Supporting Data for Asbestos ETS

As provided in 29 CFR 1953.22, the 24 States with their own OSHA-approved occupational safety and health plans are expected to adopt a comparable standard within 30 days of this publication date. These States are: Alaska, Arizona, California, Connecticut (for State and local government employees only), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming.

Also, in response to the emergency conditions faced by exposed workers, OSHA is stepping up its enforcement activities in targeting workplaces where asbestos is handled.

The temporary provisions that are being added to the existing asbestos standard prescribes the major components of an occupational safety and health standard. In general, most of the current requirements remain unaffected by the emergency temporary standard. However, compliance with some requirements will be triggered by the new exposure limit of 0.5 f/cc instead of the former PEL of 2 f/cc. For example, requirements such as change rooms remain unaffected by the ETS and the trigger level for change rooms remains the former PEL of 2 f/cc (§ 1910.1001(d)(4)). However, the ETS requires that where concentrations may exceed the new PEL, the employer must post signs indicating such locations (§ 1910.1001(k)(6)).

OSHA based its decisions concerning appropriate provisions for the ETS on its determinations of the kind and degree of protective action needed to protect against a grave danger and the feasibility of instituting these provisions during the period of the ETS.

Under section 6(b) of the Act, OSHA will shortly schedule an informal rulemaking hearing on the proposed permanent changes to the standard. OSHA will also propose other revisions to the asbestos standard that will be explained in the separate notice of proposed rulemaking. Application of certain provisions of the asbestos standard to the construction industry will be raised at that time. OSHA anticipates that this notice will be published shortly. OSHA is now accepting written comments on those issues raised in the ETS which are relevant to revising the permanent rule. The Secretary must promulgate a section 6(b) standard no later than six months after publication of the emergency standard.

II. Legal Authority and Background

A. Legal Authority

Section 6(c) of the Act provides for immediately effective emergency temporary standards in certain circumstances. The Secretary has the authority to issue such a standard, without rulemaking, "if he determines (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from such danger." 29 U.S.C. 655(c)(1). Thus, the danger must be "from" worker exposure and it must be "grave," not merely significant and the regulation must be "necessary" to address "such danger," not merely reasonably necessary or appropriate to provide safe employment. In addition, as in section 6(b) permanent standards, OSHA may impose requirements in the emergency standard only to the extent that they are "feasible" within the meaning of section 6(b)(5) of the Act.

The Fifth Circuit has emphasized the importance of the severity of health effects in OSHA's consideration of whether an ETS is appropriate:

> "* * * the danger of incurable, permanent, or fatal consequences to workers, as opposed to easily curable and fleeting effects on their health, becomes important in the consideration of the necessity for emergency measures to meet a grave danger." *Florida Peach Growers Association, Inc. v. United States Department of Labor*, 4898 F.2d. 132 (CA5).

OSHA also has interpreted relevant judicial decisions to require that its evaluation of the gravity of the danger and the necessity for emergency action must be made in the context of actual workplace conditions.

B. Background

1. *Events Leading to the ETS.* In June, 1983, OSHA received a petition for an ETS from the International Association of Machinists and Aerospace Workers (Exs. 84–244). Subsequently letters supporting this petition were received from 16 other unions (Ex. 84–284 to 84–294, 84–387 to 84–391). The petition requested an ETS to reduce the PEL to 0.1 f/cc, to modify some existing work practice requirements, and to require other protective provisions regardless of exposure level. The main reasons set forth in the petition and supporting letters are that continued exposure under current workplace conditions constitutes a grave danger and that delaying remedial action until a permanent standard is promulgated would cost large numbers of currently-exposed workers their lives. OSHA shares the genuine concern expressed by the petition and letters from unions representing thousands of employees who are directly faced with the threat of asbestos-related disease from continued exposure. And OSHA concludes that failure to issue this ETS may cost a number of exposed workers their lives.

In August 1983, OSHA completed a comprehensive risk assessment based on numerous human studies which estimated the number of excess deaths from the three major asbestos-related cancers, i.e., lung cancer, mesothelioma and gastrointestinal cancer, at the current permissible exposure level of 2 f/cc and at various reduced exposure levels. OSHA placed this document, "Quantitative Risk Assessment for Asbestos-Related Cancers", in the Asbestos docket in August 1983 (Ex. 84–349). OSHA subsequently revised this document (See Ex. 84–392).

2. *History of the Asbestos Standard.* OSHA has regulated asbestos since 1971. A 12 f/cc limit for asbestos was included in the initial promulgation of OSHA standards pursuant to section 6(a) of the Act, on May 29, 1971 (36 FR 10466). In response to a petition by the Industrial Union Department of the AFL–CIO, OSHA issued an ETS on asbestos on December 7, 1971, which established a PEL of 5 f/cc on a time-weighted average basis and peak exposures of 10 f/cc.

The current standard, promulgated in June 1972, first established an 8-hour time-weighted average PEL of 5 f/cc and a ceiling limit of 10 f/cc. The limits were intended primarily to protect employees against asbestosis, and it was hoped that they would provide some incidental degree of protection against cancer. Effective July 1976, the TWA limit was reduced by the standard to 2 f/cc. This limit has remained in effect since that time. The standard also includes provisions covering methods of compliance, monitoring, medical surveillance and housekeeping.

Court review of this standard upheld all major provisions, but remanded two issues for OSHA's reconsideration. *IUD v. Hodgson*, 499 F. 2d 467 (CADC 1974). These issues were whether the July 1976 date for the 2 f/cc standard should be accelerated for some industries and the adequacy of the 3 year retention period for exposure monitoring records. Subsequently, OSHA increased this retention period to 20 years (41 FR 11504) and the acceleration issue became moot.

After reviewing the then available scientific data, in October 1975 OSHA published a notice of proposed

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rulemaking to revise the asbestos standard because OSHA believed that "sufficient medical and scientific evidence had been accumulated to warrant the designation of asbestos as a human carcinogen" and that advances in monitoring and protective technology made reexamination of the standard "desirable." This proposal would have reduced the time-weighted average to 0.5 f/cc and imposed a ceiling limit of 5 f/cc for 15 minutes (40 FR 47652).

The basis for the 1975 proposal's reduced permissible level of 0.5 f/cc was OSHA's then current policy for carcinogens that no safe threshold level was demonstrable and, therefore, the Act required OSHA to set the PEL as low as technologically and economically feasible. This policy was rejected by the Supreme Court in the benzene decision (*IUD vs. API*, 448 U.S. 601 (1980)). OSHA limited the proposed revisions in the 1975 notice to all industries except construction. No hearing was scheduled on the 1975 proposal. Also, although OSHA announced its intention to develop a separate proposed revision applicable to the construction industry, no such proposal has been published to date.

OSHA is basing its present decision to issue an ETS, and to propose revisions to the permanent standard covering all employees, on information and analyses which postdate the 1975 proposal. Therefore, this ETS marks a new regulatory initiative, related to, but not part of the 1975 proceeding. On May 24, 1983, OSHA consulted the Construction Advisory Committee for Occupational Safety and Health (CACOSH) concerning applicability of a new asbestos standard for the construction industry. CACOSH endorsed OSHA's position that changes in the PEL made for general industry should also apply to the construction industry. OSHA is also including the comments and data received in response to the 1975 notice in the record of this proceeding, with the understanding that some commenters may have changed their positions based on intervening scientific developments and policy shifts.

In the decision to issue an ETS, the Agency has reviewed this regulatory history of asbestos. However, the Agency bases the decision to issue an ETS on the actual emergency conditions which now confront exposed workers, on epidemiologic studies that provide data to make numerical estimates of risks and on interpretations of these studies using quantitative risk analysis.

3. *The Rulemaking to Revise the Permanent Standard.* The 6(b) rulemaking initiated by this proposal is intended to be limited to the revisions made by the ETS and the additional proposed amendments raised in the notice of proposed rulemaking to be published soon. The major subjects of the 6(b) rulemaking will be: reducing the permissible exposure limit, revising the definitions of asbestos and asbestos fibers, reassessing the methods of compliance to achieve such limits, revising the provisions regarding respirator selection, revising the sampling and analytical method to improve reliability, and adding a training requirement. OSHA will also raise issues regarding the application of the permanent standard to the construction industry. As previously stated, OSHA will soon publish a separate notice of proposed rulemaking to further explain these issues.

III. OSHA's Rationale for the ETS

OSHA has determined that prevailing conditions involving worker exposure to airborne asbestos dust justify the promulgation of an emergency temporary standard. OSHA estimates that approximately 375,000 workers are exposed to asbestos at various levels (Table 1), ranging from a high value of 20 f/cc to below 0.5 f/cc. OSHA has estimated that under current exposure conditions asbestos-exposed workers face an extraordinarily high risk of contracting asbestos-related cancer whether the risk is computed over a working lifetime of exposure or for exposure periods as short as 6 months. The average excess cancer risks for all workers exposed above 0.5 f/cc using available exposure data and relying on the risk assessment are estimated as approximately 196 excess cancer deaths per 1000 workers for 45 years of exposure, 139 deaths per 1000 workers for 20 years, 10 per 1000 workers for 1 year, and 6 per 1000 workers for 6 months of exposure.

OSHA believes that risks of these magnitudes, taking into account all relevant considerations such as total numbers of workers at risk and quality of supporting data, constitute an emergency situation which requires immediate response by the agency.

The Act states that when certain statutory criteria are met, OSHA is authorized to respond to an emergency situation by issuing an ETS. The two-pronged statutory test for an ETS is that (1) employees must be exposed to a grave danger from exposure to substances or agents determined to be toxic or physicially harmful, and that (2) an emergency standard is necessary to protect employees from such dangers.

After evaluating all the evidence available to the agency concerning the severity and magnitude of the risk of asbestos-related disease to the current asbestos-exposed working population, comparing these risks to other occupational risks, applying relevant policy considerations, and reviewing all relevant judicial decisions for guidance, the agency has determined that both prongs of the statutory test are met and that an ETS should be promulgated.

For purposes of clarity, the discussion is divided into two parts, "Grave Danger" and "The Need for an ETS." OSHA believes, however, that the factors which indicate that a substance constitutes a grave danger are related to and overlap those which determine that an ETS is necessary.

A. Grave Danger

OSHA has determined that the risk to workers from exposures to asbestos at conditions that exist in the workplace pose a grave danger of death from cancer and of severe disability from the lung disease, asbestosis. In making a "grave danger" determination, the severity of the disease produced by exposure to the regulated substance and the magnitude of the predicted risks of disease must be considered. In addition, the Supreme Court has suggested that a determination of "grave danger" indicates a situation where the risk is more than "significant" (*IUD* v. *API*, *supra* n. 45).

OSHA has applied that analytic approach endorsed by the Supreme Court for "significant risk" determinations in evaluating the gravity of the danger faced by asbestos-exposed workers. The Supreme Court gave some general guidance as to the process to be followed. It recognized that while the Agency must support its finding that a certain level of risk exists with substantial evidence it also recognized that its determination that a particular level of risk is "significant" will be based largely on policy considerations (*IUD* v. *API*, 448 U.S. 655, 656, n. 62).

OSHA believes, therefore, that its determinations regarding the magnitude of the risk faced by employees should, to the extent possible, rely on quantitative expressions of that risk, utilizing the best available data.

The Court stated that the significant risk determination required by the OSH Act is "not a mathematical straitjacket," and "OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty. * * * A reviewing court [is] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge [and that] * * * the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection" [488 US at 655, 656].

In the case of asbestos, the data available are of unusual breadth and high quality. However, because risk assessment itself involves many uncertainties, OSHA made certain assumptions in its analysis and evaluation of these data. In assessing the risk for asbestos-exposed workers, OSHA has attempted to use realistic assumptions, although the court stated that the Agency was free to use "conservative assumptions" in interpreting data. OSHA, in many cases, has indicated where different assumptions may produce different results. In addition OSHA cautions that because the risk figures finally derived are the products of a process which, as the Supreme Court acknowledged, is "on the frontiers of science," they should be viewed as approximations of the degree of risk faced by asbestos-exposed workers and not as precise fixed predictions of the number of workers who will actually develop disease.

OSHA has evaluated the kinds of dangers presented by asbestos exposure, the quantification of those dangers under present asbestos exposure conditions, the quality of the data on which risk estimates are based, a comparison of asbestos risks to other occupational risks, and relevant policy and legal considerations in concluding that workers are exposed to a grave danger from asbestos.

1. *Nature of the Diseases.* As stated above, the nature of the disease associated with exposure to a toxic substance is one of the most important elements OSHA evaluates in determining whether a grave danger exists. This factor was discussed in *Florida Peach Growers Association, Inc. v United States Department of Labor, supra.* The court, in overruling OSHA's organophosphate pesticide ETS, observed:

> We reject any suggestion that deaths must occur before health and safety standards may be adopted. Nevertheless, *the danger of incurable, permanent, or fatal consequences to workers, as opposed to easily curable and fleeting effects on their health, becomes important in the consideration of the necessity for emergency measures to meet a grave danger.* 489 F 2nd at 132 (emphasis added)

OSHA is aware of no instances in which exposure to a toxic substance has more clearly demonstrated detrimental health effects on humans than has asbestos exposure. The diseases caused by asbestos exposures are in large part life-threatening or disabling. Among these diseases are lung cancer, cancer of the mesothelial lining of the pleura and peritoneum, and asbestosis. In addition, workers exposed to asbestos are at increased risk of gastrointestinal cancer, as shown by epidemiologic studies. Although colo-rectal cancer may be curable if detected in an early stage, other gastrointestinal cancers are usually fatal. OSHA also believes that asbestos might induce cancers at other sites, which are also often fatal.

Of these, lung cancer constitutes the greatest health risk for American asbestos workers and has accounted for more than half of excess mortality in some occupational cohorts. About 90% of lung cancer patients die within 5 years of diagnosis. Mesothelioma is an incurable cancer which is usually fatal within a year after diagnosis. It is epidemiologically linked to asbestos exposure, and occurs very rarely, if at all, in persons never exposed to asbestos. Asbestosis, a type of pulmonary fibrosis, is usually non-reversible, its advanced stages are disabling, and can be fatal. OSHA concludes that all these diseases are very serious, and that the excess mortality from such severe diseases must be considered an important factor for making a grave danger determination.

2. *Degree of Risk of Developing Dangerous Disease.* OSHA based its calculations of extent of risk faced by workers under current exposure conditions primarily on the results of a quantitative analysis which derived numerical estimates of cancer risk at various cumulative exposures corresponding to levels at which workers are exposed (Ex. 84-392).

Although 2 f/cc is the current PEL for asbestos exposure, actual exposure conditions vary widely, mostly by industry segment. As explained later in this document and as set forth in Table 1, average ambient exposure levels in various industries include high exposure levels such as 20 f/cc in drywall removal, renovation and demolition; 5 f/cc in shipbuilding and repair; mid-range exposure levels such as 2 f/cc in secondary fabricating of cement sheet, packing and gaskets and paper products and rebuilding and refacing brakes; 1.5 f/cc for dry processing of textiles; and lower exposure levels such as 0.5 f/cc and 0.2 f/cc in the manufacture of floor tile.

Because OSHA is required to consider the actual danger faced by workers in assessing whether exposure to a substance presents a "grave danger", OSHA looked at the risk of developing disease not only at the 2 f/cc permissible level but at all exposure levels which workers currently face. Most of the results of these calculations for cancer are presented in Table 11 in the risk assessment section of this document.

The table sets forth predicted excess lifetime cancer risks for exposures of one year, 20 years and 45 years. Risks for exposures of 6 months are closely approximated by one-half the risks for exposures of one year. Although average exposures in demolition and renovation are estimated at 20 f/cc, the table presents risks only for selected exposure levels up to 10 f/cc.

These calculations show that the risks of asbestos-related disease are alarmingly high at current occupational exposure levels. For example, an estimated total cancer risk of 265 excess deaths per 1000 workers exists for workers exposed for a 45-year lifetime at 10 f/cc, a level which currently exists on some construction sites. At 5 f/cc, the exposure levels which are considered average in shipbuilding and repair, the risk of developing asbestos-related cancer for a 45-year exposure period is 149 excess deaths per 1000 workers. At the current permissible level of 2 f/cc which also represents actual exposure levels in such industries as secondary fabricating of cement sheet, packing gaskets and paper products and rebuilding and refacing brakes, risk is estimated as 64 excess cancer deaths per 1000 workers for a 45-year exposure period.

These risks remain very high when the period of exposure for which calculations are done is shortened to 20 years, which OSHA believes is another appropriate point for examination. The period of 20 years is the approximate midpoint between 1 year and 45 years of exposure; also many workers receive 20 years of exposure. Counterpart risk calculations using a 20-year exposure period are: for workers exposed to 10 f/cc, 140 excess cancer deaths per 1000 workers; for exposures to 5 f/cc, 105 excess cancer deaths per 1000 workers and for exposures to 2 f/cc, 44 excess cancer deaths per 1000 workers.

OSHA also estimated risks of developing cancer for a one year period of exposure at various levels to which employees are exposed. The counterpart risks for exposures to 10 f/cc for one year are: 15 excess cancer deaths per 1000 workers; to 5 f/cc, 7 excess cancer deaths per 1000 workers and to 2 f/cc, 3 excess cancer deaths per 1000 workers.

Even at current workplace exposure levels which are less than the current PEL, extraordinarily high risks of disease exist. At 0.5 f/cc, 17 excess cancer deaths per 1000 workers are predicted for a 45-year lifetime exposure, and 11 excess cancer deaths per 1000 workers for a 20-year exp--ure period.

OSHA notes that the above calculations are for cancer risk only. In addition, asbestos-exposed workers face a high risk of developing asbestosis, a disabling and often fatal disease. Predictions concerning the estimated magnitude of the asbestosis risk have been performed by OSHA and are discussed in the risk assessment section of this document. Accordingly, OSHA estimates that at 2 f/cc, 50 workers per 1000 exposed to asbestos for 45 years will develop disabling asbestosis. At 0.5 f/cc for 45 years, it is estimated that 12 workers per 1000 will develop disabling asbestosis. Asbestosis risks can also be estimated for exposures for durations shorter than 45 years. For example, the risk of disabling asbestosis from exposure to 1.0 f/cc for 22.5 years is 12 cases per 1000 workers. OSHA's estimates of the magnitude of the asbestosis risk are based on sound data from good epidemiological studies. OSHA believes, however, that the confidence which can be placed in predictions of asbestosis risk is not as great as for the predictions of cancer risk. This is because the cancer risk estimates are based on a larger and more varied data base and are derived from dose-extrapolation models that are better established. Because OSHA has determined that the risks for cancer alone indicate a grave danger, the additional risks of developing asbestosis are not necessary to justify this ETS. However, OSHA has considered that the additional and independent risk of developing asbestosis increases the danger faced by exposed workers and underscores the gravity of the health threats to employees posed by asbestos.

3. *Quality of Data on Which Risk Estimates are Based.* The underlying data upon which the quantitative risk assessments for asbestos are based are high quality epidemiologic studies, conducted in occupational environments. OSHA emphasizes that the data bases for asbestos are of unusual quality and size. Unlike most potential occupational carcinogens, asbestos has been studied often and thoroughly for evaluation of its effects on occupational populations.

In deriving these quantitative estimates for cancer risk, OSHA utilized eleven studies for the calculation of the lung cancer risk, four of which were also used to calculate the mesothelioma risk. Investigations involved "cohort" studies where the frequencies of various types of cancers in workers exposed to asbestos were compared to those in "control" groups not exposed to asbestos or to those of general populations such as U.S. males. Studies of such design are able to provide direct estimates of excess risk.

The studies used by OSHA in deriving dose-response relationships for its risk assessment covered a variety of work situations and industrial processes. This variety improves the predictive value of the risk assessment because it lessens or eliminates the possibility that the results were unique to any one occupational situation or were in fact aberrational. The occupational settings studied were: workers exposed at a chrysotile textile plant from 1930–1975 (Dement *et al.* Exs. 84–036 and 84–037); Canadian workers at an asbestos cement facility (Finkelstein Ex. 84–240); Italian chrysotile miners and millers who worked during 1930–1965 (Rubino *et al.* Ex. 84–86); workers in an asbestos cement pipe plant (Weill *et al.* Ex. 84–206); workers in an asbestos production plant and asbestos cement pipe factory (Henderson and Enterline Ex. 84–48); British workers manufacturing asbestos textile products (Peto Ex. 84–169); asbestos miners and millers in Quebec, Canada (Liddell *et al.* Ex. 84–59); and in the Thetford Mines, Canada (Nicholson *et al.* Ex. 84–72); and workers manufacturing asbestos friction materials (Berry and Newhouse Ex. 84–21).

"Well-conducted epidemiologic studies that show a positive association between an agent and a disease are accepted as the most convincing evidence about human risk" (Risk Assessment in the Federal Government: Managing the Process, National Research Council, 1983, p. 21, Ex. 84–322).

No extrapolation from animal data to human data is necessary in order to show carcinogenicity of asbestos. For most substances, OSHA must infer human health effects, such as carcinogenicity, from animal data.

The results of this risk assessment performed by OSHA agree well with other recent risk assessments performed by other governmental and outside scientists (see Acheson and Gardner) (Ex. 84–216 and 84–243); EPA (Ex. 84–180); Kang and Chu (Ex. 84–001); Selikoff *et al.* (84–002); and CHAP (Ex. 84–256).

4. *Comparative Analysis.* Insight into the magnitude of the risk associated with asbestos exposure can be gained by reviewing other occupational risks. OSHA believes it is instructive to compare asbestos risks with other workplace hazards agreed on as presenting an unusually high degree of hazard, where the data are considered both available and reliable.

The risk of excess mortality estimated as a result of exposure to asbestos at the conditions in the workplace today appears to be substantially higher than other risks experienced by workers from occupational injury hazards. The National Safety Council (NSC) has reported the annual death rates in 1981 from work accidents in a variety of industries (Ex. 84–339). Using the NSC data OSHA has reviewed the annual mortality from work accidents per 1000 workers in several industries in light of the excess cancer mortality from a single year of exposure to asbestos per 1000 workers. For example, in the high risk occupations of agriculture and mining-quarrying, the annual mortality rates from work accidents were 0.54 and 0.55 per 1000 workers respectively in 1981 (Ex. 84–339). In contrast, the death rate from work accidents for all industries combined was 0.12 per 1000 workers in 1981.

OSHA has estimated that the lifetime risk for one year of exposure to 2 f/cc of asbestos is about 3 excess cancer deaths per 1000 exposed workers during the remainder of the workers' lifetimes (Ex. 4–349). Thus, asbestos workers' risk of excess cancer mortality from a single year of exposure to 2 f/cc is roughly 5 times higher than the risk of accidental occupational fatalities from one year of employment in agriculture and mining-quarrying. 7

As shown in Table 1, OSHA estimates that many workers are exposed to asbestos in the vicinity of 2 f/cc. In addition, OSHA calculated the average excess cancer risk to workers exposed at conditions that exist in the workplace today (for those above 0.5 f/cc and using the scenario described in Table 3). OSHA estimates that 10 excess cancer deaths will occur per 1000 workers for 1 year exposure; thus the average risk to workers (exposed above 0.5 f/cc) in the workplace today is approximately 20 times the annual fatal accident rates in agriculture and mining-quarrying.

These comparisons are striking. They show that the estimated risk of dying of cancer from asbestos exposure at levels existing at the workplace today far exceeds the accidental death rate in the riskiest of industries. Although the estimated mortality rates for cancer due to asbestos exposure are not completely comparable to the total actual accidental fatalities, the review is clearly useful in showing that the magnitude of the asbestos risk is grave.

One example of predicted cancer risk as a result of occupational exposure is the following cancer risk estimated from occupational exposure to ionizing radiation. The estimated excess cancer fatality rate from 47 years of exposure to the maximum permissible occupational exposure to ionizing radiation (5 rems) is 17 to 29 per 1000 workers (Committee on the Biological Effects of Ionizing Radiation (BEIR) III predictions, see 48 FR 1902). However, most radiation standards (unlike OSHA standards) require that exposure limits be reduced to the lowest level reasonably achievable below the exposure limit (the ALARA principle). Approximately 95 percent of radiation workers have exposures less than one-tenth the maximum permitted limit. The excess cancer deaths at one-tenth the permitted level are 1.7 to 2.9 per 1000 workers exposed 47 years. Asbestos exposures of 45 years to 2 f/cc are predicted by OSHA to result in 64 excess cancer deaths per 1000 workers beginning work at age 25 (Ex. 84-392). OSHA's calculation for the average excess cancer risk to worker exposed at conditions that exist in the workplace today (for those above 0.5 f/cc) for a 45-year exposure, is 196 excess cancer deaths per 1000 workers. This figure was calculated by taking the number of cancer deaths estimated from exposure to existing conditions for 45 years for those workers exposed to greater than 0.5 f/cc of asbestos and dividing by the number of workers exposed to asbestos greater than 0.5 f/cc (multiplied by 1000).

Therefore, the excess cancer risk at 2 f/cc for asbestos workers is estimated as more than twice as high as the maximum permitted radiation cancer risk and about 25 times higher than the estimated cancer risk of 95 percent of the workers exposed to radiation. At existing conditions, asbestos workers' excess cancer risks are estimated to be 85 times higher than the cancer risk faced by 95 percent of the workers exposed to radiation. The risk of asbestosis further increases the significance of the risk from asbestos exposure.

At 0.5 f/cc, OSHA estimates that 17 excess cancer deaths will occur in 1000 workers exposed 45 years. This risk is approximately 7 times higher than the cancer risk faced by 95 percent of the workers exposed to radiation. OSHA finds that these comparative risks strongly support OSHA's finding that workers exposed to air concentrations above 0.5 f/cc are far above the point of significant risk and are at grave danger of dying from cancer.

5. *Conclusion.* OSHA's finding of "grave danger" is based on evidentiary and policy considerations. OSHA's determination that the magnitude of the estimated risk to exposed workers is alarmingly high constitutes the major component of the "grave danger" finding. The overall extraordinary degree of risk, the extent that very high risk is found in many asbestos using industries, and the unusually high quality of the data utilized to make these assessments present a very strong evidentiary basis for a "grave danger" finding. Just as importantly, the unique gravity of asbestos-caused diseases, in particular cancer, such as mesothelioma which is linked almost exclusively to asbestos exposure, strongly supports OSHA's finding of grave danger. Also OSHA's comparison of the risk of asbestos-related disease to other industrial risks underscores the extraordinarily high risk estimated for asbestos exposure. OSHA has also noted the concerns of workers about current workplace conditions and the numerous petitions for an ETS from unions representing many exposed workers. Finally OSHA has relied on its experience in evaluating and regulating workplace hazards in recognizing the extraordinary degree of risk currently faced by asbestos workers and in determining that such risk constitutes a grave danger to those workers.

B. Need for an ETS

OSHA has determined that this ETS is necessary to protect employees from grave danger, the second prong of the Act's test of OSHA's exercise of its ETS authority (Section 6(c) of the Act). As explained in detail, the effect of this ETS is to save many lives which would otherwise be lost to asbestos-related disease if current working conditions were not changed. OSHA believes that employees can be adequately protected against this grave danger only by issuing an ETS. This is because no other Agency action and no other foreseeable event would result in sufficiently reduced asbestos exposures that would alleviate the grave danger. Further, the provisions of the ETS are tailored to effect the necessary exposure reductions expeditiously.

1. *Lives Saved by Issuing an ETS.* OSHA has estimated the number of deaths avoided as a result of an ETS which would reduce the PEL to 0.5 f/cc (see Tables 2 and 3). For cancer only, based on continuing exposures under currently existing conditions for 6 months, the potential number of lives saved is estimated as approximately 210. Based on continuing exposures at currently existing conditions for 1 year, the potential number of lives saved is estimated at approximately 426. Also, OSHA has estimated that the promulgation of an ETS setting a 0.5 f/cc PEL may avoid 5725 cancer deaths assuming 20 years exposure to asbestos of the current workforce at current conditions and 7815 cancer deaths assuming 45 years exposure.

OSHA is aware, of course, that Section 6(c) of the Act limits the effective time of an ETS to 6 months, and OSHA concludes that a grave danger exists and an ETS is necessary even if OSHA focuses exclusively on this six month period. However, the Agency believes it is appropriate to calculate benefits deriving from an ETS using lifetime risks from 20 and 45 years of exposure to the PEL of 0.5 f/cc established by the ETS. Although the ETS expires within 6 months, Section 6(c) requires that rulemaking on a permanent standard also be completed within 6 months, so that there will be no gap in protection for exposed employees. In OSHA's experience and judgment, complying with this statutory directive and completing rulemaking for a permanent standard within 6 months of an ETS has and can be done.

OSHA also believes, based on its experience, that it is very likely that the PEL established after 6(b) rulemaking will be no higher than 0.5 f/cc, the ETS limit. Therefore, OSHA believes that the ETS will result in a reduced lifetime worker exposures of 0.5 f/cc or lower for 20 or 45 years, and that the benefits derived from these exposure reductions for these time periods are appropriately attributed to OSHA's promulgation of this emergency standard.

a. *Employee Exposures.* To derive these estimates of numbers of lives saved, OSHA depended on its knowledge of the following factors: (1) The employee exposure levels from the ambient asbestos air concentrations in the workplace; (2) the number of workers exposed at the various asbestos levels; (3) the duration of the exposure; and (4) the probability of the disease (or the risk) associated with the cumulative exposure.

Employee exposure levels are conventionally measured in terms of the number of asbestos fibers that are 5 microns or more in length in one cubic centimeter of air, f/cc. In these terms, an ambient concentration may seem to be a small amount of asbestos. However, in physical terms, 2.0 f/cc equals 2,000,000 fibers per cubic meter (f/m^3). Humans inhale about one cubic meter of air per hour, depending on degree of physical activity. Thus, at this concentration, a worker would inhale roughly 16,000,000 fibers, 5 microns or more in length, over an eight hour workday.

respirators (with a protection factor exceeding 10) must be worn drops from 20 f/cc (10 times the former PEL of 2 f/cc) to 5 f/cc (10 times the new PEL of 0.5 f/cc). Therefore OSHA believes that more workers will wear more protective respirators under the ETS than under the current permanent standard, that their actual exposure levels will be reduced to below 0.5 f/cc and consequently that their risks will be reduced even more than the calculations indicate.

OSHA finds also that requiring a training program to be instituted as quickly as possible is one of the most effective methods of maximizing the beneficial impact of the exposure reduction and of all the protective provisions of the current standard. Thus, the content of this ETS has been chosen as the most effective short-term strategy to reduce asbestos risks which will be accepted and implemented.

6. *Conclusion.* OSHA finds that workers exposed to asbestos in the workplace at existing exposure conditions need this emergency temporary standard to protect them from the grave danger presented by these conditions. OSHA finds that by compelling a reduction in exposure to 0.5 f/cc for those employees presently exposed over that level, many lives will be saved. Training imposed by the ETS will enhance the risk reductions, although quantification of that additional reduction cannot be calculated. 0.5 f/cc is the lowest feasible level achievable through this emergency action, where short-term implementation of the controls is required.

Only by issuing an ETS compelling reductions in exposure levels below the current permissible limit of 2 f/cc can OSHA bring about adequate reductions in risks. The administrative action of stepping up enforcement of the current standard is an inadequate response to OSHA's finding that current conditions present a grave danger.

OSHA does not believe that any significant reduction will occur within an acceptable time period without this emergency standard action. OSHA has observed a gradual reduction in asbestos use, but, in the Agency's experience, significant and rapid exposure reductions usually occur in response to standards. The provisions of the ETS will significantly reduce the risk and reduce it quickly. Therefore OSHA has determined that the ETS is necessary to reduce the grave danger.

IV. Occupational Health Data

A. Introduction

1. *Asbestos-related Diseases.* Asbestos exposure can cause a number of disabling and fatal diseases. Among these diseases are lung cancer, cancer of the mesothelial lining of the pleura and peritoneum, and asbestosis. It is also likely that asbestos increases the risk of gastrointestinal cancers. Of all the diseases caused by asbestos, death from lung cancer constitutes the greatest health risk for American asbestos workers. Lung cancer has been responsible for over half of the excess mortality from asbestos exposure in some occupational cohorts.

The relationship between lung cancer and asbestos exposure has been established by numerous epidemiologic studies of diverse groups. Asbestos-induced lung cancer usually has a latency period in excess of 20 years and may be diagnosed at an earlier age than for non-exposed persons (Craighead et al., 1982; Ex. 84-033). Few cases of lung cancer are curable despite advances in medical and surgical oncology. Only 9% of lung cancer patients survive five or more years after diagnosis (American Cancer Society, 1983; Ex. 84-160). Asbestos exposure acts synergistically with cigarette smoke to multiply the risk of developing lung cancer.

Mesothelioma also has been conclusively shown to be associated with asbestos by many studies. In some asbestos-exposed occupational groups, 10%-18% 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 to 30 years is required in order to observe mesotheliomas in an occupational cohort. Some victims of mesothelioma have had a latency period exceeding 40 years since their initial exposure to asbestos (Craighead et al., 1982; Ex. 84-033). This form of cancer is rarely curable and is usually fatal within a year after diagnosis. There is no evidence for a relationship between cigarette smoking and mesothelioma risk.

Asbestos exposure can cause pleural and/or other pulmonary disease. Pleural plaques are one of the markers of exposure and may develop within 10 to 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 commercial types of asbestos induce plaques. Plaques can occur even when fibrosis is absent 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., 1982; Ex. 84-033).

Asbestosis is pulmonary fibrosis caused by the accumulation of asbestos fibers in the lungs. Adverse effects of asbestosis range from shortness of breath upon exertion to cyanosis, effusions of serous fluid, respiratory failure, cardiac decompensation, and death. Often, asbestosis is a progressive disease, even in the absence of continued exposure. Symptoms of 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 upon the presence of characteristic radiologic changes, symptoms, rales, other clinical features of fibrosing lung disease and a history of exposure to asbestos. Cigarette-smoking asbestos workers may have an increased risk of asbestosis relative to non-smoking asbestos workers. (Craighead et al., 1982; Ex. 84-033).

Some epidemiologic studies have observed increases in esophageal, stomach, colo-rectal, kidney, laryngeal, pharyngeal, and buccal cavity cancers. While the magnitude of increased cancer risk for these sites is not as great as for lung cancer and mesothelioma, the increased risk is nevertheless of considerable importance because of the high background rates of some of these tumors in the general population. A 50% increase in a common cancer such as colo-rectal cancer results in many more deaths than a 50% increase in a rare cancer. Colo-rectal cancer, if detected and treated in an early localized stage, has a five year survival rate of about 70% (American Cancer Society 1983; Ex. 84-160). Surgical and medical treatment is less successful for the other sites listed above.

Adverse effects from exposure to asbestos have been observed in workers involved in asbestos cement pipes and shingles manufacturing (Enterline et al., 1973a, 1973b; Weill et al., 1979; Finkelstein, 1982, 1983) (Exhibits 84-122, 84-123, 84-206, 84-044, 84-240), asbestos mining and milling (Wagner et al. 1960; Liddell et al., 1977; McDonald et al., 1980; Hobbs et al., 1980; Nicholson et al., 1979; Rubino et al., 1979) (Exhibits 2-21, 84-059, 84-065, 84-132, 84-072, 84-086), asbestos textile manufacturing (Doll, 1955; Peto et al., 1980; Berry et al., 1979;

Dement et al., 1983) (Exhibits 84–040, 84–169, 84–020, 84–037), insulation work (Selikoff et al., 1979) (Exhibit 84–090), shipbuilding (Selikoff et al., 1979; Blot et al., 1980; Tagnon et al., 1980) (Exhibits 84–091, 84–109, 84–182), and in a variety of asbestos products manufacturing industries (Jones et al., 1980; Henderson and Enterline, 1979; McDonald and McDonald, 1978; Seidman et al., 1979; Robinson et al., 1979; Acheson et al., 1981) (Exhibits 84–138, 84–048, 84–154, 84–087, 84–082, 84–103).

It should be noted that 2 fibers per cubic centimeter, which is the current OSHA standard, is equivalent to 2 million fibers per cubic meter of air. Because humans breathe in about a cubic meter of air every hour, depending on physical exertion, the current OSHA PEL for asbestos allows workers to inhale 2 million asbestos fibers per hour during an 8-hour work day. For the sake of brevity, subsequent discussion in this preamble will express exposure in terms of fibers per cubic centimeter (f/cc) rather than fibers per cubic meter.

Note.—The current OSHA standard includes asbestos fibers 5 micrometers or more in length, thereby excluding shorter fibers. Since up to 98% of airborne asbestos fibers are shorter than 5 micrometers, workers may inhale up to 100 million asbestos fibers per hour during an 8-hour work day.

Since OSHA's publication of a notice of proposed rulemaking in 1975, additional studies have confirmed that asbestos exposure causes a high risk of cancer. In addition, much more complete data on the nature of dose-response relationships for asbestos-induced diseases are now available. These studies generally indicate that the PEL set by OSHA in 1972 is inadequate to protect asbestos workers from either lung disease or cancer.

The following agencies and organizations have reviewed the health data for asbestos: International Agency for Research on Cancer (IARC) (1977, Ex. 84–321), Organization for Economic Cooperation and Development (OECD) (1979, Ex. 84–337), NIOSH (1976, 1980, Exhibits 84–338 and 84–320), Advisory Committee of the Health and Safety Commission of the United Kingdom (1979, Ex. 84–216), the Chronic Hazard Advisory Panel on Asbestos (CHAP) (1983, Ex. 84–256), and the U.S. Environmental Protection Agency (1982, 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 reduction of the PEL for asbestos to 0.1 fibers 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 fibers per cubic centimeter (0.1 f/cc), based on the limitations of current technologies of measuring air concentrations of asbestos. The 1979 report of the Advisory Committee of the Health and Safety Commission of the United Kingdom, hereafter referred to in this section 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. Currently, it appears that the United Kingdom may lower the PEL for chrysotile to 0.5.

2. *Evaluation of Risk.* OSHA's first step in analysis of risk of disease from exposure to a potentially hazardous agent is a qualitative evaluation of scientific data. This evaluation involves reviewing human and experimental studies to consider such factors as overall study design, methods of data collection, biologic plausibility of findings, consistency of findings from different studies, temporal correctness of the association, and other factors as well as general scientific judgment.

Subsequently, after a specific agent has been judged to be hazardous, the quantitative exposure-response relationships between the agent and disease can be investigated. The available data on air concentrations of the substance or biological indices of exposure, such as fiber contents within lungs, can be reviewed for cohorts of workers demonstrated to have an increased risk of disease. If workers with an observed excess risk of disease have received cumulative exposures permitted by the current OSHA permissible exposure limit, then a potential significant health risk from exposure to the PEL has been established. If the workers with observed excess risk received cumulative exposures above those permitted by the current PEL, then risk from the current PEL may be estimated from risk observed at higher levels by using dose-response extrapolation models.

The section, *Epidemiologic Evidence on Risk from Exposure at the Current PEL,* will discuss the extent to which excess risk has been *observed* from low exposures to asbestos. Section V., *Quantitative Risk Analysis,* will discuss the *prediction* of excess risk from low asbestos exposures using dose-extrapolation models based on studies observing excess risk in humans. OSHA considers that both risks *observed* by studies and risks *predicted* by dose-extrapolation models are valid indicators of the existence of significant health risks.

Exposure data frequently are not available for workers exposed before 1970. Where historical exposure data are available, the data often have such limitations as having been collected and analyzed using industrial hygiene techniques no longer in use or having been collected in only some areas of the worksite or having been collected on only a few occasions. Therefore, of necessity, estimates of dose-response based on epidemiologic studies will have a fairly broad range of uncertainty. OSHA must examine the best available data on exposure-response to arrive at a determination of significance of risk, despite inherent and inevitable uncertainties in the data.

The current 8-hour time-weighted average PEL for asbestos of 2 fibers per cubic centimeter (2 f/cc) envisages that workers will not receive a cumulative exposure exceeding 100 f/cc-years (=2 f/cc × 50 years of occupational exposure). For asbestos, OSHA believes that a number of studies suggest that increased risk of lung cancer, asbestosis, and mesothelioma have occurred from cumulative exposures estimated as close to or below 100 f/cc-years.

Note.—OSHA typically uses 45 years as the period of a full working lifetime for purposes of quantifying risk from exposure to toxic agents. For asbestos, many scientists have used 50 years to represent a full working lifetime. Thus, both 45 years of exposure and 50 years of exposure are used in this document for the purpose of analyzing dose-response relationships for asbestos.

In these studies, the cumulative exposures resulted from exposure *levels* greater than the current OSHA PEL of 2 f/cc for an 8-hour day. For example, workers who accumulated 100 f/cc-years could have been exposed to an average level of 5 f/cc for a period of 20 years. Section B.(3), below, discusses the epidemiologic evidence for risk from low exposures in more detail. OSHA believes that a significant health risk has been observed for cumulative exposures that could be accumulated by workers exposed to no more than the present PEL of 2 fibers per cubic centimeter (2 f/cc).

Estimates of cumulative exposure are approximations of total dose received by a worker during the period of employment involving exposure to asbestos. Cumulative exposures generally are estimated by multiplying the varying intensities of exposure, such as the 8-hour time-weighted averages, by the number of year's exposed. Most theories of the mechanism of