestosis. In addition, evidence is presented pertaining to the relationship between exposure to various types and sizes of asbestos fiber and the risks of asbestos-related disease; evidence concerning the synergistic effect of smoking and asbestos exposure on the risks of developing lung cancer is also presented. Most of the health effects evidence was previously presented in OSHA's November proposal (48 FR 51099-51122). The current publication summarizes the evidence contained in that Federal Register notice and presents in detail new evidence obtained during and after the public hearing.

B. Epidemiologic Evidence of Risk of Lung Cancer and Mesothelioma Mortality

1. Epidemiologic Studies

The epidemiologic studies of greatest interest are those that show a correlation between the intensity and duration of asbestos exposure and an observed excess in lung cancer and mesothelioma. In the November proposal, OSHA reviewed several studies that provided information on exposure level and incidence of lung cancer (Exs. 84-21; 84-38; 84-37; 84-48; 84-87; 84-90; 84-208; 84-240) and mesothelioma (Exs. 84-30; 84-87; 84-90; 84-208; 84-240). These studies, which provide the basis for OSHA's Quantitative Risk Assessment are briefly reviewed here, along with a number of more recent investigations (Exs. 182-C; 163-E; 168-A; 168-B; 261-A) that were submitted to the record after publication of the November proposal.

Seidman et al. (Ex. 84-087) studied cause specific mortality among 820 amosite insulation manufacturing workers employed sometime during 1941-1945 at the Patterson insulation facility, which was known to have a deficient ventilation system. Estimates of asbestos exposure at this facility