among 24,487 employees of the NY Department of Corrections. Subjects included in the study had to have two sequential PPD skin tests, have a negative test the first year, and have complete demographic information. The overall conversion rate was estimated to be 1.9%. Preliminary results show that after controlling for age, ethnicity, gender, and residence in New York City, corrections offices and medical personnel, working in prisons with inmate active TB cases, had odds ratios of TB infection of 1.64 and 2.39, respectively, compared to maintenance and clerical personnel who had little opportunity for prisoner contact. Based on these results, the annual excess risk due to occupational exposure is estimated to be 1.22% and 2.64% for corrections officers and medical personnel, respectively. This translates into lifetime occupational risks of 423 and 700 per 1,000 exposed employees, respectively. In prisons with no known inmate TB cases, there were no significant differences in TB infection rates among employees in different job categories.

Homeless Shelters

Employees in homeless shelters also have a significantly increased likelihood of frequent exposure. A high prevalence of TB infection and disease is common in many homeless shelters. Screening in selected shelters has shown the prevalence of TB infection to range from 18 to 51% (Ex. 6–15). Many shelter residents also possess characteristics that impair their immunity and thus place them at greater risk of developing active disease. For example, homeless persons often suffer from poor nutrition and poor overall health status, and they also have poor access to health care. In addition, they may suffer from alcoholism, drug abuse and infection with HIV. Screening of selected shelters has shown the prevalence of active TB disease to range from 1.6 to 6.8% (Ex. 6–15). Thus, there is an increased likelihood that employees at homeless shelters will frequently encounter individuals with infectious TB in the course of their work.

In addition, as in the case for correctional facilities, homeless shelters also tend to be overcrowded and have poor ventilation, factors that promote the transmission of disease and place shelter residents and employees at risk of infection. Outbreaks reported among homeless shelters (Exs. 7–51, 7–75, 7–73, 6–25) also provide evidence that where there is exposure to individuals with infectious TB and effective infection control measures are not implemented, employees are at risk of infection. It is reasonable to assume, therefore, that risk estimates calculated for hospital employees who have an increased likelihood of exposure to individuals with infectious TB can be used to estimate the risks for homeless shelter employees.

Facilities That Provide Treatment for Drug Abuse

Employees in facilities that provide treatment for drug abuse have an increased likelihood of frequent exposure to individuals with infectious TB. Surveys of selected U.S. cities by the CDC have shown the prevalence of TB infection among the clients of drug treatment centers to range from approximately 10% to 13% (Ex. 6–8). Clients of these centers are also generally at higher risk of developing active disease. The clients typically come from medically underserved populations and may suffer from poor overall health status. As discussed in the Health Effects section, drug dependence has also been shown to be a possible risk factor in the development of active TB. Moreover, many of the drug treatment center clients are intravenous drug users and are infected with HIV, placing these individuals at an increased risk of developing active TB. Given these risk factors for the clients served at drug treatment centers, there is an increased likelihood that employees in these work settings will be exposed frequently to individuals with infectious TB.

Medical Laboratories

Medical laboratory work is a recognized source of occupational hazards. CDC considers workers in medical laboratories that handle *M. tuberculosis* to be at high risk for occupational transmission of TB either because of the volume of material handled by routine diagnostic laboratories or the high concentrations of pathogenic agents often handled in research laboratories.

Few surveys of laboratory-acquired infections have been undertaken; most reports are of small outbreaks in specific laboratories. Sulkin and Pike's study of 5,000 laboratories suggested that brucellosis, tuberculosis, hepatitis, and enteric diseases are among the most common laboratory-acquired infections (Ex. 7–289). In 1957, Reid noted that British medical laboratory workers had a risk of acquiring tuberculosis two to nine times that of the general population (Ex. 7–289). This result was validated in 1971 by Harrington and Channon in their study of medical laboratories (Ex. 7–289). A retrospective postal survey of approximately 21,000 medical laboratory workers in England and Wales showed a five-times increased risk of developing active TB among these workers as compared with the general population. Technicians were at greater risk, especially if they worked in anatomy departments. A similar survey carried out in 1973 of 3,000 Scottish medical laboratory workers corroborates the results from England and Wales. Three cases, one doctor and two technicians, were noted in the 1973 survey, which resulted in an overall incidence rate of 109 per 100,000 person-years. The general population incidence rate for active TB was 26 per 100,000 person-years, giving a risk ratio of 4.2 (Ex. 7–289).

The studies reviewed in this section indicate that workers in medical laboratories with potential for exposure to *M. tuberculosis* during the course of their work have a several-fold (ranging from 2- to 9-fold) increased risk of developing active disease compared with the risk to the general population. Although these studies were conducted over two decades ago, they represent the most recent data available to the Agency, and OSHA has no reason to believe that the conditions giving rise to the risk of infection at that time have changed substantially in the interim. The Agency is not aware of any more current data on transmission rates in medical laboratories. OSHA solicits information on additional studies addressing occupational exposure to active TB in laboratories; such studies would then be considered by OSHA in the development of a final rule.

Other Work Settings and Activities

In addition to the information available for correctional facilities, homeless shelters, and facilities that provide treatment for drug abuse, there are other work settings and activities where there is an increased likelihood of frequent exposure to aerosolized *M. tuberculosis.* For example, hospices serve client populations similar to those of hospitals and perform similar services for these individuals. Individuals who receive care in hospices are likely to suffer from medical conditions (e.g., HIV disease, end-stage renal disease, certain cancers) that increase their likelihood of developing active TB disease once infected. Thus, employees providing hospice care have an increased likelihood of being exposed to aerosolized *M. tuberculosis.* CDC has recommended that hospices follow the same guidelines for controlling TB that hospitals follow.

Emergency medical service employees also have an increased likelihood of

encountering individuals with infectious TB. Like hospices, emergency medical services cater to the same high risk client populations as hospitals. Moreover, emergency medical services are often used to transport individuals identified with suspected or confirmed infectious TB from various types of health care settings to facilities with isolation capabilities.

In addition, other types of services (e.g., social services, legal counsel, education) are provided to individuals who have been identified as having suspected or confirmed infectious TB and have been placed in isolation or confined to their homes. Employees who provide social welfare services, teaching, law enforcement or legal services to those individuals who are in AFB isolation are exposed to aerosolized *M. tuberculosis*. In particular, employees performing high-hazard procedures are likely to generate aerosolized *M. tuberculosis* by virtue of the procedure itself. Thus, employees providing these types of services also have an increased likelihood of exposure to aerosolized *M. tuberculosis* and are therefore likely to experience risks similar to those described above for hospital workers.

Although they do not have contact with individuals with infectious TB, employees who repair and maintain ventilation systems which carry air contaminated with *M. tuberculosis* and employees in laboratories who manipulate tissue samples or cultures contaminated with *M. tuberculosis* also have an increased likelihood of being exposed to aerosolized *M. tuberculosis*. Like employees in the work settings discussed above, these employees have an increased risk of frequent exposure to aerosolized *M. tuberculosis*.

Therefore, OSHA believes that the quantitative risk estimates derived from data observed among health care workers in the hospital setting can be generally used to describe the potential range of risks for workers in other occupational settings where there is a reasonable anticipation of exposure to aerosolized *M. tuberculosis*. The reasonableness of this assumption is supported by the overall weight of evidence of the available health data. As discussed in the Health Effects section, epidemiological studies, case reports and outbreak investigations have shown that in correctional facilities, homeless shelters, long-term care facilities for the elderly, drug treatment centers, and laboratories where appropriate TB infection control programs have not been implemented, employees have become infected with TB as a result of occupational exposure to individuals with infectious TB or to other sources of aerosolized *M. tuberculosis*. Thus, although the data on employee conversion rates in other work settings cannot be used to directly quantify the occupational risk of infection for those work settings, there is strong evidence that employees in various work settings other than hospitals can reasonably be anticipated to have exposure to aerosolized *M. tuberculosis* and that TB can be transmitted in these workplaces when appropriate TB infection control programs are not implemented.

VI. Significance of Risk

Section 6(b)(5) of the OSH Act vests authority in the Secretary of Labor to issue health standards. This section provides, in part, that:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.

OSHA's overall analytical approach to making a determination that workplace exposure to certain hazardous conditions presents a significant risk of material impairment of health is a four step process consistent with interpretations of the OSH Act and rational, objective policy formulation. In the first step, a quantitative risk assessment is performed where possible and considered with other relevant information to determine whether the substance to be regulated poses a significant risk to workers. In the second step, OSHA considers which, if any, of the regulatory alternatives being considered will substantially reduce the risk. In the third step, OSHA examines the body of ''best available evidence'' on the effects of the substance to be regulated to set the most protective requirements that are both technologically and economically feasible. In the fourth and final step, OSHA considers the most cost-effective way to achieve the objective.

In the Benzene decision, the Supreme Court indicated when a reasonable person might consider the risk significant and take steps to decrease it. The Court stated:

> It is the Agency's responsibility to determine in the first instance what it considers to be ''significant'' risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it. (*I.U.D.* v. *A.P.I.*), 448 U.S. at 655).

The Court indicated that ''while the Agency must support its findings that a certain level of risk exists with substantial evidence, we recognize that its determination that a particular level of risk is 'significant' will be based largely on policy considerations.'' The Court added that the significant risk determination required by the OSH Act is ''not a mathematical straitjacket'' and that ''OSHA is not required to support its findings with anything approaching scientific certainty.'' The Court ruled that ''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.'' (448 U.S. at 655, 656).

As a part of the overall significant risk determination, OSHA considers a number of factors. These include the type of risk presented, the quality of the underlying data, the reasonableness of the risk assessments, and the statistical significance of the findings.

The hazards presented by the transmission of tuberculosis, such as infection, active disease, and death are very serious, as detailed above in the section on health effects. If untreated, 40–60% of TB cases have been estimated to result in death (Exs. 5–80, 7–50, 7–66). Fortunately, TB is a treatable disease. The introduction of antibiotic drugs for TB has helped to reduce the mortality rate by 94% since 1953 (Ex. 5–80). However, TB is still a fatal disease in some cases. From 1989–1991 CDC reported 5,452 deaths among adults from TB (see TABLE V–13, Risk Assessment section). In addition, there has been an increase in certain forms of drug-resistant TB, such as MDR–TB, in which the tuberculosis bacilli are resistant to one or more of the front line drugs such as isoniazid and rifampin, two of the most effective anti-TB drugs. The information available today is not adequate to estimate the future course of MDR–TB, but the reduction in the potential of transmitting this deadly form of the disease is itself another benefit of this standard. The current data indicate that among MDR–TB cases, the risk of death is increased compared to drug-susceptible forms of the disease. A CDC investigation of 8

outbreaks of MDR–TB revealed that among 253 people infected with MDR–TB, 75% died within a period 4 to 16 weeks after the time of diagnosis (Ex. 38–A). MDR–TB may be treated, but due to the difficulty in finding adequate therapy which will control the bacilli's growth, individuals with this form of the disease may remain infectious for longer periods of time, requiring longer periods of hospitalization, additional lost worktime, and an increased likelihood of spreading TB infection to others until treatment renders the patient non-infectious. Because of the difficulty in controlling these drug-resistant forms of the disease with antibiotics, progressive lung destruction may progress to the point where it is necessary to remove portions of the lung to treat the advance of the disease.

The OSH Act directs the Agency to set standards that will adequately assure, to the extent feasible, that no employee will suffer ''material impairment of health or functional capacity.'' TB infection represents a material impairment of health that may lead to active disease, tissue and organ damage, and death. Although infected individuals may not present any signs or symptoms of active disease, being infected with TB bacilli is a serious threat to the health status of the infected individual. Individuals who are infected have a 10% chance of developing active disease at some point in their life, a risk they would not have had without being infected. The risk of developing active disease is even greater for individuals who are immunocompromised, due to any of a large number of factors. For example, individuals infected with HIV have been estimated as having an 8–10% risk *per year* of developing active disease (Ex. 4B).

In addition, since infected individuals commonly undergo treatment with anti-TB drugs to prevent the onset of active disease, they face the additional risk of serious side effects associated with the highly toxic drugs used to treat TB. Preventive treatment with isoniazid, one of the drugs commonly used to treat TB infection, has been shown in some cases to result in death from hepatitis or has damaged the infected person's liver to the extent that liver transplantation was performed (Ex. 6–10). Thus, the health hazards associated with TB infection clearly constitute material impairment of health.

Clinical illness, i.e., active disease, also clearly constitutes material impairment of health. Left untreated, 40 to 60 percent of active cases may lead to death (Exs. 7–50, 7–66, 7–80). Individuals with active disease may be infectious for various periods of time and often must be hospitalized. Active disease is marked by a chronic and progressive destruction of the tissues and organs infected with the bacteria. Active TB disease is usually found in the lungs (i.e., pulmonary tuberculosis). Long-term damage can result even when cases of TB are cured; a common result of TB is reduced lung function (impaired breathing) due to lung damage (Ex. 7–50, pp. 30–31). Inflammatory responses caused by the disease produce weakness, fever, chest pain, cough, and, when blood vessels are eroded, bloody sputum. Also, many individuals have drenching night sweats over the upper part of the body several times a week. The intensity of the disease varies, ranging from minimal symptoms of disease to massive involvement of many tissues, with extensive cavitation and debilitating constitutional and respiratory problems. Long-term damage can also result from extrapulmonary forms of active disease; such damage may include mental impairment from meningitis (infection of membranes surrounding the brain and spinal cord) and spinal deformity and leg weakness due to infection of the vertebrae (i.e., skeletal TB) (Ex. 7–50, p. 31). Active disease is treatable but it must be treated with potent drugs that have to be taken for long periods of time. The drugs currently used to treat active TB disease may be toxic to other parts of the body. Commonly reported side effects of anti-TB drugs include hepatitis, peripheral neuropathy, optic neuritis, ototoxicity and renal toxicity (Ex. 7–93). Active disease resulting from infection with MDR–TB is of even greater concern due to the inability to find adequate drug regimens. Although OSHA has not been able to precisely quantify the increase in incidence of MDR–TB, the number of cases of MDR–TB is clearly on the rise. In these cases, individuals may remain infectious for longer periods of time and may suffer more long-term damage from the chronic progression of the disease until adequate therapy can be identified.

In this standard, OSHA has presented quantitative estimates of the lifetime risk of TB infection, active disease and death from occupational exposure to *M. tuberculosis*. Qualitative evidence of occupational transmission is also included in OSHA's risk assessment.

In preparing its quantitative risk assessment, OSHA began by seeking out occupational data associated with TB infection incidence in order to calculate an estimate of risk for TB infection attributable to occupational exposure for all U.S. workers. Unfortunately, an overall national estimate of risk for TB infection attributable to occupational exposure is not available. CDC, which collects and publishes the number of active TB cases reported nationwide each year, does not publish occupational data associated with the incidence of TB infection and active TB on a nationwide basis. There has been some effort to include occupational information on the TB reporting forms, but only a limited number of states are currently using the new forms and capturing occupational information in a systematic way. In the absence of a national database, OSHA used two statewide studies, from North Carolina and Washington (Exs. 7–7, 7–263), and data from an individual hospital, Jackson Memorial Hospital (Ex. 7–108), on conversion rates of TB infection for workers in hospitals. The Washington State database also contained information on three additional occupational groups: long-term care, home health care and home care employees. OSHA used these data to model average TB infection rates and estimate the range of expected risks in the U.S. among workers with occupational exposure to TB.

The conversion rates in the selected studies were used to estimate the annual excess relative risk due to occupational exposure, which was expressed as the percent increase of infection above each study's control group. In order to estimate an overall range of occupational risk of TB infection, taking into account regional differences in TB prevalence in the U.S. and indirectly adjusting for factors such as socio-economic status, which might influence the rate of TB observed in different parts of the country, OSHA: (1) Estimated background rates of infection for each state by assuming that the number of new infections is functionally related to the number of active cases reported by the state each year (i.e., the distribution of new infections is directly proportional to the distribution of active cases), and 2) applied estimates of the annual excess relative risk, derived from the occupational studies, to the state background rates to calculate estimates of excess risk due to occupational exposure by state. Thus, the excess occupational risk estimates are actually calculated from the three available studies, on a relative increase basis, and these relative increases are multiplied by background rates for each state to derive estimates of excess occupational risk by state. The state estimates are then used to derive a national estimate of annual occupational risk of TB infection. Given an annual rate of infection, the lifetime risk of infection was calculated assuming that workers

are exposed for 45 years and that the worker's exposure profile and working conditions remain constant throughout his or her working lifetime. Lifetime infection rates are then used to calculate the lifetime risk of developing active disease based on the estimate that 10% of all infections result in active disease. Given a number of active cases of TB, the number of expected deaths can be calculated based on the estimated average TB case death rate (i.e., number of TB deaths per number of active TB cases averaged over 3 years as reported by CDC).

OSHA estimates that the risk of material impairment of health or functional capacity, that is, the average lifetime occupational risk of TB infection for hospital workers ranges from 30 to 386 infections per 1,000 workers who are occupationally exposed to TB. These are different national averages, each derived by calculating the risk in each state and weighting it by the state's population. The low end of this range is derived by using the Washington State data, and is likely to seriously underestimate the true risk to which workers are exposed. This is because the Washington data represent occupational exposures among employees in hospitals which are located in areas of the country with a low prevalence of active TB and which have implemented TB controls (e.g., early identification procedures, annual skin testing, and negative pressure in AFB isolation rooms). The high end of this range is derived by using the Jackson Memorial Hospital study, and represents occupational risk for workers in hospitals located in high TB prevalence areas, serving high risk patients, and with a high frequency of exposure to infectious TB.

OSHA also used information from the Washington State database to estimate national average estimates of lifetime risk for workers in long-term care (i.e., nursing homes), home health care, and home care. The national average lifetime risk of TB infection is estimated to be 448 per 1,000 for workers in long-term care facilities, 225 per 1,000 for workers in home health care (primarily nursing staff), and 69 per 1,000 for workers in home care. The higher likelihood of occupational exposure in long-term care facilities (early identification of suspect TB cases is often difficult among the elderly) and the presence of fewer engineering controls in these facilities may explain the high observed occupational risk in that work setting.

The national average lifetime risk of developing active disease ranges from approximately 3 to 39 cases per 1,000 exposed employees for workers in hospital settings. Similarly, the average lifetime risk of active disease is estimated to be approximately 45 per 1,000 for workers in long-term care, 26 per 1,000 in home health care, and 7 per 1,000 in home care. This range is based on the estimate that 10% of infections will progress to active disease over one's lifetime. This risk may be greater for immunocompromised individuals.

The national average lifetime risk of death from TB ranges from 0.2 to approximately 3 deaths per 1,000 exposed employees for workers in hospital settings. Similarly, the average lifetime risk of death from TB is estimated to be approximately 3.5 per 1,000 for workers in long-term care, 2 per 1,000 for workers in home health care, and 0.5 per 1,000 in home care. The lower range of the national lifetime risk of deaths, 0.2 per 1,000, is based on the Washington State hospital data where the prevalence of TB is low and infection control measures have been implemented. Thus, this lower range of risk underestimates the risk of death from TB for other employees who work in settings where infection control measures, such as those outlined in this proposed standard, have not been implemented. The risk assessment data show that where infection control measures were not in place, the estimated risk of death from TB was as high as 6 deaths per 1,000 exposed employees.

The quantitative risk estimates are based primarily upon data from hospitals and selected other work settings. However, it is frequent exposure to aerosolized *M. tuberculosis* which places workers at substantially increased risk of infection and not factors unique to the health care profession or any job category therein. Qualitative evidence, such as that from the epidemiological studies, case reports and outbreak investigations reported for various types of work settings, as discussed earlier in the Health Effects section, clearly demonstrates that employees exposed to aerosolized *M. tuberculosis* have become infected with TB and have gone on to develop active disease. These work settings share risk factors that place employees at risk of transmission. For example, these work settings serve client populations that are composed of a high prevalence of individuals who are infected with TB, are immunocompromised, are injecting drug users or are medically underserved and of poor general health status. Therefore, there is an increased likelihood that employees in these work settings will encounter individuals with active TB. In addition, high-hazard procedures, such as bronchoscopies, are performed in some of these work settings, which greatly increases the likelihood of generating aerosolized *M. tuberculosis.* Moreover, some of the work settings have environmental conditions such as overcrowding and poor ventilation, factors that facilitate the transmission of disease. Therefore, OSHA believes that the quantitative risk estimates based on hospital data and other selected health care settings can be extrapolated to other occupational settings where there is a similar increased likelihood of exposure to aerosolized *M. tuberculosis.*

Having specific data for non-health care workers and workplace conditions would add more precision to the quantitative risk assessment, but that level of detail is not possible with the currently available information. However, the Agency believes that such a level of detail is not necessary to make its findings of significant risk because the risk of infection is based upon occupational exposure to aerosolized *M. tuberculosis.* Nevertheless, OSHA seeks information on conversion rates and the incidence of active disease among employees in non-health care work settings in order to give more precision to its estimates of risk.

OSHA's risk estimates for TB infection are comparable to other risks which OSHA has concluded are significant, and are substantially higher than the example presented by the Supreme Court in the Benzene Decision. After considering the magnitude of the risk as shown by the quantitative and qualitative data, OSHA preliminarily concludes that the risk of material impairment of health from TB infection is significant.

OSHA also preliminarily concludes that the proposed standard for occupational exposure to TB will result in a substantial reduction in that significant risk. The risk of infection is most efficiently reduced by implementing TB exposure control programs for the early identification and isolation of individuals with suspected or confirmed infectious TB. Engineering controls to maintain negative pressure in isolation rooms or areas where infectious individuals are being isolated will reduce the airborne spread of aerosolized *M. tuberculosis* and subsequent exposure of individuals, substantially reducing the risk of infection. In addition, for those employees who must enter isolation rooms or provide services to individuals with infectious TB, respiratory protection will reduce exposure to aerosolized *M. tuberculosis* and thus reduce the risk of infection.

Several studies have shown that the implementation of infection control measures such as those outlined in this proposed standard have resulted in a reduction in the number of skin test conversions among employees with occupational exposure to TB. For example, results of a survey conducted by the Society of Healthcare Epidemiology of America (SHEA) of its member hospitals (Exs. 7–147 and 7–148) revealed that among hospitals that treated 6 or more patients with infectious TB per year there were 68% fewer tuberculin skin test conversions in hospitals that had AFB isolation rooms with one patient per room, negative pressure, exhaust air directed outside and six or more air changes per hour, compared to hospitals that did not have AFB isolation rooms with these same characteristics. Similarly, an 88% reduction in tuberculin skin test conversions was observed in an Atlanta hospital after the implementation of infection control measures such as an expanded respiratory isolation policy, improved diagnostic and testing procedures, the hiring of an infection control coordinator, expanded education of health care workers, increased frequency of tuberculin skin tests, implementation of negative pressure, and use of submicron masks for health care workers entering isolation rooms (Ex. 7–173). Improvements in infection control measures in a Florida hospital after an outbreak of MDR-TB reduced tuberculin skin test conversions from 28% to 18% to 0% over three years (Ex. 7–167). These improvements included improved early identification procedures, restriction of high-hazard procedures to AFB isolation rooms, increased skin testing, expansion of initial TB treatment regimens, and daily inspection of negative pressure in AFB isolation rooms. Thus, these investigations show that the implementation of infection control measures such as those included under OSHA's proposed standard for TB can result in substantial reductions in infections among exposed employees.

As discussed in further detail in the following section of the Preamble to this proposed standard, OSHA estimates that full implementation of the proposed standard for TB will result in avoiding approximately 21,400 to 25,800 work-related infections per year, 1,500 to 1,700 active cases of TB resulting from these infections and 115 to 136 deaths resulting from these active cases. In addition, because the proposed standard encourages the identification and isolation of active TB cases in the client populations served by workers in the affected industries, there will also be non-occupational TB infections that will be averted. OSHA estimates that implementation of the proposed standard will result in avoiding approximately 3,000 to 7,000 non-occupational TB infections, 300 to 700 active cases of TB resulting from these infections, and 23 to 54 deaths resulting from these active cases. OSHA preliminarily concludes that the proposed standard for TB will significantly reduce the risk of infection, active disease and death from exposure to TB and that the Agency is thus carrying out the Congressional intent and is not attempting to reduce insignificant risks.

Although the current OSHA enforcement program, which is based on the General Duty Clause of the Act, Section 5(a)(1), and the application of some general industry standards, such as 29 CFR 1910.134, Respiratory Protection, has reduced the risks of occupational exposure to tuberculosis to some extent, significant risks remain and it is the Agency's opinion that an occupational health standard promulgated under section 6(b) of the Act will much more effectively reduce these risks for the following reasons. First, because of the standard's specificity, employers and employees are given more guidance in reducing exposure to tuberculosis. Second, it is well known that a standard is more protective of employee health than an enforcement program based upon the general duty clause and general standards. Unlike the proposed standard, the general duty clause specifies no abatement methods and the general industry standards do not set forth abatement methods specifically addressing occupational exposure to TB. Third, the general duty clause imposes heavy litigation burdens on OSHA because the Agency must prove that a hazard exists at a particular workplace and that it is recognized by the industry or the cited employer. Since the proposed standard specifies both the conditions that trigger the application of the standard and the employer's abatement obligations, thereby establishing the existence of the hazard, no independent proof that the hazard exists in the particular workplace need be presented. The reduction in litigation burdens will mean that the Labor Department, as well as the employer, will save time and money in the investigation and litigation of occupational TB cases. Finally, the promulgation of this proposed standard will result in increased protection for employees in state-plan states which, although not required to adopt general duty clauses, must adopt standards at least as effective as Federal OSHA standard.

In summary, the institution of the enforcement guidelines has been fruitful, but it has not eliminated significant risks among occupationally exposed employees. Therefore, OSHA preliminarily concludes that a standard specifically addressing the risks of tuberculosis is necessary to further substantially reduce significant risk. OSHA's preliminary economic analysis and regulatory flexibility analysis indicate that the proposed standard is both technologically and economically feasible. OSHA's analysis of the technological and economic feasibility is discussed in the following section of the preamble.

VII. Summary of the Preliminary Economic Analysis and Regulatory Flexibility Analysis

OSHA is required by the Occupational Safety and Health Act of 1970 and several court cases pertaining to that Act to ensure that its rules are technologically and economically feasible for firms in the affected industries. Executive Order (EO) 12866 and the Regulatory Flexibility Act (as amended) also require Federal agencies to estimate the costs, assess the benefits, and analyze the impacts on the regulated community of the regulations they propose. The EO additionally requires agencies to explain the need for the rule and examine regulatory and non-regulatory alternatives that might achieve the objectives of the rule. The Regulatory Flexibility Act requires agencies to determine whether the proposed rule will have a significant economic impact on a substantial number of small entities, including small businesses and small government entities and jurisdictions. For proposed rules with such impacts, the agency must prepare an Initial Regulatory Flexibility Analysis that identifies those impacts and evaluates alternatives that will minimize such impacts on small entities. OSHA finds that the proposed rule is ''significant'' under Executive Order 12866 and ''major'' under Section 804(2) of the Small Business Regulatory Enforcement Fairness Act of 1996. Accordingly, the Occupational Safety and Health Administration (OSHA) has prepared this Preliminary Economic and Regulatory Flexibility Analysis (PERFA) to support the Agency's proposed standard for occupational exposure to tuberculosis (TB). The following is an executive summary of that analysis. The entire test of the PERFA can be found in the rulemaking docket as Exhibit 13.

The complete PERFA is composed of various chapters that describe in detail the information summarized in the following section.

Statement of Need

TB is a communicable, potentially lethal disease caused by the inhalation of droplet nuclei containing the bacillus *Mycobacterium tuberculosis* (*M. tuberculosis*). Persons exposed to these bacteria can respond in different ways: by overcoming the challenge without developing TB, by becoming infected with TB, or by developing active TB disease. Those who become infected harbor the infection for life, and have a 10 percent chance of having their infection progress to active disease at some point in their life. Those with active disease have the signs and symptoms of TB (e.g., prolonged, productive cough; fatigue; night sweats; weight loss) and have about an 8 percent risk of dying from their disease.

TB has been a worldwide health problem for centuries, causing millions of deaths worldwide. In the United States, however, there has been a decline in the number of active TB cases over the last four decades. Between 1953 and 1994, the number of active cases declined from 83,304 to 24,361, an annual rate of decline of 3.6 percent over the period as a whole (Figure VII–1). The 1988–1992 period, however, saw the first substantial increase in the number of active cases since 1953. A number of outbreaks of this disease have occurred among workers in health care settings, as well as other work settings, in recent years. To add to the seriousness of the problem, some of these outbreaks have involved the transmission of multi-drug resistant strains of *M. tuberculosis,* which are often fatal. Very recently, i.e., after 1992, this trend has reversed, and the number of such cases appears once again to have begun to decline. Nevertheless, TB remains a major health problem, with 22,813 active cases reported in 1995. Because active TB is endemic in many U.S. populations—including groups in both urban and rural areas—workers who come into contact with diseased individuals are at risk of contracting the disease themselves.

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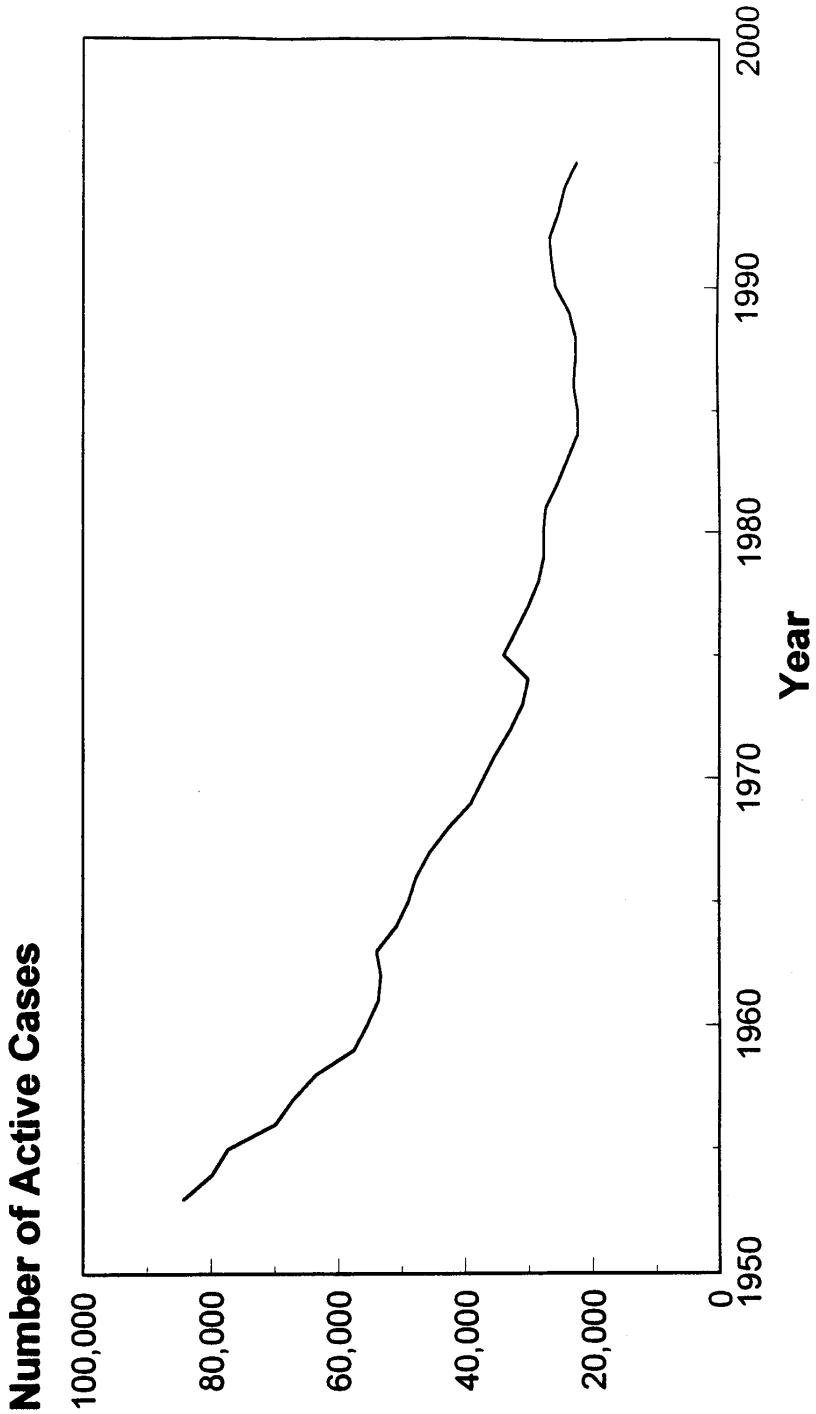
Figure VII-1. Cases of Tuberculosis by Year (1953-1995)



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Many occupational groups, including workers in health care, nursing homes, homeless shelters, hospices, correctional facilities, laboratories, physicians' offices, and other settings are at risk of contracting TB on the job. These workers are at risk because they are exposed in the course of their work to patients and others with active TB disease, perform procedures that expose them to airborne concentrations of *M. tuberculosis,* or serve client populations where the incidence of active disease is unusually high.

The purpose of OSHA's standard is to reduce these risks in health care and other work settings where active TB cases are likely to be encountered by employees. To accomplish this goal, the proposed standard requires those employers who are responsible for the working conditions where such encounters occur to implement a program of infection prevention and infection control that is designed to prevent occupational infections in the first place, and to identify and treat any job-related infections that do occur. The approach taken in the proposed standard is similar to that adopted by OSHA in its 1991 bloodborne pathogens standard, which is given credit for achieving a dramatic reduction in the number of cases of hepatitis among health care and other workers since it was issued. OSHA predicts that, once implemented, the proposed TB standard will have similar results, achieving reductions on the order of 70 to 90 percent in the number of TB infections, active cases, and directly related deaths.

This Preliminary Economic and Regulatory Flexibility Analysis includes an introductory chapter that describes the major provisions of the standard. The proposal would apply to occupational exposure to TB occurring in, during, or through the provision of services by:

- Hospitals.
- Nursing homes.
- Correctional facilities.
- Immigration detainment facilities.
- Law enforcement facilities.
- Hospices.
- Substance abuse treatment centers.
- Homeless shelters.
- Medical examiners' offices.
- Home health care providers.
- Emergency medical services.
- Research and clinical laboratories handling TB.
- Contract work on ventilation systems or areas of buildings that may contain aerosolized *M. tuberculosis.*
- Physicians performing certain high hazard procedures.
- Social service workers providing services to individuals identified as having suspected or confirmed infectious TB.
- Personnel service agencies when providing workers to covered facilities.
- Attorneys visiting known or suspected infectious TB patients.

The groups, industries, and work settings covered by the standard have been included in its scope for specific reasons. For example, hospitals are included because they treat patients with active TB disease, while hospices, certain laboratories, pulmonary and certain other physicians, medical examiners, and contract HVAC workers are covered because employees in these settings/jobs are exposed to aerosolized *M. tuberculosis* during the performance of high-hazard procedures, such as bronchoscopies, sputum induction, autopsies, and during work on ventilation systems that may contain TB bacteria. Other work settings, such as homeless shelters and nursing homes, are covered because their employees serve a client population known to have a high incidence of TB infection. Another group of employees included within the scope of the standard are workers who must occasionally serve patients with active TB who are being treated in ''isolation,'' i.e., a room or area specifically designed to contain the TB microorganism and prevent its spread to surrounding areas. Attorneys and social workers are typical of this group. Finally, the proposed standard covers personnel service agencies that provide temporary, seasonal, or ''leased'' personnel to hospitals and other covered work settings.

OSHA estimates that the standard would apply to approximately 102,000 establishments and provide protection to more than 5 million workers currently at risk of occupational exposure to TB. More than half of these workers—almost 4 million—work in the two industries most affected by the standard: hospitals and nursing homes. Other covered industries with large numbers of workers are home health care, emergency medical services, and correctional institutions.

Table VII–1 shows the number of affected establishments and the population at risk for each covered industry. (Table VII–1 does not include all sectors that might hypothetically be covered by the standard. For example, a chiropractor who engaged in high hazard procedures would be covered by the standard. However, this possibility is sufficiently rare for this activity not to have been included in this analysis. OSHA solicits comments on any affected job categories or industries it may have omitted.) Because the standard requires employers in the covered industries to make an initial determination that will identify which job classifications, employees, and activities within their workplace involve occupational exposure to TB, its requirements are narrowly targeted to those workers most at risk. Thus, for example, only approximately 57 percent of hospital workers are potentially affected by the standard; these workers would include those working on infectious disease floors or wards, radiology units, autopsy suites, and in other, similarly exposed locations.

TABLE VII–1.—NUMBER OF AFFECTED ESTABLISHMENTS AND POPULATION AT RISK, BY INDUSTRY

Industry	Number of affected establishments	Population at risk
Hospitals	5,749	2,663,996
Nursing Homes	20,254	1,200,034
Correctional Institutions	2,079	268,432
Immigration Detainment	12	990
Law Enforcement	4,950	27,469
Hospices	1,755	17,250
Homeless Shelters	10,450	85,168
Substance Abuse Treatment Centers	9,730	120,115
Medical Examiners	100	2,000
Home Health Care	10,921	418,538
Emergency Medical Services	5,099	255,200
Laboratories	851	11,108
Contract HVAC	300	2,500
Social Services	2,342	20,000
Physicians	21,698	43,395
Pulmonary Physicians	1,853	3,705
Personnel Services	1,426	161,608
Attorneys	2,306	4,611
Total	101,875	5,306,119

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

Technological Feasibility

Chapter III of the analysis evaluates the technological feasibility of the proposed standard for affected establishments. OSHA preliminarily concludes that no provisions of the rule pose technological feasibility problems for any potentially affected entities. This is the case because the standard emphasizes administrative controls, such as the early identification of suspected or confirmed cases of TB and employee information and training, rather than engineering controls. In

addition, the engineering controls that are required, such as AFB isolation rooms, biological safety cabinets, and temporary AFB isolation facilities, would be mandated only in those situations where individuals with suspected or confirmed infectious TB are admitted and isolated, where high hazard procedures are performed, and in situations where individuals cannot be placed into AFB isolation rooms within five hours of being identified as having suspected or confirmed infectious TB. All of the engineering controls required by the standard are currently available and in widespread use in many affected establishments.

Benefits of the Proposed Standard

Workers employed in the work settings covered by the standard are at significant risk of material impairment of health as a result of exposure to *M. tuberculosis* on the job. These workers will be the primary beneficiaries of the protection provided by the rule. However, because TB is a communicable disease, many other individuals will also benefit from the standard. Reducing the number of cases of TB among workers who are regularly in contact both with patients and infected members of client populations will reduce the incidence of TB infections and active cases in these client populations (since infected individuals spend the most time with other members of their group) and among members of the families of exposed workers. OSHA has expressed the benefits of the standard in terms of the numbers of TB infections, active cases, and TB-related deaths averted by the standard. In addition to reducing morbidity and mortality among workers, their families, and client populations, the standard will also generate readily quantifiable cost savings in the form of lower medical costs, less lost production, and reduced costs for administering workers' compensation claims and other private and social insurance system transactions.

OSHA's estimates of the potential benefits of the standard take into account the extent of current industry compliance with the provisions of the proposed standard, i.e., the benefits estimates do not include the benefits that employers in affected sectors are already garnering as a result of their voluntary efforts to provide protections to their TB-exposed employees. The benefits assessment presented in Chapter IV of the economic analysis is based on OSHA's Preliminary Risk Assessment (see that section of the preamble), which quantifies the occupational risk of TB infection among workers in hospitals, nursing homes, home health care work settings, and home care work settings. The estimates of risk are based on the rate of tuberculin skin test (TST) conversions among these populations. TST conversions are a widely used and well-documented index of TB infection; rates of conversion among the exposed populations are then compared with rates in unexposed or less-exposed ''control'' populations to obtain an estimate of the ''excess'' risk associated with occupational exposure. Table VII–2 shows the results of OSHA's estimates of the risks confronting workers in various work settings, based on statistical analyses and studies in the literature.

TABLE VII–2.—ESTIMATES OF OCCUPATIONAL RISK CONFRONTING WORKERS IN VARIOUS SETTINGS

Setting	Location and date	Excess risk (percent)	Estimated annual excess rate of TB infection per 1,000 workers
Hospital	North Carolina Western Region—1984–1985	398	5.7
Hospital	Washington State—1994	47	.68
Hospital	Jackson Memorial Hospital, Miami, Florida—1991	795	11.8
Nursing Homes	Washington State—1994	1019	14.6
Home Health Care	Washington State—1994	478	6.9
Home Care	Washington State—1994	112	1.6

Source: OSHA, Preliminary Assessment of Risk.

Where risk data of good quality were available for a specific industry, OSHA relied on that data. However, such data were available only for the hospital, nursing home, home health care, and home care industries. Accordingly, OSHA identified the best data to use to characterize the occupational risk of TB infection posed to workers in the other work settings covered by the proposed rule. After a careful review of the available data, OSHA chose to rely on data from western North Carolina that looked at occupational risk in a total of eight hospitals. These data were selected because they derived from hospitals that were relatively ''uncontrolled,'' i.e., that had not yet implemented many of the controls that would be required by the proposed standard. Data from the other hospitals shown in Table VII–2 were judged to be less appropriate for the purpose of extrapolation because Washington State hospitals are already generally in compliance with the requirements of the proposed rule and Jackson Memorial Hospital had recently experienced an outbreak of multi-drug resistant TB among its patients at the time the risk data were gathered. OSHA believes that using occupational risk data from hospitals to characterize the risk in other occupational settings for which risk data are unavailable is appropriate because employees in these other settings serve client populations that have a high incidence of active TB cases, perform high-hazard procedures, or visit hospitalized TB patients. The use of a hospital-based risk estimate results in a lower estimate of risk than would be the case if OSHA had used risk data from nursing homes or home health care to characterize the risk in other settings, but a higher risk than if OSHA had used risk data from the home care industry to do so.

To predict the effectiveness of the proposed standard, OSHA evaluated the reduction in occupational risk that various control measures required by the standard can be expected to achieve. Effectiveness is measured as the percent reduction in TST conversions and in the TB infections, active cases, and deaths represented by those conversions. Based on a thorough review of the available literature on the effectiveness of control programs that have actually been implemented in a number of hospitals, OSHA believes that the proposed standard, once implemented, would

reduce TB infections among occupationally exposed hospital workers by 90 percent, and would decrease such infections in the other work settings covered by the standard by 70 to 90 percent. OSHA also estimated the effectiveness and medical surveillance and follow-up in preventing infections from advancing to active cases of TB. OSHA found that such measures reduced the probability of an infection advancing to an active case by 35 to 47 percent, depending on the frequency of testing.

Using these effectiveness data, taking account of the current levels of compliance in various workplaces, and relying on the estimates of excess risk presented in OSHA's Preliminary Risk Assessment, OSHA predicts that the proposed standard will avert about 21,000 to 26,000 work-related TB infections per year, 1,500 to 1,750 active disease cases resulting directly from these infections, and 115 to 136 deaths directly related to the same infections. Preventing this number of infections among workers will, in turn, prevent about 3,000 to 7,000 infections, 300 to 700 active cases, and 23 to 54 deaths among the families, friends, clients, and contacts of these workers. In addition, the standard will annually generate cost savings of $89 to $116 million dollars in avoided medical costs, lost production caused by absence from work and other factors, and insurance administration costs. Table VII–3 shows the benefits of the proposed standard.

TABLE VII–3.—SUMMARY OF BENEFITS ASSOCIATED WITH THE PROPOSED STANDARD

Type of benefit	Work-related	Transmissions from work-related sources	Total number averted
Infections Avoided	21,380–25,769	2,954–6,978	24,334–32,747.
Active Cases Avoided	1,477–1,744	295–698	1,772–2,442.
Deaths Avoided	115–136	23–54	138–190.
Cost Savings	$80,721,000–$95,393,000	$8,614,000–$20,381,000	$89,335,000–$115,774,000.

Source: Office of Regulatory Analysis, OSHA, DOL.

Chapter V of the economic analysis projects the costs employers in the various industries covered by the standard are estimated to incur to achieve compliance with the rule's requirements. OSHA estimated costs for each covered industry and for each provision of the standard. These costs take account of the baseline levels of compliance prevailing in each industry at the present time and are presented as annualized costs discounted at 7 percent. Annualized costs are the sum of annualized initial costs and recurring annual costs. For example, a temporary AFB isolation room costing $4,095 with annual maintenance costs of $50 would have annualized costs of $633 ($583 + $50).

The total estimated costs of compliance for the standard as a whole are $245 million per year. The most costly provisions of the standard are those requiring medical surveillance and training for occupationally exposed employees. Together, these two provisions account for 60 percent of the costs of compliance. The two industries projected to incur the highest costs are hospitals and nursing homes. Together, the costs incurred by these two industries are estimated to be $138 million per year. Tables VII–4 and VII–5 summarize the annualized costs of compliance, by provision and industry, respectively.

TABLE VII–4.—TOTAL ANNUALIZED COSTS, BY PROVISION

Provision	Total annualized cost
Exposure Control	$12,858,183
Work Practice Controls	9,740,559
Transfers	9,740,559
Engineering Controls	22,529,248
AFB Isolation Rooms	7,547,912
Temporary AFB Isolation	10,792,678
Laboratories	780,270
Autopsies	2,903,077
Daily Testing of Negative Pressure	505,310
Respiratory Protection	45,771,276
Respirators	32,225,228
Respirator Program	1,670,677
Fit Testing	8,905,821
Evaluation of Program	2,969,549
Medical Surveillance	94,901,455
Medical History/Physical Exam	62,974,255
Tuberculin Skin Testing (TST)	21,907,252
Medical Management/Follow-up	4,773,377
Medical Removal	5,246,570
Communication of Hazards	52,268,172
Signs and Labels	58,284
Training	52,209,888
Recordkeeping	7,228,533
Engineering Control Maintenance	20,052
Medical	6,785,014
Training	423,467

TABLE VII–4.—TOTAL ANNUALIZED COSTS, BY PROVISION—Continued

Provision	Total annualized cost
Total	245,297,426

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

TABLE VII–5.—SUMMARY OF COMPLIANCE COSTS, BY INDUSTRY

Provision	Total annualized cost
Hospitals	$61,819,637
Nursing Homes	76,500,314
Correctional Institutions	20,187,666
Immigration Detainment	145,378
Law Enforcement	6,708,174
Hospices	2,237,959
Homeless Shelters	11,287,278
Substance Abuse Treatment Centers	12,751,545
Medical Examiners	557,811
Home Health Care	16,448,605
Emergency Medical Services	4,981,780
Laboratories	1,696,383
Contract HVAC	396,197
Social Services	3,063,444
Physicians	5,663,949
Pulmonary Physicians	930,775
Personnel Services	18,363,135
Attorneys	1,557,398
Total	245,297,426

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

Chapter VI assesses the economic impacts of the proposed standard on the industries affected by the proposed standard and also analyzes the impacts on the small businesses within each of these industries. OSHA preliminarily concludes that the standard is economically feasible for affected firms. On average, annualized compliance costs for all entities amount only to 0.06 percent of revenues and only 1.8 percent of profits. For all industries, costs as a percentage of revenues are less than 1 percent. For two industries, costs as a percentage of profits exceed 5 percent; these industries are substance abuse treatment centers and personnel services. OSHA does not believe, however, that these profit impacts will actually be incurred by facilities in these two sectors. Only 18.5 percent of substance abuse treatment centers operate on a for-profit basis. If substance abuse treatment centers can increase their revenues by as little as 0.34 percent, they can completely offset their compliance costs. The revenue increases or reductions in services needed to achieve cost passthrough are not expected to represent significant impacts for these facilities. The situation for personnel service firms is similar; these firms would have to increase the prices charged to their customers by as little as 0.56 percent to completely offset the costs of compliance. It is likely that these agencies will be able to pass such a small increase in costs through to their customers, i.e., to facilities purchasing personnel services. Table VII–6 shows compliance costs as a percentage of revenues, by industry.

TABLE VII–6.—SCREENING ANALYSIS TO IDENTIFY POTENTIAL ECONOMIC IMPACTS ON AFFECTED ENTITIES

Industry	Number of affected establishments	Percent of for-profit establishments in industry	Cost as a percentage of revenues
Hospitals	5,749	15.5	0.02
Nursing Homes	20,254	71.4	0.16
Correctional Institutions	2,079	0.0	0.10
Immigration Detainment	12	0.0	0.16
Law Enforcement	4,950	0.0	0.03
Hospices	1,755	12.0	0.09
Homeless Shelters	10,450	0.0	0.64
Substance Abuse Treatment Centers	9,730	18.5	0.34
Medical Examiners	100	0.0	0.28
Home Health Care	10,921	40.6	0.11
Emergency Medical Services	5,099	14.5	0.11

TABLE VII–6.—SCREENING ANALYSIS TO IDENTIFY POTENTIAL ECONOMIC IMPACTS ON AFFECTED ENTITIES—Continued

Industry	Number of affected establishments	Percent of for-profit establishments in industry	Cost as a percentage of revenues
Laboratories	851	100.0	0.13
Contract HVAC	300	100.0	0.17
Social Services	2,342	0.0	0.27
Physicians	21,698	95.0	0.03
Pulmonary Physicians	1,853	95.0	0.06
Personnel Services	1,426	100.0	0.56
Attorneys	2,306	89.8	0.10
Total	101,875	48.7	0.06

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

OSHA has preliminarily concluded that the proposed standard will have a significant impact on a substantial number of small entities and has therefore, as required by the Regulatory Flexibility Act Amendments of 1996, conducted an Initial Regulatory Flexibility Analysis (IRFA). This analysis has identified significant impacts on the small entity portion of the hospital, nursing home, correctional institution, homeless shelter, substance abuse treatment center, contract HVAC, and personnel services industries.

For the purposes of this analysis, OSHA defines small for-profit entities using the Small Business Administration's (SBA's) Table of Size Standards. For businesses affected by the proposed standard, the SBA classifies entities with annual revenues of less than $5 million as small for all industries, with the exception of contract HVAC firms, for which entities with less than $7 million in annual revenues are classified as small.

A small not-for-profit entity is defined as any nonprofit enterprise that is independently owned and operated and is not dominant in its field. Based on this definition, all not-for-profit entities affected by the proposed standard are considered small.

Many of the affected industries consist almost entirely of public sector facilities, such as correctional facilities, immigration detainment facilities, law enforcement facilities, medical examiners' offices, and social service organizations. Several other affected industries include some government-owned facilities, such as hospitals, nursing homes, and emergency medical services. Under the Regulatory Flexibility Act, ''small governmental jurisdiction'' refers to governments of cities, counties, towns, townships, villages, school districts, or special districts with populations of less than 50,000. For most of the affected industries, information on the number of such entities was not readily available. Where data were unavailable, the number of small publicly-owned entities was estimated based on the average number of people served per employee in each industry, from which OSHA estimated the average employment size of establishments serving populations of less than 50,000. These entities are considered small for the purposes of this analysis. OSHA requests information on size standards for public-sector entities.

OSHA requests comment on these definitions and estimates of the number of small entities. The complete IRFA is presented in Chapter VI of the economic analysis, and is also presented here.

Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act, as amended in 1996, requires that an Initial Regulatory Flexibility Analysis contain the following elements:

(1) A description of the reasons why action by the agency is being considered;

(2) A succinct statement of the objectives of, and legal basis for, the proposed rule;

(3) A description of, and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;

(4) A description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and

(5) An identification, to the extent practicable, of all relevant Federal rules that may duplicate, overlap or conflict with the proposed rule.

In addition, a regulatory flexibility analysis must contain a description of any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes (in this case the OSH Act) and that minimize any significant economic impact of the proposed rule on small entities.[3] This section of the analysis closes with a review of the recommendations of the SBREFA Panel concerning this proposed rule and discusses how OSHA has responded to these recommendations.

Reasons for the Proposed Rule

From 1985 to 1994, the number of active TB cases in the United States increased by 9.4 percent, reversing a 30-year downward trend. Although the number of cases reported to the CDC has declined over the past few years, TB remains a serious problem in the United States. In 1994, 24,361 active TB cases were reported to the Centers for Disease Control and Prevention (CDC), and TB was reported to have caused 1,590 deaths in that year alone (Ex. 7–283).

Transmission of *M. tuberculosis* is a recognized risk in several work settings. A number of outbreaks of this dreaded disease have occurred among workers in health care settings, as well as other work settings, in recent years. To add to the seriousness of the problem, some of these outbreaks have involved the transmission of multidrug-resistant strains of *M. tuberculosis*, a form of the disease that is often fatal.

Objectives of the Proposed Rule

The objective of this proposal is to reduce the risk of occupational exposure to *M. tuberculosis* in exposed working populations through the use of engineering controls, work practice controls, respiratory protection, medical

[3] The Regulatory Flexibility Act states that a Regulatory Flexibility Analysis need not contain all of the above elements *in toto* if these elements are presented elsewhere in the documentation and analysis of the rule. The Regulatory Flexibility Analysis should, however, summarize where these elements can be found elsewhere in the rulemaking record.

surveillance, training, signs and labels, and recordkeeping. Implementation of these measures has been shown to minimize or eliminate occupational exposure to *M. tuberculosis*, and thus to reduce the risk of TB infection among workers. The legal authority for this proposed standard is the Occupational Safety and Health Act, 29 U.S.C. 655(b).

Description of the Number of Small Entities

The proposed rule would cover 80,400 establishments operated by 67,116 small entities, as defined above. Of the 67,116 small entities, about 49 percent (32,605 entities) are for-profit small entities, 20 percent (13,622 entities) are publicly-owned, and 31 percent (20,889 entities) are not-for-profit. About 79 percent of the total number of affected establishments are operated by small entities. The proposed rule covers 48,804 establishments operated by 48,044 very small entities, defined as entities of all kinds employing fewer than 20 workers. Almost 48 percent of the affected establishments are operated by very small entities.

Description of Proposed Reporting, Recordkeeping and Other Compliance Requirements

Avoiding a One-Size-Fits-All Standard. Occupational TB occurs in a wide variety of settings, which means that the risk varies substantially, and control measures differ, from one facility to another. OSHA's proposed TB standard has been tailored to recognize these differences. With respect to the background risk of exposure, the OSHA standard distinguishes between work settings in counties that have had no cases of TB in one of the past two years and fewer than 6 cases in the other of the past two years, work settings in counties with one or more cases of TB in both of the past two years or that have had 6 or more cases of TB in one of the past two years, and work settings that have encountered 6 or more cases of TB in the past 12 months. In addition, the OSHA standard treats different types of exposure to TB differently. For example, the standard has different requirements for employers who own facilities that treat TB patients, employers whose client populations have high TB rates, employers whose employees (such as attorneys and social service providers) visit patients who have been identified as having suspected or confirmed cases of TB, employers whose employees engage in various high hazard procedures, employers whose employees provide maintenance for ventilation systems serving confirmed or suspected TB patients, and employers who provide personnel to treat patients in their own homes. In part because of these many distinctions, the SBREFA Panel found that the regulation was difficult for many employers to understand (Ex. 12). To make the tailoring of the standard to specific situations easier to see, OSHA has developed tables showing which provisions of the standard are most likely to apply to employers in different circumstances and in various affected sectors (see the Scope paragraph discussion in Section X of the Preamble, ''Summary and Explanation''). In addition, OSHA intends to provide extensive outreach when the standard is published in final form. OSHA solicits comments on other ways to avoid a ''one-size-fits-all'' standard while at the same time making the standard easier to follow. For example, would developing a flow chart and/or expert system that asks employers a series of questions and then directs employers to applicable requirements be an aid to affected small entities?

Description of the Proposed Standard. The proposed rule would require that employers develop and implement exposure control plans; institute work practice and engineering controls; provide respiratory protection in various situations; provide medical surveillance (e.g., tuberculin skin testing, medical histories, medical management, medical follow-up, medical removal); and communicate hazards through the use of signs, labels, and training. These proposed requirements are discussed in greater detail in the Introduction (Chapter I) of this analysis.

The proposed standard would also require that employers establish and maintain medical, training, illness/injury, and engineering control maintenance and performance monitoring records. All establishments affected by the proposed rule would be affected by these proposed requirements. However, only establishments with engineering controls would be required to maintain records of the maintenance and monitoring of engineering controls.

In estimating the cost of establishing and maintaining medical records, OSHA used the wage rate of a clerical worker with some knowledge of medical recordkeeping as the base wage. However, the knowledge required to perform such duties can be acquired by most clerical workers with little effort. All recordkeeping requirements included in the proposed rule could therefore be performed by the existing staff in any of the covered industries. A detailed description of the proposed requirements appears in the Introduction and in the Costs of Compliance chapters of this analysis.

Relevant Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

On October 28, 1994, the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services published ''Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities,'' which recommends that facilities adopt many of the requirements included in this proposed standard. CDC has also published guidelines for the prevention of transmission of TB in homeless shelters, long-term care facilities for the elderly, and correctional institutions. OSHA has consulted with CDC in developing the proposed standard, and the basic elements of the standard correspond to the basic elements in the CDC guidelines. However, the CDC publication is only recommendatory and is therefore not enforceable. OSHA's studies (see chapters IV and V) show that few facilities are following all elements of these guidelines. Further, many portions of the CDC guidelines are written in language that does not lend itself to enforcement even if the guidelines were made mandatory. For example, portions of the CDC guidelines for health care facilities suggest that the employer ''consider'' adopting certain controls. A fuller discussion of the similarities and differences between OSHA's proposed rule and the CDC's recommendations is provided in Section III of the Preamble, which describes the events leading to the proposed standard. Although the U.S. Public Health Service has overall responsibility for the control of TB in the U.S. population, OSHA is the only agency specifically mandated to address the problem of TB transmission in occupational settings.

The Health Care Financing Administration (HCFA) of the U.S. Department of Health and Human Services requires that facilities undergo an initial accreditation inspection prior to receiving Medicare and Medicaid funding. Such facilities include hospitals, nursing homes and other long-term care facilities, and clinical laboratories. Hospitals are reinspected annually, nursing homes every 15 months, and laboratories every two years. One of the requirements of such accreditation is the implementation of an infection control program. However, unlike the OSHA proposed rule, HCFA's requirements do not specify the elements that must be included in such

a program. HCFA may cite facilities with poor results for specific program deficiencies but does not have the authority to cite facilities for failing to include specific elements in their infection control programs, unless those program elements are specifically required by an OSHA standard. This means that in the absence of an OSHA TB standard, HCFA could not require implementation of specific controls. The proposed rule does not in any way conflict with HCFA requirements. Further, the existing HCFA requirements have not ensured that health care facilities adopt the elements of an effective infection control and have not prevented outbreaks of TB in this workforce.

One small entity representative to the SBREFA Panel suggested that the OSHA regulation might conflict with state and local requirements for skin testing and for tracing contacts of active cases of TB (Ex. 12). OSHA has considered this suggestion and believes there is no conflict. Some states do have rules covering TB testing and contact tracing, but most states do not. In 1993, only 18 states had requirements for TB screening of employees in medical facilities, and only 23 states had testing requirements for nursing home employees. Further, these requirements are sometimes not as stringent as those OSHA is proposing; for example, some states require only an initial skin test. Although 49 states require the investigation of reported cases of TB, only 29 states require contact tracing by health departments. In states where local health departments provide contact tracing, such contact tracing would constitute compliance with OSHA's requirements for contact tracing by employers. Employers merely need to assure that contact tracing takes place; they need not do the contact tracing themselves if others are available to do this job for them. Thus, there is no conflict between the OSHA standard and existing state requirements, nor do existing state laws obviate the need for a standard that requires TB testing of exposed employees and the investigation of reported TB exposures. However, OSHA solicits comment on the interaction of state rules regarding testing and tracing and the proposed standard.

One small entity representative was concerned with how medical removal protection and worker compensation programs would interact (Ex. 12). Medical removal protection requires that workers receive full salaries, full benefits, and no loss of job position or seniority while the employee is unable to work, or unable to work at his/her usual position, as a result of incurring an occupational case of TB. The purpose of medical removal protection is to assure that workers provide timely and accurate information to their employers concerning their medical symptoms. In the absence of medical removal protection, workers have financial and job security incentives to avoid reporting symptoms. OSHA counts any payments workers receive from workers' compensation toward the goal of assuring medical removal protection; that is, employers may deduct from the amount they pay out to the worker any monies paid to the ill worker by workers' compensation. Workers' compensation is not an adequate substitute for medical removal protection because workers' compensation does not fully replace lost wages and provides no guarantee of maintenance of seniority, job security, current position, or non-wage benefits. Medical removal protection requires the employer to provide any of these elements that are not a part of workers' compensation. Thus, the employer of a worker already receiving workers' compensation would need to provide an additional salary increment in order to restore the employee's full salary and would need to provide the worker his or her full non-wage benefits.

One small entity representative expressed concern over a possible conflict between the proposed rule and Federal Confidentiality Regulations covering chemically abusive or dependent clients participating in licensed and federally-funded programs [Ex. 12]. These regulations prohibit disclosing information regarding the identification of a patient as a substance abuser without the patient's consent. This representative noted that, without patient consent, a disclosure may be made only to medical personnel to meet a situation that has been declared a medical emergency by the Surgeon General. This small entity representative was referring to Public Health regulations: Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR 2, and a similar state statute: Confidentiality of Records, Minnesota Statute 254A.09. Both the Federal Confidentiality Regulations and the state statute cover records that would identify a patient as an alcoholic or drug abuser or concern his or her prognosis, diagnosis, treatment, attendance, status or physical whereabouts. No requirements of the standard would require the disclosure of records of this kind. These are not the kinds of records that are relevant to determining whether an individual has suspect or confirmed infectious TB. In addition, a medical referral for the client who is exhibiting signs and symptoms of TB can be made without revealing any of the prohibited confidential information. Moreover, in the case of an exposure incident, the identity of the individual with suspected or confirmed infectious TB need not be told to employees. Records maintained by employers on their employees are not covered by the regulations or statute, but would be subject to the same confidentiality requirements that govern all medical records. The identification and notification requirements in the proposed TB standard are the minimum necessary to prevent transmission of TB to employees. The contagious nature of the disease mandates early detection and early monitoring of individuals who have had an exposure incident.

One small entity representative to the SBREFA Panel expressed concern over possible interactions between the proposed standard and the Family and Medical Leave Act (FMLA) (Ex. 12). The Family and Medical Leave Act does not provide for leave with pay, and does not guarantee the continuation of any benefits other than health insurance. Further, the Family and Medical Leave Act covers a more limited timeframe (12 weeks) than the proposed standard's medical removal protection provisions (18 months). Thus, the only overlap between the proposed standard and the FMLA would occur in the area of health insurance benefits in the first 12 weeks of the worker's absence from work. Since the standard would specifically allow the employer to deduct from medical removal protection benefits any benefits paid to the worker from other sources, employers would not pay for the same benefits twice.

One small entity representative felt that the Americans with Disabilities Act (ADA) may offer protection to the ''worker who becomes ill as a result of an occupational exposure or who cannot work because of an inability to wear a PR [respirator].'' (Ex. 12) The ADA prohibits employers of 15 or more employees from discriminating, because of the disability, against a qualified individual with a disability with regard to terms, conditions and privileges of employment. An employer must provide reasonable accommodation for known physical or mental limitations for a qualified individual with a disability, unless accommodation can be shown to impose undue hardship on the employer. OSHA representatives noted that there is no conflict between an OSHA standard and the ADA requirements prohibiting discrimination. The ADA says that:

Nothing in this Act shall be construed to invalidate or limit the remedies, rights and procedures of any Federal law * * * that provides greater or equal protection for the rights of individuals with disabilities that are afforded by this Act. 42 U.S.C.A. 12201(b).

Further, the ADA would not provide the same protections as medical removal protection. In order for an employee to take advantage of the provisions of the ADA, certain conditions must be met. For example, the employee must work for a covered employer and be a qualified individual with a disability, i.e., one who can perform his or her job with or without reasonable accommodation. Thus, while the ADA may offer some protection to an employee who has or is suspected of having infectious TB or who cannot work because he or she cannot wear a respirator, the protection proposed to be provided by the OSHA standard for TB is more comprehensive and will lead to greater participation in the entire medical surveillance program. The OSHA proposed standard, in paragraph (g)(5)(ii), would provide to the employee with suspected or confirmed infectious TB:

* * * his or her total normal earnings, seniority, and all other employee rights and benefits, including the employee's right to his or her former job status * * * until the employee is determined to be noninfectious or for a maximum of 18 months, whichever comes first.

For each employee who must be removed for his or her job because he or she cannot wear a respirator (paragraph (g)(5)(iii)), the employer is required to:

transfer the employee to comparable work for which the employee is qualified or can be trained in a short period (up to 6 months), where the use of respiratory protection is not required [and] * * * maintain the total normal earnings, seniority, and all other employee rights and benefits. If there is no such work available, the employer shall maintain the employee's total normal earnings, seniority, and all other employee rights and benefits until such work becomes available or for a maximum of 18 months, whichever comes first.

OSHA's MRP provisions provide each employee, who must be medically removed, with the level of protection that is needed to assure that the employee promptly reports his or her symptoms of TB (which makes the workplace safer for all employees) and reports his or her difficulty with wearing a respirator (which makes the workplace safer for that employee).

Significant Alternatives to the Rule Considered by OSHA

This section first considers alternatives that OSHA was urged to consider by the SBREFA Panel and then turns to other alternatives considered by the Agency.

Alternatives Suggested by SBREFA Panel Members

Small entity representatives and SBREFA Panel members suggested a wide variety of possible clarifications and alternatives to the regulation. In response to these suggestions, OSHA has made a number of changes to the regulation, clarified the meaning of many sections of the rule, provided additional analysis, and added tables to the Preamble designed to clarify the requirements of the rule in various situations. A full discussion of OSHA's responses to all of the SBREFA Panel recommendations is given in the next section. This section only presents alternative approaches to the proposed rule and a discussion of the extent to which OSHA has adopted these alternative approaches. OSHA welcomes comments on these and other alternatives and on ways OSHA could adopt additional aspects of these alternative approaches and still meet the requirements of the OSH Act, particularly that Act's requirement to control significant risk to the extent feasible.

Less Stringent Trigger Mechanisms for the More Burdensome Portions of the Standard, Including Raising the Zero-Case Per County Per Year Trigger

OSHA has re-examined each provision of the proposed standard to ensure that it is necessary and appropriate to reduce risk. In the draft of the proposal reviewed by the Panel, OSHA required that a facility would only be eligible for the reduced TB control program requirements of Appendix A if the facility did not treat TB patients and if there had been no cases of TB in the county or the facility in the previous year. In its review, OSHA found that applying the standard's Appendix A requirements to facilities in counties with no TB cases in one of the last two years and fewer than 6 TB cases in the other of the last two years would not substantially increase the risk to employees in facilities located in such counties. This change from the trigger OSHA originally considered increases the number of counties qualifying for the Appendix A program from 43 percent to 55 percent of all U.S. counties.

Consider Allowing Portability of Training

The draft proposal reviewed by the SBREFA Panel required that all new employees be provided complete training. OSHA has examined its training provisions and decided that the non-site-specific components of training, such as training in the difference between tuberculosis infection and disease, can be transferred between employers without reducing the protection such training affords employees.

Do Not Require Annual Retraining

The draft proposal reviewed by the SBREFA Panel required annual retraining of all employees. OSHA believes that some method of assuring continuing competency is necessary, and that one-time training will not provide such assurance. However, the proposal now would allow employers to develop methods of assuring the competency of their employees, such as asking them questions about procedures, controls, etc., as an alternative to retraining. This change in the regulation will result in cost savings of $20 million per year.

Cooperative Initiatives, Such as Expanding OSHA's Current Cooperative Initiative With JCAHO

Some Panel members felt that cooperative initiatives could substitute for regulation in some areas. As noted above, however, in the absence of an OSHA standard, HCFA (and accrediting associations working with HCFA, such as JCAHO) does not have the authority to enforce specific infection control requirements. As a result, a cooperative initiative alone would leave employees exposed to TB in hospitals, who account for 13 percent of the active cases of TB projected to be prevented by the standard, without any new initiative designed to prevent these active cases of TB. If this approach were extended to nursing homes, and all nursing homes chose to be accredited, then 70 percent of the active cases of TB projected to be prevented by the standard would be denied coverage. Thus, OSHA does not feel that cooperative initiatives, even with accrediting organizations, can substitute for regulation.

Others suggested that OSHA could turn over enforcement of any TB regulation to HCFA, JCAHO or another accrediting or standards organization. In the eyes of its proponents, the suggestion that others could enforce OSHA's regulation has several major advantages. First, it would assure regular and more frequent inspections at health care facilities and nursing homes than OSHA alone could provide. Second, it would require health care facilities and nursing homes to deal only with a single inspection for infection control procedures, rather than

inspections by two different federal agencies. Third, these organizations may have greater penalty powers than OSHA, in that denial of HCFA acceptance or of accreditation can result in a health care facility losing significant funding or even being required to close.

For several reasons, providing exclusive HCFA enforcement of OSHA's TB requirements is an unsound approach. First, OSHA inspectors already inspect health care facilities, just as they inspect any other facility covered by the OSH Act, for possible violations of any OSHA requirement, e.g., safety as well as health requirements. The need for these OSHA inspections would not change even if HCFA or accrediting agencies enforced OSHA's TB requirements. Second, OSHA does not believe that it is legally appropriate under the OSH Act to tell its inspectors that, when they inspect health care facilities, they must ignore violations of the Agency's occupational exposure to TB requirements. Third, OSHA also cannot legally ignore employee complaints relating to occupational exposure to TB. For all of these reasons, OSHA believes that exclusive enforcement of the rule by HCFA or by agencies, such as JCAHO, that are authorized to provide accreditation, is not an appropriate or legally defensible approach.

However, OSHA does favor expanding its cooperative agreements, such as the current agreement with JCAHO, in any ways that both agencies agree would be beneficial, and OSHA is currently pursuing this option. On August 5, 1996, OSHA and JCAHO announced a 3-year partnership to promote health and safety for healthcare workers. This partnership will help health care facilities to meet accreditation expectations and OSHA compliance requirements. The initiatives of this partnership will include cataloging and evaluating duplicative compliance activities; undertaking cross-education and training of JCAHO and OSHA staff on corresponding requirements that relate to the management of worker safety and health; and developing a series of collaborative publications and user education programs.

A Federal-State Government Public Health Partnership to Develop Guidelines in Various Industry Sectors

The CDC is already charged with developing guidelines for the control of TB, and has already issued guidelines for correctional institutions, laboratories, health care facilities, long-term care facilities for the elderly, and homeless shelters. In fact, OSHA has made extensive use of these guidelines in developing its proposed occupational exposure to TB standard. OSHA feels that the CDC guidelines alone have not served adequately to protect TB-exposed workers, however. OSHA research indicates that the CDC guidelines are not being followed in most facilities, and believes that this is the reason that occupational exposure to TB remains such a serious problem in this country. In Chapter VII of the analysis, OSHA shows that these guidelines are not being followed and explains why many employers have little economic incentive to implement these guidelines.

Performance Standards Developed With the Assistance of Federal, State, and Local Government, and Labor and Industry

OSHA feels that its standard is a performance oriented standard that has benefited from both CDC's expertise and from many stakeholder meetings (which include representatives of other federal, state and local government agencies, labor, and industry) and the SBREFA Panel Process.

OSHA's proposed standard is performance oriented in a variety of ways. For example, OSHA does not specify procedures by which facilities must achieve AFB isolation, but instead allows any workable design. Similarly, OSHA sets performance criteria for respirators, but does not specify the types of respirators that must be used. OSHA does specify procedures for identification of suspect cases, but allows any method that assures that persons with the appropriate symptoms are identified as suspect cases. However, OSHA did not consider it appropriate to specify performance in terms of rates of TB cases or TB skin test conversions. Such an approach is not preventive, in that application of proper procedures would only occur after TB infection had occurred. Furthermore, most smaller facilities do not have enough TST conversions for statistically meaningful trends to be established. OSHA requests comments on this issue.

Some proponents of this approach feel that OSHA's proposed standard may not reflect the best ideas for controlling occupational exposure to TB and argue that stakeholder meetings would be a useful way of developing a better approach. OSHA held five stakeholder meetings involving representatives from more than thirty interested organizations. Furthermore, the CDC has made use of the best expertise in the country in developing its guidelines, and OSHA has adopted most elements of these guidelines and will hold public hearings on the standard at which interested parties can present their views. OSHA welcomes comments about alternative approaches to reducing occupational exposure to TB, particularly suggestions concerning more performance oriented approaches, but feels that this proposal is the result of an extensive review of the literature and of input from stakeholders on the available prevention and control methods and should be issued as a proposal at this time to prompt further discussion and exchange of information. OSHA is particularly interested in alternative methods of identifying suspected cases of TB and in whether the proposed requirements would preclude or impede programs that employers have found to be effective.

Separate Approaches for Health and Non-Health Industries The Approach for Health Industries Should Be Keyed to Existing Industry Standards and That for Non-Health Industries to Guidelines

This suggested alternative incorporates several concepts. First, it assumes that the health and non-health care sectors should be given separate treatment because of differences in existing regulations and expertise. OSHA agrees that sectors that differ in relevant ways should be given different treatment, and the standard therefore has provided for different approaches to different sectors. For example, OSHA's standard does treat facilities that treat TB patients differently from the way it treats those that transfer TB patients out of their facilities, and treats employers whose employees are routinely in contact with client populations with high rates of infectious TB (such as homeless shelters and drug abuse treatment centers) differently from employers whose employees only come into contact with infectious TB cases on an occasional basis (such as attorneys and social workers).

Second, this alternative posits that the health care sector is already subject to an extensive regulatory system with respect to occupational exposure to TB. Although some states have laws on contact tracing and skin testing, and HCFA inspects infection control systems in hospitals and long-term care facilities for the elderly, there are no existing enforceable standards aimed specifically at occupational exposure to TB. Thus OSHA's proposed provisions with respect to preventive measures have no equivalent in existing regulations, and only a limited number of states require skin testing of the kind OSHA's proposed standard requires. OSHA (and CDC) believes that these

provisions are essential to any program to control occupational exposure to TB. Third, proponents of this alternative believe that the non-health care sectors, particularly those engaged in charitable work such as homeless shelters, are better approached through guidelines than regulations. OSHA believes that there is relatively little need to develop guidelines for non-healthcare sectors, such as correctional institutions and homeless shelters, because such guidelines already exist and have not been implemented in many, if not most, facilities. Some proponents of this approach believe that the failure of non-health care sectors to implement existing guidelines is due to the absence of outreach and information. OSHA is not substituting a system of regulation for a system of outreach. OSHA intends to continue a program of outreach on occupational TB, and hopes that facilities in all sectors will adopt appropriate policies before the regulation is finalized. However, given that even in the relatively knowledgeable health care sector, implementation of the CDC guidelines has been limited, it is unlikely that outreach alone can assure the full implementation of suitable measures for control of occupational exposure to TB.

Different Levels of Requirements for Different Industries, Depending on Their Expertise, Resources, and Risk

OSHA's proposed standard recognizes three levels of risk and provides separate treatment for employers engaged in different kinds of activities, where those differences are relevant to the purposes of the standard. This subject is discussed in the next sections. Such tailoring, however, must be consistent with the mandate of the Occupational Safety and Health Act to reduce significant risk to the full extent feasible. OSHA has preliminarily found all of the standard's provisions to be technologically and economically feasible, within the meaning of the Act, for facilities in all affected industries. (The special potential problems of homeless shelters and substance abuse treatment centers are discussed further below.) The statutory requirement to eliminate significant risk to the extent feasible means that if inadequate resources and expertise would make any provision of the proposed standard infeasible, then OSHA would have to consider alternative approaches. However, it also means that the resources and expertise that are feasible for an employer to acquire must be employed if they will reduce significant risk.

Separate Standards for Each Affected Industry

Proponents of this alternative had two goals: first, to assure that OSHA gave full consideration to the circumstances of each affected industry, and second, to make the standard easier to follow for affected small entities. With respect to the first goal, OSHA has recognized a wide variety of distinctions in risk of exposure and practice among affected employers. Some of these differences follow industry lines. Accordingly, the proposed standard includes special provisions for laboratories and home health care providers. However, most of the relevant differences among employers do not strictly follow industry lines, and attempts to write separate standards for different industries would not significantly reduce the complexity of the regulation. For example, all industries need to realize that different requirements are applicable for each of three types of risk of exposure. Similarly, the applicability of certain requirements depends on whether TB patients are treated onsite and on whether certain hazardous procedures are performed. While, for example, the typical nursing home would not treat TB patients or perform high hazard procedures on site, some might, and thus these provisions would need to be included in an industry standard written for nursing homes. OSHA's proposed standard carefully distinguishes a variety of activities that may occur in different industries and has different requirements for each activity. Although this makes the standard somewhat more complex, this approach is essential to avoid a ''one size fits all'' standard. In addition, as presented in the discussion of the scope in the Summary and Explanation of the Preamble, OSHA has developed charts showing the requirements of the proposed standard that are applicable to each industry. OSHA welcomes any suggestions on ways to make the standard easier to understand, or on ways to adapt the standard to the situation of specific industries while reducing significant risk.

Revise the Proposed Standard for Consistency With CDC Guidelines

The issue of how the CDC Guidelines fit into a regulatory scheme to prevent or reduce occupational exposure to TB has been considered by OSHA and other reviewers. OSHA's view is embodied in the proposed standard, in which the Agency has attempted to translate the CDC's recommendations into enforceable regulatory language that can be applied to a variety of occupational settings where the risk of transmission of TB is significant. The Agency believes that, in addition to the basic difference between a ''guideline'' and a ''regulation,'' there are only three general areas where the proposed standard differs substantially from the CDC Guidelines for health care facilities: the use of site-specific risk assessment, the frequency of skin testing in certain situations, and the required use of respiratory protection around unmasked individuals with suspected or confirmed infectious TB. Several small entity representatives, along with some SBREFA Panel members, have suggested that the Agency consider allowing employers to follow the CDC Guidelines as an additional option to comply with the OSHA standard.

Both the OMB and SBA Panel representatives believe that for at least some of the work sites OSHA has proposed to cover, the CDC Guidelines currently provide an adequate measure of protection. They believe it would be burdensome for employers who are already in compliance with the Guidelines to have to become familiar with the OSHA proposal and to implement its provisions. These employers have already invested in a TB prevention and response program consistent with the Guidelines. In other words, the employers have conducted their risk assessments, implemented the suggested provisions and trained their workers to comply. Moreover, these reviewers point out that where the Guidelines have allowed for discretion on the part of the employer as, for example, where an employer may first consider the symptoms specified in the several CDC Guidelines' definition of ''suspected infectious TB'' before adopting a definition for his or her own work site, prevention of the transmission will more easily be achieved because the employer is allowed to tailor the requirements to actual conditions in his or her workplace. To assure that the employer's adoption of the CDC Guidelines is effective, these reviewers recommended that the employer assert or certify that he or she is in compliance and, if challenged in an OSHA inspection, prove the efficacy of his or her program through a performance measure, such as skin test conversion rates. These reviewers believe that this approach will result in a more efficient use of scarce health resources.

OSHA agrees that the various CDC Guidelines are the most important sources for setting an occupational health standard that will reduce or prevent the spread of TB. However, although certain facilities adhere to the

Guidelines, OSHA's research has shown that most facilities have not fully implemented the CDC recommendations. TB remains an occupational hazard, and OSHA has preliminarily concluded that the risk of transmission of TB to employees is significant. OSHA believes there are a number of reasons why the Guidelines cannot take the place of an OSHA standard. First, the Guidelines are not written in language that can be enforced. For example, the Guidelines suggest, recommend and set forth what an employer could or should do, not what he or she must do. Unless the Guidelines are converted to regulations, an employer may adhere to some applicable recommendations while not implementing others, which could result in uneven and inadequate employee protection. OSHA standards are written in mandatory language, letting employers and employees know what they have to do in order to be in compliance with the regulation. This permits an employer, an employee or a compliance officer to determine easily whether an entity is in compliance with a standard. Second, the establishment-specific risk assessment approach of the Guidelines imposes a tremendous paperwork burden on covered entities and requires a level of professional expertise in risk assessment that few entities outside of large hospitals possess. OSHA believes that recommendations or regulations that necessitate this level of expertise could make it difficult to determine if an entity is in compliance. Third, OSHA knows of no objective criterion that could be reliably used as a measure of proof of an effective program. Tuberculin skin testing has been suggested as a means of proving compliance with the CDC Guidelines, e.g., zero conversions would be accepted as proof that an entity was complying with the Guidelines. However, the use of conversions as a compliance measurement has two problems. First, skin test conversions are not necessarily indicative of implementation of the Guidelines' recommendations. For example, an entity may have implemented very few of the Guidelines' recommendations, yet been fortunate enough to experience no conversions. Therefore, compliance with the Guidelines' recommendations has not been achieved even though there have been no employee conversions. Furthermore, while an increase in the number of conversions indicates employee exposure, a lack of conversions does not necessarily mean that employees are not being exposed. For example, some employees have already skin-tested positive, not all exposures result in conversions, and many entities will not have enough TST-negative employees to generate sufficient statistical power to accurately determine an increased conversion rate. With regard to this last point, the CDC states:

> A low number of HCWs in a specific area may result in a greatly increased rate of conversion for that area, although the actual risk may not be significantly greater than that for other areas. Testing for statistical significance (e.g., Fisher's exact test or chi square test) may assist interpretation; however, lack of statistical significance may not rule out a problem (i.e., if the number of HCWs tested is low, there may not be adequate statistical power to detect a significant difference). Thus, interpretation of individual situations is necessary. (Ex. 4B)

Second, OSHA believes that reliance on number of TST conversions as a performance measure is reactive rather than proactive, because it emphasizes the identification of employees who have already incurred a status change as a result of an exposure instead of averting exposures.

OSHA believes that compliance with the proposed standard by all affected facilities within the covered sectors is the way to assure that employees will be protected from occupational transmission of TB. The Agency believes that compliance will not be difficult for employers who have already implemented the Guidelines, because many of the elements of the Guidelines have been incorporated into the proposed standard. Also, employers who are not in compliance with the Guidelines will find that the standard gives them clear instructions on what to do. In addition, the structure of OSHA's proposed TB standard is similar to that of the Bloodborne Pathogens standard (BBP). Since the vast majority of workplaces that will be covered by the TB standard are subject to BBP, becoming familiar with and implementing the requirements of the TB standard should not be difficult.

Another issue raised in the review process was what would happen if, after the OSHA standard was promulgated, the CDC issued a new guideline that was different from the OSHA standard on an item addressed by the standard. OSHA believes this is already addressed by OSHA's citation policy, in particular, the policy for De Minimis Violations, which states that violations of standards which have no direct or immediate relationship to safety or health are not to be included in citations. An example of a de minimis violation occurs when an employer complies with a proposed OSHA standard or a consensus standard rather than with the OSHA standard in effect at the time of the inspection and the employer's action clearly provides equal or greater employee protection [OSHA Field Inspection Reference Manual, Instruction CPL 2.103, September 26, 1994]. In cases where an employer is complying with another provision, such as a consensus standard, the Agency looks at the consensus standard to make sure the consensus standard is at least as protective as the OSHA standard. Because CDC Guidelines reflect the views of many of the country's leading experts and practitioners in public health measures to prevent the spread of TB, the updated CDC Guidelines can be assumed to provide equal or greater protection against occupational transmission of TB to employees. Because these guidelines carry great authority, the De Minimis Violation policy would not only be a defense, but would be accorded such deference that OSHA would incur a heavy burden in showing that an updated CDC guideline on an item addressed by the OSHA TB standard did not provide equal or greater protection against occupational transmission of TB to employees. In order to ensure that the new CDC Guidelines would be communicated to the OSHA Regions and others who would need to know, OSHA will issue a Memorandum for Regional Administrators that will address how the new Guideline could be implemented in the work place, include a copy of the new Guideline, and instruct the Regional Administrator to contact area offices and the OSHA state designees. In addition, the Memorandum would be posted on the OSHA Computer Information Service (OCIS) and OSHA CD–ROM, which are accessible to the public.

OSHA seeks comment on all issues related to the CDC Guidelines, particularly whether they could be implemented in lieu of an OSHA standard and, if so, how compliance and efficacy could be determined.

Change the Approach to the Identification of Suspect Cases for Homeless Shelters or Substance Abuse Treatment centers

The SBREFA Panel found that ''Given the current definition of suspect cases, it is not clear that homeless shelters can comply fully with the standard. Accordingly, OSHA should reexamine the definition of suspect cases and/or reexamine its approach to homeless shelters.'' The SBREFA Panel also noted that this same finding might be relevant to substance abuse treatment centers. The Panel arrived at this finding as a

result of statements made by small entity representatives from the homeless shelter sector. Small entity representatives concerned with homeless shelters had serious problems with OSHA's definition of a suspect case and questioned the feasibility of screening the homeless by using questions about symptoms. Mr. Wayne Anderson of the National Health Care for the Homeless Council argued that OSHA's definition of a suspect case would result in the identification of most of the homeless as suspect cases during the winter months. Major Dalberg of the Salvation Army found OSHA's definition of a suspect case confusing and ambiguous, and stated that it would cover a substantial portion of the homeless. All three small entity representatives from this sector questioned whether the standard's screening procedures were workable in the homeless shelter context. They asserted that the homeless might avoid screening questions, be unable to answer them, learn how to lie in response to such questions, or choose to remain on the street rather than be transferred to a hospital. The small entity representatives for this sector felt that this portion of the standard should be abandoned. Because substance abuse treatment centers serve a similar clientele, the Panel was concerned that the same problems might apply to substance abuse treatment centers.

To address this issue, and other issues related to the feasibility of the proposed standard for homeless shelters, OSHA has decided to hold special sessions during the public hearings on the proposed standard and to study these issues further through an onsite survey of a number of homeless shelters. The study will address the following issues:

- Percentage of homeless persons that would be identified by OSHA's definition of a suspected infectious TB case. (Breakdown of which symptoms are particularly common so a better definition might be designed.)
- Turnover among the homeless who use shelters.
- Employee turnover in homeless shelters.
- Trends in number of homeless persons served in shelters.
- Criteria currently used by some homeless shelters to identify suspected infectious TB cases.
- Current practices used in homeless shelters to address the TB hazard (baseline compliance with the draft proposed standard).

—Methods of isolation.
—How suspected TB cases are handled.

- Feasibility of having hospitals provide cards to the homeless indicating TB skin test status.
- Number of TB skin test conversions and active cases among the homeless and homeless shelter employees.
- Types of benefits offered to homeless shelter employees (e.g., health insurance).
- Economic feasibility:

—Costs of running a shelter.
—Revenue sources.
—How costs are accommodated as the number of homeless persons served increases.
—Opportunities for cost pass-through.

- Number, location and types (e.g., family-oriented, walk-in, all-male) of homeless shelters.
- Number or proportion of homeless shelter workers who are unpaid volunteers.

The study will also address the issue of volunteers. The OSH Act applies to employees, not bona fide volunteers; however, OSHA understands that some states may, as a matter of state law, require facilities to provide volunteers with the protections established by OSHA standards. Thus, OSHA's study will address the following issues:

- Economic impacts, in such states, of covering volunteers (e.g., how costs would be handled, cost pass-through opportunities).
- Protections currently offered to volunteers.

The results of the study will be made available for comment in the public record.

OSHA does not feel that the same problems apply to substance abuse treatment centers, even if a high percentage of clients might be defined as suspect cases. Inpatient substance abuse treatment centers routinely provide some form of entrance physical: this would be an appropriate time to screen for suspect cases and provide for their referral.

Outpatient substance abuse treatment centers do not provide any form of shelter for patients, and thus could readily refer suspect cases to a hospital without either denying them shelter or having to pay for the referral. Such a facility could simply insist that suspect cases not return without data showing that they had been to a doctor and did not have TB. Since outpatient facilities handle a known population, such an approach might involve high initial referrals, but could thereafter settle into a system that checked for suspect cases on entry to the program.

OSHA estimates that the proposed standard will result in a reduction of 28 to 33 active disease cases and 2 to 3 deaths per year in the homeless shelter sector. A standard requiring skin testing and follow-up treatment alone would have only one third the benefits (such an approach would reduce the number of active disease cases to only 10 per year and the number of lives saved to 1 per year). The annual costs of the proposed standard for homeless shelters are estimated to be $11,287,278, or approximately $1,080 per shelter per year.

OSHA solicits comments on all of the issues listed above to be covered by its study of homeless shelters, and solicits comment on the feasibility of the standard for substance abuse treatment centers, and particularly on the extent to which substance abuse treatment centers already provide for medical examinations prior to entry into their programs.

Other Alternatives Considered by OSHA

OSHA considered several additional alternatives but has preliminarily concluded that the proposed rule will better carry out the objectives of the OSH Act, while minimizing the economic impact on affected establishments, and especially on small establishments. OSHA requests comment on the validity of this preliminary conclusion. First, OSHA considered making all of the proposed requirements applicable to every establishment in the covered industries. The prevalence of TB, however, varies by geographical areas and by the populations served by facilities in different industries. OSHA therefore believes it will be possible to reduce significant risk without imposing the full regulatory requirements on each covered employer. Second, OSHA considered proposing requirements similar to the CDC's guidelines, which recommend that risk assessments be conducted to determine the level of risk in each facility and that the controls implemented vary in accordance with the level of risk in each facility. This would require that employers conduct risk assessments by evaluating factors, such as the number of suspected or confirmed TB cases among patients and employees, employee tuberculin skin testing results, and the amount of TB in the community. The CDC recommendations include five levels of risk (i.e., minimal, very-low, low, intermediate, and high), and the recommended controls vary by the level of risk. However, adopting such a requirement in the OSHA standard would impose a large cost and a heavy paperwork burden on affected facilities.

To avoid imposing unnecessary burdens on facilities where the risk of

occupational exposure to *M. tuberculosis* may be lower, OSHA is proposing to exempt facilities from certain requirements (i.e., respiratory protection, annual medical histories, and annual skin tests) if the facility transfers, instead of admits, individuals with suspected or confirmed infectious TB and can additionally demonstrate that there have been (1) no reported confirmed infectious TB cases in the county within one of the last two 12-month reporting periods; (2) fewer than 6 infectious cases of TB in the other 12-month reporting period; and (3) no infectious cases of TB encountered within their employees' work settings within the past 12 months.

OSHA also considered proposing a requirement that facilities implement engineering controls in all intake areas in which early identification procedures are performed, if the facility had encountered six or more individuals with confirmed infectious TB in the past 12 months. The engineering controls considered were single-pass ventilation, filtration of air through the use of HEPA filters installed as part of the ventilation system, or stand-alone auxiliary HEPA filtration units. However, areas where early identification procedures are performed vary widely in size and configuration, making it difficult to assess the effectiveness of such controls in reducing the risk of occupational exposure to *M. tuberculosis* in a particular setting. Given the high cost of such controls and the lack of data on their effectiveness, OSHA is not proposing such a requirement. However, the Agency requests comment on the potential effectiveness of such controls in intake areas.

Another alternative considered was to propose that each occupationally exposed employee be provided with a baseline medical examination, including a physical examination that emphasized the pulmonary system and an evaluation for the signs and symptoms of active TB disease and factors affecting immunocompetence. However, requiring a baseline physical examination for all exposed employees would impose a heavy cost burden on affected establishments, and OSHA could find no evidence that providing a baseline physical examination would accomplish more than a baseline and annual medical history and tuberculin skin test in identifying or reducing occupationally induced TB infections. Thus, OSHA is proposing to require physical examinations only when they are deemed necessary by the physician or other licensed health care professional, as appropriate.

OSHA also considered providing medical management and follow-up to each employee who had been exposed to air originating from an area where an individual with suspected or confirmed infectious TB was present. However, stakeholders contacted prior to the issuance of this proposal stated that a requirement for medical management and follow-up would impose an unnecessary burden on affected establishments for those cases that were suspected but were subsequently ruled out. In response to stakeholders' comments, the Agency is proposing that medical management and follow-up be provided only when an employee is actually exposed to an individual with confirmed infectious TB or to air containing aerosolized *M. tuberculosis* without the benefit of the applicable exposure control measures (e.g., respiratory protection) that would be required under the proposed rule.

Another alternative considered was to require tuberculin skin tests every six months for all employees assigned to wear respirators. However, to reduce the burden on facilities that do not encounter many infectious TB cases, OSHA is not requiring 6-month skin testing for workers assigned to wear respirators and who work in the intake areas of facilities where fewer than six confirmed infectious TB cases are encountered each year.

Rejecting these regulatory alternatives has reduced the estimated costs of the proposed rule by a minimum of $100 million.

The RFA emphasizes the importance of performance-based standards for small businesses. OSHA considers the proposed standard to be highly performance oriented. The proposed standard emphasizes the early identification and isolation of individuals with suspected or confirmed infectious TB. Affected employers have been allowed wide discretion in the selection of procedures they use to achieve this. Without early identification and isolation, prevention of the spread of TB from patients and clients to workers is virtually impossible. OSHA has also limited requirements for work settings located in a county that, in the past 2 years, has had zero cases of confirmed infectious TB reported in one year and fewer than 6 cases of confirmed infectious TB reported in the other year. OSHA welcomes comment on other ways that the standard can be made more performance oriented.

Another approach considered is compliance date phase-ins for small businesses. OSHA is proposing to extend the standard's compliance deadlines for engineering controls and has considered extending the compliance deadlines for the other proposed requirements; however, since these other requirements are not capital-intensive for most affected facilities, such an extension would do little to reduce the burden on small entities and would only result in a delay in the protection of workers provided by compliance with the proposed rule. OSHA solicits comment on the effects of extending phase-in dates for the other proposed requirements, particularly those for respirators, for small entities.

After considering all of the above alternatives and adopting those that were consistent with the mandate imposed by the OSH Act, OSHA has developed a proposed rule that will minimize the burden on affected employers, while maintaining the necessary level of worker protection.

OSHA's Response to SBREFA Panel Recommendations

Table VII–7 lists the SBREFA Panel Recommendations and OSHA's response to these recommendations. The complete SBREFA Panel Report is available for comment in the record as Exhibit 12 of Docket H–371.

TABLE VII–7.—OSHA'S RESPONSES TO SBREFA PANEL RECOMMENDATIONS

Panel recommendation	OSHA response
OSHA should define the terms ''establishment,'' ''firm'' and ''facility'' in the IRFA.	These terms are now defined in Chapter VI of the PEA.
OSHA should consider analyzing additional size classes of firms	OSHA now uses the SBA definitions of small entities and also analyzes entities with fewer than 20 employees in the IRFA.
OSHA should clarify and more carefully explain the requirements and engage in extensive outreach efforts to assure that the regulated community understands the regulation.	OSHA has provided tables illustrating requirements for groups of affected firms, added many clarifications to the Preamble and regulatory text, and plans extensive outreach upon publication of the final standard (see Preamble Section IX).

TABLE VII–7.—OSHA'S RESPONSES TO SBREFA PANEL RECOMMENDATIONS—Continued

Panel recommendation	OSHA response
OSHA should reexamine the definition of a suspect case and/or reexamine its approach to homeless shelters.	OSHA will conduct a special study of homeless shelters. This study is discussed in the IRFA. OSHA will also designate certain hearing dates for persons who wish to testify on homeless shelter issues.
OSHA should reconsider applying the standard to substance abuse centers.	OSHA has explained in the IRFA why it thinks that its treatment of substance abuse treatment centers is feasible and has solicited comment on this issue in the Issues Section of the Preamble.
OSHA should more carefully address the economic impacts on facilities that rely on Medicaid/Medicare or charitable funding.	OSHA has added a discussion of this issue to Chapter VI of the PEA.
OSHA's preamble and IRFA should explain OSHA's role and authority as compared to other voluntary and regulatory organizations; preamble should explain ongoing cooperative efforts; solicit comments on conflicts and ways of better coordinating with other organizations.	OSHA has added a preamble discussion of why OSHA regulates occupational exposure to TB, why other organizations are unable to do so effectively, and how OSHA has worked with other organizations. OSHA solicits comments on possible conflicts and better methods of coordination.
OSHA should examine additional alternatives, such as revising the proposed standard for greater consistency with CDC guidelines.	OSHA has added a discussion of additional alternatives suggested by SBREFA Panel members to the IRFA and has solicited comment on these alternatives in the Preamble.
OSHA should clarify that employers would only be required by the standard to determine the TB status of their county once per year, rather than monthly.	OSHA has clarified this issue in the Preamble.
OSHA should reexamine the standard and the economic analysis to ensure that the issues of part-time, multi-employer, and off-site workers have been adequately addressed. OSHA should also specifically address the issue of portability of training. OSHA should clarify the term ''accessibility'' in the context of employers with off-site employees.	OSHA has modified the standard to allow portability of non-site specific elements of training and to allow portability of skin tests. For off-site workers, OSHA has clarified in the Preamble that the standard may be made available at the primary workplace facility, provided there is a mechanism for immediate availability of information during the workshift.
OSHA should clarify exactly what is required for temporary AFB isolation.	The Summary and Explanation Section of the Preamble describes temporary AFB isolation, and OSHA's assumptions concerning the costs of such units are given in Chapter V of the PEA.
OSHA should clarify that engineering control provisions do not apply to home health care.	OSHA has clarified the point in Section IX of the Preamble.
OSHA should explain the differences in protection provided by surgical masks and respirators.	OSHA has explained this difference in Section IX of the Preamble.
OSHA should explain the reasons for its detailed respiratory protection program, why it considers manufacturers' instruction inadequate as a substitute for a respirator program, and why annual respirator program evaluation is necessary.	OSHA has discussed this issue in the Summary and Explanation Section of the Preamble.
OSHA should explain its intent to fold many aspects of respiratory protection provisions for occupational exposure to TB into the upcoming respirator standard.	OSHA has discussed this issue in the Summary and Explanation Section of the Preamble.
OSHA should explain the number of employees required to have medical surveillance in homeless shelters, the elements of a written medical opinion, and the importance of two-step skin testing.	OSHA provides an estimate of the number of employees requiring medical surveillance in Chapter V of the PEA. The regulation lists the elements of a medical opinion. The Preamble explains the importance of two-step skin testing.
OSHA should explain its basis for believing that two-step skin testing is appropriate for employees who have had BCG vaccinations.	OSHA has discussed this issue in the Summary and Explanation Section of the Preamble.
OSHA should clarify the interaction of workers' compensation and medical removal protection and examine more carefully the costs and impacts of medical removal protection on small firms that actually have an employee with a serious and costly active case of TB.	OSHA has addressed this interaction in both the Preamble and the IRFA, and has provided a special discussion in Chapter VI of the PEA on the economic impacts of the medical removal protection provision on small firms. OSHA has solicited comment on this issue.
OSHA should examine the potential cost savings associated with a provision that allows training to be ''portable'' (assuming the training is equivalent to that required by the standard). OSHA should clarify that posting a copy of the standard will be considered an adequate means of providing employees with the standard. OSHA should clarify its performance-oriented interpretations of the training requirements in the Preamble, and OSHA should examine the need for annual retraining for all employees.	OSHA has modified the proposed regulation to allow portability of non-site specific training and to allow employers to demonstrate employee competence rather than provide annual retraining. OSHA has clarified in the Preamble that posting a copy of the standard will be considered an adequate means of providing employees with the standard. OSHA has clarified in the preamble that the training is performance oriented and need not include training in topics not relevant to an employee's duties.
OSHA should clarify how the identification, referral, and notification requirements of the proposed standard can be met without breaching federal and state confidentiality regulations and statutes.	OSHA has added a discussion of this issue to the IRFA and the Preamble.
OSHA should include a discussion of the interaction between medical removal protection provisions and the Americans with Disabilities Act and the Family and Medical Leave Act.	OSHA has added a discussion of this issue to the IRFA and the preamble.
OSHA should solicit comment and request data on industry turnover rates in the Summary of the Preliminary Economic Analysis in the Preamble.	OSHA has solicited comment on this issue.
OSHA should reexamine its estimate of the number of hospices and adopt the most accurate figure.	OSHA has reexamined the issue of the number of hospices and retained its original estimate. OSHA has clarified that this estimate includes only free-standing hospices. Hospices that are parts of nursing homes and hospitals are included in estimates for those sectors.

TABLE VII–7.—OSHA'S RESPONSES TO SBREFA PANEL RECOMMENDATIONS—Continued

Panel recommendation	OSHA response
OSHA should clarify why family practice physicians were not included in the analysis, and solicit comment on the extent to which family practitioners conduct the kind of hazardous procedures that would place them within the scope of the rule.	OSHA has added physicians who conduct high hazard procedures to its economic analysis and has sought comment on whether family practitioners commonly conduct such procedures.
OSHA should consider estimating the effects of the rule on volunteers and should include a discussion explaining that the proposed rule does not apply to volunteers, although some states may choose to apply it to these categories of individuals.	OSHA has explained in the Preamble that the standard does not apply to bona fide volunteers. OSHA has solicited comments on states or localities that elect to extend OSHA requirements to volunteers and on the number of affected volunteers. OSHA will further examine the issue of the number of potentially affected volunteers in homeless shelters in its homeless shelter study.
OSHA should solicit comment on the number of small government jurisdictions affected by the draft proposed standard.	OSHA has solicited comments on this issue in the Preamble.
OSHA should include a discussion of tribal governments in its analysis and solicit comment on this issue.	OSHA has provided an estimate of the number of affected tribal facilities and has sought comment from tribal governments in the Preamble.
OSHA should remind small entities that OSHA's risk assessment will be part of the public record and is subject to comment, and that small entities may submit any appropriate additional literature or studies that OSHA should consider in determining the risk of occupational TB.	OSHA has solicited comments on several specific aspects of the risk assessment and benefits analysis, and on these analyses as a whole.
OSHA should discuss the annualization of costs in greater detail in the economic analysis.	Chapter V of the PEA and the summary of the PEA in the Preamble now discuss the annualization of costs.
OSHA should clarify its position on the costs and durability of various respirators that can be used to comply with the standard, and should seek additional comment on the costs and durability of respirators.	OSHA has reanalyzed the costs of respirators in hospitals, and has added a discussion of the uncertainties concerning the costs and durability of respirators to the PEA. OSHA has solicited comments on these issues in the Preamble.
OSHA should perform further analyses to identify the marginal costs of medical removal protection above and beyond worker compensation, should further assess the probability that employers will actually incur costs for medical removal protection if they have an employee with an active case of TB, and should incorporate the results of this reexamination into its determination of feasibility.	OSHA specifically addresses this issue in Chapter VI of the PEA and has sought comment on this issue.
OSHA should reassess whether affected facilities have reasonable access to facilities with AFB isolation rooms, solicit comments on this issue, and incorporate the results of this reexamination into its determination of feasibility.	OSHA has further examined this issue, and found that affected facilities do have reasonable access to AFB isolation rooms; however, OSHA is seeking comments on whether some affected facilities may not have adequate local access to facilities with AFB isolation.
OSHA should reexamine its analysis of the economic impacts of the proposed rule on firms, such as emergency medical services firms, that operate under the constraint of being unable to charge some of their clients.	OSHA has discussed this issue in Chapter VI of the PEA.

VIII. Unfunded Mandates Analysis

The proposed TB standard has been reviewed in accordance with the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*) and Executive Order 12875. OSHA estimates that compliance with the proposed standard will require expenditures of more than $100 million each year by employers in the private sector. Therefore, the proposed TB standard establishes a federal private sector mandate and is a significant regulatory action within the meaning of Section 202 of UMRA (2 U.S.C. 1532). OSHA has included this statement to address the anticipated effects of the proposed TB standard pursuant to Section 202.

OSHA standards do not apply to state and local governments except in states that have voluntarily elected to adopt an OSHA State Plan. Consequently, the proposed TB standard does not meet the definition of a ''federal intergovernmental mandate'' (Section 421(5) of UMRA (2 USC 658 (5)). In sum, the proposed TB standard does not impose unfunded mandates on state, local, and tribal governments.

The remainder of this section summarizes OSHA's findings as required by Section 202 of UMRA (2 U.S.C. 1532):

This standard is proposed under Section 6(b) of the OSH Act. The proposed standard has annualized costs estimated at $245 million and would save an estimated 138 to 190 lives per year as a result of TB infections avoided. An estimated 1,772 to 2,442 active TB cases will be averted annually as a result of the proposed rule. Compliance will also result in an estimated 24,333 to 32,719 infections averted. The proposed standard will impose no more than minimal costs on state, local or tribal governments. OSHA pays 50 percent of State plan costs but does not provide funding for state, local or tribal governments to comply with its rules.

OSHA does not anticipate any disproportionate budgetary effects upon any particular region of the nation or particular state, local, or tribal governments, or urban or rural or other types of communities. Chapters V and VI of the economic analysis provide detailed analyses of the costs and impacts of the proposed standard on particular segments of the private sector. OSHA has analyzed the economic impacts of the standard on the affected industries and found that compliance costs are, on average, only 0.18 percent of sales, and that few, if any, facility closures or job losses are anticipated in the affected industries. As a result, impacts on the national economy would be too small to be measurable by economic models. OSHA requests information on state and local government issues.

Pursuant to Section 205 of the UMRA (2 U.S.C. 1535), and having considered a variety of alternatives outlined in the Preamble and in the Regulatory Flexibility Analysis above, the Agency preliminarily concludes that the

proposed rule is the most cost-effective alternative for implementation of OSHA's statutory objective of reducing significant risk among employees to the extent feasible. OSHA solicits comment on these issues.

IX. Environmental Impacts

The provisions of this proposed standard have been reviewed in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969 [42 U.S.C. 432, *et seq.*], the Council on Environmental Quality (CEQ) NEPA regulations [40 CFR Part 1500], and OSHA's DOL NEPA Procedures [29 CFR Part 11]. As a result of this review, OSHA has preliminarily determined that this proposed standard will have no significant effect on air, water, or soil quality, plant or animal life, use of land, or other aspects of the environment.

X. Summary and Explanation of the Standard

Based on currently available data in the record, OSHA has preliminarily concluded that the requirements set forth in this proposed standard are those that are necessary and appropriate to provide adequate protection to employees exposed to tuberculosis (TB). In the development of this proposed standard, OSHA has carefully considered the numerous reference works, journal articles, and other data collected by OSHA since the initiation of this proceeding. In particular, OSHA has carefully considered the recommendations given in the document, ''Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities'' published by the Centers for Disease Control and Prevention beginning on page 54242 in the **Federal Register** of October 28, 1994 (Ex. 4B). OSHA also held a series of informal stakeholder meetings during the development of the proposal and considered the major points raised by the stakeholders during these meetings (Ex. 10). In addition, the proposal has undergone the Panel review process required by the Small Business Regulatory Enforcement Fairness Act (SBREFA)(5 U.S.C. Chapter 8) (Exs. 11 and 12). All of the information developed to assist the small entity representatives involved in the SBREFA panel process, the comments of these representatives, and the Panel's findings and recommendations to OSHA have been placed in the rulemaking record (Exs. 11 and 12).

Upon publication of the final standard, the Agency will undertake a number of compliance assistance activities that will be particularly beneficial to small entities. Past compliance assistance activities have included: publication of booklets summarizing the provisions of the standard; development of a compliance directive that answers compliance-related questions about the standard; development of compliance guides directed at assisting small businesses in complying with the standard; designation of certain OSHA employees in each Regional office with the responsibility of answering questions from the public about the standard; development of training materials; and provision of speakers and information for meetings and workshops of affected parties (particularly small business entities). OSHA anticipates initiating similar activities upon publication of the final standard for occupational exposure to tuberculosis.

Paragraph (a) Scope

Tuberculosis is a well-recognized occupational hazard (Ex. 4B). As discussed in the Health Effects section above, there are numerous epidemiological studies, case reports, and outbreak investigations that provide evidence to show that employees who are exposed to aerosolized *M. tuberculosis* have become infected with TB and in some cases have developed active TB disease. Of particular concern is the emergence of strains of multidrug-resistant TB. MDR–TB presents an additional hazard because individuals with MDR–TB may be infectious for weeks or months until an effective drug regimen can be successfully implemented and the patient rendered noninfectious. This in turn increases the likelihood that employees who must provide health care or other services to these individuals will be exposed. The risk of death from infections with MDR–TB is markedly increased. Outbreaks involving strains of MDR–TB have had mortality rates as high as 75% with death occurring 4 to 16 weeks after the diagnosis of disease (Ex. 3–38A).

Most of the TB outbreaks investigated occurred in large metropolitan areas. However, a recent study has shown that MDR–TB spread from New York City to patients in Florida and Nevada and health care workers in Atlanta, Georgia and Miami, Florida and to staff and patients in a nursing home in Denver, Colorado (Ex. 7–259). In addition, a growing percentage of TB cases are occurring among the foreign born. CDC reported that in 1995 the number and proportion of cases among the foreign-born had increased 63% since 1986 (Ex. 6–34). These two pieces of information taken together clearly illustrate the relationship between population mobility and the spread of TB disease. Thus, TB is a nationwide problem. Although the total number of cases declined to its pre-1985 levels after a resurgence from 1985 to 1994, the rate of active TB cases reported in 1995 (i.e., 8.7/100,000) is still two and one half times greater than the target rate of 3.5 active cases per 100,000 population for the year 2000 proposed by the Advisory Committee on the Elimination of Tuberculosis (Ex. 6–19). In addition, there is substantial variability from year to year in the increases and decreases in the number of cases reported by each state. In 1995, all fifty states reported cases of TB, and fifteen of these reported increases over 1994 (Ex. 6–34). At the county level, approximately 57% of counties in the U.S. reported one or more cases of active TB, with 17% of the counties in the U.S. reporting 5 or more cases (Ex. 7–262). In addition, approximately 91% of the U.S. population resides in the counties that reported one or more cases of active TB. Thus, while 43% of the counties in the U.S. reported no cases of active TB, 10% of the U.S. population resides in those counties. The nationwide prevalence of TB infection in the U.S. population in 1994 (age 18 years an older) is approximately 6.5 percent.

The recent resurgences in the number of reported cases of active TB have brought to attention a number of problems in existing TB control plans. The problem is most apparent in health care facilities such as hospitals, but it also extends to other work settings where the population served is at increased risk for tuberculosis, such as shelters for the homeless, correctional institutions and settings where high-hazard procedures are performed.

There are a number of factors that make occupational exposure to tuberculosis an important concern at the present time. One factor is that the results from OSHA's quantitative risk assessment show a high potential for TB infection for employees who work in close proximity to individuals with infectious TB. A second factor is that the cases of tuberculosis are not distributed evenly throughout the entire population. There is a relatively high prevalence of tuberculosis infection and disease in certain populations, such as residents of nursing homes and inmates of correctional institutions. A third factor is the rise of MDR-TB. These factors increase the risk for workers who have occupational exposure. Occupational exposure occurs through contact with air that may contain aerosolized *M. tuberculosis* as a result of the performance of an employee's

duties. Most often this occurs when an employee is working in the same environment with an individual with infectious TB. It could also occur when repairing air systems that may be carrying aerosolized *M. tuberculosis.*

Individuals with infectious tuberculosis expel airborne particles called droplet nuclei when they cough, sneeze, or speak. These droplet nuclei contain the organism that causes tuberculosis, *M. tuberculosis.* Normal air currents can keep these droplet nuclei airborne for long periods of time and spread them throughout a building (Ex. 5–5). When employees breathe the air that contains *M. tuberculosis,* they are at risk for TB infection which may result in illness and, in some cases, death. Employees also may be exposed when laboratory procedures produce aerosols of *M. tuberculosis.* There is an extensive discussion of the scientific literature related to occupational transmission in Section IV, Health Effects, which will not be repeated here.

Because the CDC does not consider fomites, e.g., objects such as clothing or silverware, to present a hazard for transmission of *M. tuberculosis,* this standard is designed to eliminate or reduce airborne exposures only. Even though it is well established that exposure to TB contaminated air is the route of exposure related to the development of disease, it is not known what levels of contamination in the air cause the disease. Unlike toxic chemicals, a Permissible Exposure Limit (PEL) for air concentration of TB cannot be determined. As described in the Health Effects section of this preamble, it is known that a number of factors contribute to the probability of infection. For example, exposures of relatively short duration, such as a day or two, can result in infection of the employee. OSHA has used these findings to show that certain types of work, in certain industries, can result in significant risk of TB infection. For these reasons, OSHA is defining the scope of the standard by listing the locations and services where this proposed standard would apply. Employers with employees working at those locations, and employers whose employees provide the listed services, are covered by the standard. The proposed standard applies to occupational exposures to tuberculosis that occur in certain specified workplaces, such as a hospital, or as the result of providing services, such as emergency medical treatment. Paragraphs (a)(1) through (10) of the proposal describe the various work settings and services that are covered under the scope of the standard.

Paragraph (a)(1) states that the standard applies to occupational exposure to TB occurring in hospitals. The record contains many examples of occupational exposures with resultant TB infection and disease that have occurred in hospitals (e.g., Exs. 5–11; 5–15; 7–43; 7–45). Recent outbreaks involving multidrug-resistant strains of *M. tuberculosis* have compounded the long recognized risk of TB in such settings.

Hospitals not only provide medical care for persons with diagnosed tuberculosis, they also provide medical care for individuals who may be at increased risk for TB. For example, hospitals provide isolation for individuals with suspected or confirmed infectious TB and contain rooms or areas where high-hazard procedures on individuals with infectious TB are performed that place employees at risk of exposure. In addition, the client population encountered in hospitals is generally at higher risk of developing active TB. Individuals with HIV disease, for example, are at increased risk for developing disease when they have been infected with *M. tuberculosis.* In addition, medically underserved populations with an increased prevalence of tuberculosis (e.g., homeless persons) may seek acute care in the emergency rooms of hospitals.

Employees who are at risk for occupational exposure and potential infection and disease include all employees who have direct contact with persons with infectious tuberculosis. These may include but are not limited to physicians, nurses, aides, dental workers, medical technicians, workers in laboratories and autopsy suites, and emergency medical service personnel (Ex. 4B). They may also include persons not involved in direct patient care but who have occupational exposure as a result of providing other services such as dietary, housekeeping, and maintenance staff.

Paragraph (a)(2) covers occupational exposure occurring in long-term care facilities for the elderly. Persons aged 65 and older constitute a large repository of *M. tuberculosis* infection in the United States (Ex. 6–14). Many of these individuals were infected many decades ago when TB was a much more common disease. Some of the TB occurring in this age group arises from preexisting infection of long duration and other cases may be the result of recent infections. In addition, elderly persons residing in nursing homes are at greater risk than elderly persons living in the community. In its 1990 guidelines, ''Prevention and Control of Tuberculosis in Facilities Providing Long-term Care to the Elderly,'' the CDC cited 1984–1985 data indicating a TB case rate of 39.2 per 100,000 population, a rate that was twice that of elderly persons living in the community (Ex. 6–14). The same document stated that CDC had found that the increased risk for nursing home employees was three times higher than the rate expected for employed adults of similar age, race, and sex. Examples of employees in long-term care facilities who may have occupational exposure include, but are not limited to, registered nurses, licensed practical nurses, nursing assistants, and auxiliary personnel. OSHA has not included other long-term care facilities under the scope of the standard. The Agency requests comment and supporting data on whether it is appropriate to expand the scope of the standard to include other long-term care facilities that may provide health care or other services to individuals who may be at an increased risk of developing infectious TB, thereby presenting a potential source of exposure to employees working in those facilities. An example of another long-term care facility is a psychiatric hospital.

Paragraph (a)(3) covers occupational exposure occurring in correctional facilities and other facilities that house inmates or detainees. Facilities such as prisons, jails and detainment centers operated by the Immigration and Naturalization Service (INS) would be included in the scope of the standard. The CDC considers TB to be a ''major'' problem in correctional institutions, with cases occurring at a frequency three times that of the general population (Ex. 7–25). In addition to a number of outbreaks that have occurred, the overall incidence of tuberculosis in the prison population is increasing. This can be attributed to, (1) the over-representation of populations at high risk for TB in prisons and jails, and (2) environmental factors that promote the transmission of TB. Compared to the general population, inmates have a higher prevalence of TB infection. The population of correctional facilities is also characterized as having a high prevalence of individuals with HIV infection and intravenous drug users, factors that place these inmates at a higher risk of developing active TB. In addition, many prisons and jails are old, overcrowded, and have inadequate ventilation. Inmates may be moved frequently within a facility and between facilities, increasing the number of persons, both inmates and employees, exposed to an infected individual and making contact tracing difficult.

Medical records and treatment information may not follow the inmate in a timely manner, which may, in turn, lead to inadequate drug therapy.

Detention facilities, such as those operated by the INS, may house persons who are entering this country from countries with a prevalence of TB many times that of the U.S. population (Ex. 6–26). In addition, there may be a substantial number of individuals in these facilities currently awaiting deportation who have an additional increased risk of TB because they have been previously incarcerated in correctional institutions. In 1995, CDC reported that approximately 36% of the total reported cases of active TB were among the foreign-born (Ex. 6–34). This marks a 63% increase since 1986. In addition, among those persons whose records contained information on date of arrival to the U.S., approximately 30% developed active TB within one year of entering the country and approximately 53% developed active TB within 5 years of entering the country. Employees who may have occupational exposure in these facilities include, but are not limited to, correctional officers, physicians, dentists, nurses, and other health care workers.

Paragraph (a)(4) covers occupational exposure occurring in hospices. CDC identified hospices as one of the inpatient health care facilities to which its 1994 TB guidelines apply. CDC's Guidelines recommend that individuals with suspected or confirmed infectious TB be managed in the same manner using similar methods of infection control as recommended for hospitals. Hospices serve the same high-risk populations that hospitals serve. In addition, individuals receiving hospice care may be at increased risk for tuberculosis if they are members of a high risk group, which includes groups whose members have a medical condition that increases the likelihood of developing active tuberculosis (e.g., HIV disease, end stage renal disease, certain carcinomas). Employees who may have occupational exposure include, but are not limited to, physicians, nurses, aides, social workers, and other health care workers.

Occupational exposure occurring in shelters for the homeless is covered under paragraph (a)(5). Residents of shelters for the homeless comprise a population that is also at increased risk for tuberculosis. Members of this population are more likely to have risk factors that are associated with TB than the general population although the exact prevalence of TB in this population is unknown. The data quoted in CDC's 1992 document ''Prevention and Control of Tuberculosis Among Homeless Persons'' indicated a prevalence of clinically active tuberculosis among homeless adults ranging from 1.6% to 6.8% (Ex. 6–15). The prevalence of latent tuberculosis ranged from 18% to 51% and there was a point prevalence of active TB of 968 cases/100,000 homeless adults (Ex. 6–15). Similar to the population in correctional facilities, residents of homeless shelters have a high prevalence of HIV infection and intravenous drug use, factors that increase the likelihood that their infections will progress to active TB. In addition, environmental factors such as overcrowding and poor ventilation promote the transmission of disease. Examples of employees who may have occupational exposure include, but are not limited to, intake workers and health care workers who have contact with residents of homeless shelters.

Paragraph (a)(6) covers occupational exposure occurring in facilities that provide treatment for drug abuse. Based on tuberculin skin testing reported in 1993, 13.3% of the clients of drug treatment facilities had evidence of TB infection (Ex.6–8). Many of these persons have a history of intravenous-drug use and either have or are at risk for HIV infection. These persons are at increased risk for developing active TB and transmitting the disease to others. Many of these individuals may discontinue treatment prematurely even if they are diagnosed and started on effective drug treatment. In addition, the CDC reported that studies in some areas have shown that over 20% of selected inner city intravenous drug user populations have tuberculous infection (Ex. 3–37). The CDC thus concluded that drug center clients and staff are at risk of becoming infected. Employees in drug treatment facilities who may have occupational exposure include, but are not limited to, counselors, nurses, physicians and other staff.

Work settings where occupational exposure occurs as a result of the performance of high-hazard procedures, which, for the purposes of this standard, are certain procedures performed on individuals with suspected or confirmed infectious TB, are also covered under the scope of the standard as stated under paragraph (a)(7). High-hazard procedures are procedures that are cough-inducing or aerosol-generating that are likely to result in droplet nuclei being expelled into the air. A definition and discussion of high-hazard procedures can be found under paragraph (j), Definitions, of this Summary and Explanation. Health care workers and other employees who are either performing or assisting with these procedures or are in the general vicinity are at an increased risk of inhaling droplet nuclei and therefore have occupational exposure. The 1994 CDC guidelines recommend in Section G, ''Cough-Inducing and Aerosol-Generating Procedures'' that special precautions be taken when these procedures are performed (Ex. 4B). Health care workers, such as physicians, nurses, technicians and others who perform or assist in the performance of high-hazard procedures have occupational exposure. Other employees who may be in the room or area when such procedures are performed would be expected to have occupational exposure as well.

Paragraph (a)(8) applies to occupational exposure that occurs in laboratories that handle specimens that may contain *M. tuberculosis,* process or maintain those specimens or the resulting cultures, or perform any related activity that may result in the aerosolization of *M. tuberculosis. M. tuberculosis* is a proven hazard to laboratory personnel (Exs. 7–68, 7–72, 7–142, 7–143). Aerosols present the greatest hazard in laboratories. Tubercle bacilli may be present in sputum, gastric lavage fluids, cerebrospinal fluid, urine, and in lesions from a variety of tissues. In addition, the bacilli are grown in culture to increase their concentration beyond what would normally be found in the sample for purposes of identification and susceptibility testing. The bacilli may survive in heat-fixed smears and may be aerosolized in the preparation of frozen sections and during manipulation of liquid cultures. CDC/NIH's manual ''Biosafety in Microbiological and Biomedical Laboratories'' recommends Biosafety Level 2 or 3 for such laboratories depending on the procedures being performed (Ex. 7–72). Employees who may have occupational exposure include a wide variety of laboratorians. Examples include, but are not limited to, medical technologists, laboratory technicians, physicians, and research scientists.

Occupational exposure incurred by temporary or contract employees is also covered under the Scope to the extent that the occupational exposure occurs in one of the work settings listed under paragraphs (a)(1) through (a)(8). For example, if a nurse working for a temporary employment service were hired by a hospital to work on a TB ward, that temporary nurse would be covered under the scope of the standard. Physicians who are employees (e.g., of an independent corporation) yet who

practice and are exposed in a covered facility, such as a hospital, are also covered by the standard. Similarly, in any of the work settings listed under paragraph (a)(1), temporary or contract personnel who incur occupational exposure to TB as a result of their temporary or contract work would be covered by the standard. The occupational exposure experienced by these employees would be expected to be similar to that of other employees performing the same tasks and procedures in the work setting that has contracted for their services. A note has been added to the proposed standard to make clear that these types of employees are covered under the scope.

This note also clarifies that repair, replacement, or maintenance personnel, working in any of the work settings covered under paragraphs (a)(1) through (a)(8), who service air systems or equipment or who renovate, repair or maintain areas of buildings that may reasonably be anticipated to contain aerosolized *M. tuberculosis* are also covered under the scope of the standard. The standard requires the use of engineering controls, such as isolation rooms, to reduce the concentration of droplet nuclei and therefore reduce the likelihood of TB infection and subsequent illness. The ventilation systems that exhaust air from isolation rooms may reasonably be anticipated to contain aerosolized *M. tuberculosis.* Maintenance and other workers who are responsible for the servicing and repair of ventilation systems that handle air that may contain aerosolized *M. tuberculosis* are at risk for occupational exposure when, as the result of performing their duties, they are exposed to TB contaminated air moving through the ventilation system. Examples of employees who may have occupational exposure include heating, ventilation, and air conditioning (HVAC) maintenance personnel.

In addition, there may be employees who are responsible for renovating, repairing, or maintaining areas of buildings where exposure to aerosolized *M. tuberculosis* may occur other than those associated with the ventilation systems. Maintenance staff who need to repair fixtures in an isolation room, or contractor personnel hired to provide housekeeping in isolation rooms or areas, are examples of such employees who would also be covered under the standard. OSHA expects that such exposures would occur only rarely. In many circumstances, minor non-emergency maintenance activities could be performed by health care personnel required to enter the isolation rooms or areas for other reasons, such as to care for a patient. However, there may be activities that necessitate the expertise of certain maintenance employees which could place those employees at risk of occupational exposure. Those employees would therefore be covered under the scope of the standard.

Paragraph (a)(9) applies to occupational exposure occurring during the provision of social work, social welfare services, teaching, law enforcement or legal services, where the services are provided in the facilities included in paragraphs (a)(1) through (a)(8), or in residences, to individuals who are in AFB isolation, or are segregated or otherwise confined due to having suspected or confirmed infectious tuberculosis. This paragraph is intended to cover those types of employees who must provide services to individuals who have been identified beforehand as having suspected or confirmed infectious tuberculosis and who have either been isolated or segregated in isolation rooms or areas or have been confined in their homes. For example, certain social workers may need to enter AFB isolation rooms or areas or visit homes of people who have suspected or confirmed infectious tuberculosis for the purposes of collecting information or providing discharge planning. While OSHA believes that it would be preferable to collect such information over the telephone in order to prevent occupational exposure, the Agency realizes that there may be situations where direct contact with these isolated or confined individuals may be necessary. In these limited situations, these employees would be covered under the scope of the standard. There may also be situations where teachers may be providing tutoring to individuals isolated with suspected or confirmed infectious tuberculosis. Again, OSHA believes that such situations would be limited and that most educational instruction could be delayed until an individual was determined to be noninfectious. However, where teachers must provide instruction to individuals identified as having suspected or confirmed infectious TB, those teachers would be covered under the scope of the standard. In addition, certain law enforcement officers might have to be in contact with individuals who have been identified as having suspected or confirmed infectious tuberculosis. For example, they may have to transfer such an individual from a correctional or detainment facility to a hospital for diagnosis or treatment. Because these workers must be in direct contact with the individual during transport, perhaps for long periods of time and probably in an enclosed vehicle, such employees could incur significant occupational exposure. Paragraph (a)(9) would assure that such employees would be covered under the standard. Similarly, there may be occasions where attorneys must consult with clients or inmates who have been isolated or segregated because they have been identified as having suspected or confirmed infectious tuberculosis. Such attorneys would be covered under the standard in the limited situations where these consultations cannot be done by phone or delayed until the individual has been determined to be noninfectious. Under paragraph (a)(9), OSHA has specified certain employee groups that it believes would have to enter AFB isolation rooms or areas or homes where individuals are confined due to suspected or confirmed infectious TB, in order to provide services which may result in occupational exposure. OSHA requests comments and data as to whether there are other employee groups that may incur occupational exposure and thus need protection under this paragraph.

Paragraph (a)(10) applies to occupational exposure occurring during the provision of emergency medical services, home health care, and home-based hospice care. Emergency medical service employees may provide emergency treatment and transportation for individuals with suspected or confirmed tuberculosis. For example, in addition to serving the same high-risk client population as hospitals, emergency medical services are often used to transport individuals who have been identified as having either suspected or confirmed infectious tuberculosis from a facility with inadequate isolation capabilities to another facility better equipped to isolate these individuals. Proximity to the patient and time spent within an ambulance or other emergency vehicle affects the likelihood of occupational exposure as the result of breathing droplet nuclei generated when the patient coughs or speaks. Examples of employees who may have occupational exposure include but are not limited to emergency medical technicians, paramedics, and, in some localities, fire fighters.

The 1994 CDC guidelines identify health care workers who provide medical services in the homes of patients with suspected or confirmed infectious tuberculosis as being at risk and recommend precautions to be used in these settings (Ex. 4B). Employees who provide home-based care serve a

client population similar to that of hospitals (e.g., individuals who may be immunocompromised). Employees such as nurses and aides who provide care to these individuals would be expected to have occupational exposure.

OSHA is also proposing that certain limited construction activities be included under the scope of the standard; however, the Agency believes that the proposed standard would have little impact on this sector. The standard would apply to construction operations occurring in the work settings covered by the scope of the standard where there is a reasonable anticipation of exposure to aerosolized *M. tuberculosis*, e.g., while rebuilding an HVAC system that would connect to an existing one that is in use. The standard is not intended to cover employees involved in other construction operations where they would not have occupational exposure to air which may reasonably be anticipated to contain aerosolized *M. tuberculosis* (e.g., a crane operator constructing a new wing of a hospital). The standard would apply only to construction employees who would incur occupational exposure to tuberculosis. Such a case might arise during maintenance operations on an air system that carries air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* or during renovation, repair, or alteration of areas of buildings that may reasonably be anticipated to contain aerosolized *M. tuberculosis.* The probability of exposure to *M. tuberculosis* during these activities may be high and it is necessary, therefore, for employees performing the work to wear respirators, receive medical surveillance and be protected by the other provisions of the proposed TB standard. Employees of such contractors are subject to the same levels of TB exposure and need the same protection as other exposed employees. Therefore, OSHA proposes to cover these employees under the TB standard and has included construction within the standard's scope.

Thus, although the impact of the standard will be limited, OSHA believes that construction should not be exempted from the proposed standard. OSHA believes that a loophole would be opened in the enforcement of the standard if construction were exempted. The distinction between maintenance and construction is often an ambiguous one. If construction were excluded, contractors, such as HVAC contractors, might argue that their work is ''construction'' and that they are not covered by the standard. By covering construction, this ambiguity does not arise. This approach is consistent with that taken in other standards (e.g., Ethylene Oxide, 29 CFR 1910.1047; Benzene, 29 CFR 1910.1028).

Several of the sectors covered by the proposed standard may be utilizing volunteers for assistance in the workplace. Under the OSH Act, OSHA is mandated to protect employees against workplace hazards. Consequently, volunteers are not covered by OSHA standards because they are not employees. However, employers should be aware that simply labeling a person as a volunteer is not determinative of whether an employer/employee relationship exists, if the person is compensated for his or her services. Some states or localities may decide to extend the protections of OSHA standards to volunteers; however, such action is the independent decision of these jurisdictions and is not a requirement of the OSH Act.

In addition, the proposed standard applies in situations when an employer has part-time employees, or where employees of other employers are working in a covered facility. These employees are covered by the standard in the same manner as other employees who have occupational exposure to tuberculosis. For example, they would be provided with the same protections as full-time on-site employees, such as being included in the exposure determination, being trained, being provided with medical surveillance, and being issued respiratory protection if necessary. With regard to employers who provide employees to other employers (e.g., personnel providers, temporary help agencies, nurse registries), a shared responsibility for worker protection exists between the provider and the client or ''host'' employer. The safety and health rights of temporary or ''leased'' or contracted employees are the same as the rights of those who are employed directly by the host employer. The host employer is generally responsible for safety and health measures taken to address hazards that are an integral part of the workplace the host employer controls. Where other employers are involved, contractors or other ''providers,'' a joint employer-employee relationship may exist in which both (or more) employers share responsibility for the safety and health of the employees. OSHA's concern is to assure that workers receive full protection under this standard. Who provides which protections to the various employees may be specified as a matter of contract or employment agreement existing between the client/host and the contractor/provider. In a typical arrangement, for example, the provider employer might provide the generic training required by the standard and assure that proper follow-up medical evaluation occurs after an exposure incident. Host employers would typically control potential exposure conditions and fulfill other requirements of the standard, such as site-specific training and respiratory protection.

While the proposed standard covers a number of different work settings, as described above, OSHA recognizes that many different types of activities occur in these different settings. Thus, not all provisions of the proposed standard would apply in each work setting. The provisions that are required will vary to some degree, depending on the type of activities done in the work setting. In order to give employers guidance as to what provisions would be applicable in their work setting, OSHA has developed a series of charts of the requirements that are most likely to be applicable for the affected industries.

The following charts outline provisions that would be required for employers covered under the scope of the proposed TB standard. (*Employers who qualify for the limited program as outlined under Paragraph (b), Application, should consult Appendix A for applicable provisions.*) The charts are categorized either by the types of infection control activities that may be common among different work settings (e.g., early identification and transfer of individuals with suspected or confirmed infectious TB) or by a particular occupational work group (e.g., emergency medical services, home health care). These charts are designed to give employers a guide to the regulatory text by outlining the provisions of the proposed standard that are applicable for various types of work settings. These charts summarize the general responsibilities of a particular required provision. The regulatory text should be consulted for more specific details on particular provisions.

In addition, it should also be kept in mind that even though these charts are categorized by the type of activities occurring at a worksite, the categories do not necessarily always follow industry lines (i.e., an employer under a specific industry sector may not always fall under a particular category outlined in the following charts). The charts are not designed to serve as a stand alone check list for any one industry sector. Due to the varying activities that may take place in work settings encompassed by an industry sector, the charts may not account for every applicable provision in every work setting. The charts are intended to provide general guidance as to what

OSHA anticipates to be applicable provisions. Therefore, it is important that employers evaluate the types of activities occurring in settings where their employees work to determine which of the provisions of the proposed standard would be applicable. In order to give employers guidance, OSHA has listed some of the types of industry sectors that the Agency assumes are likely to fall under a particular category, given OSHA's current understanding of the activities commonly occurring in these work settings.

OSHA requests comments on these assumptions and on the charts, and particularly, on how the charts can be made more user friendly and be better organized to help serve as a guide for employers trying to comply with the standard. The following charts are included:

Chart 1: What Would Be Required in Work Settings Where Individuals with Suspected or Confirmed Infectious TB are Admitted or Provided Medical Services?

Chart 2: What Would Be Required in Work Settings Where Early Identification and Transfer Procedures are Used for Individuals with Suspected or Confirmed Infectious TB?

Chart 3: What Would Be Required for Employers with Employees Who Provide Services to Individuals Who Have Been Isolated or Otherwise Confined Due to Having Suspected or Confirmed Infectious TB or Who Work in Areas Where the Air Has Been Identified As Reasonably Anticipated to Contain Aerosolized *M. tuberculosis*?

Chart 4: What Would Be Required for Home Health Care and Home-Based Hospice Care?

Chart 5: What Would Be Required for Emergency Medical Services?

Chart 6: What Would Be Required for Clinical and Research Laboratories?

Chart 7: What Would Be Required for Personnel Services?

Chart 1: What Would Be Required in Work Settings Where Individuals with Suspected or Confirmed Infectious TB Are Admitted or Provided Medical Services?

OSHA anticipates that Hospitals will be the primary type of facility falling under this category. In general, individuals requiring isolation are transferred to hospitals that have isolation capabilities. In addition, medical services such as diagnostic testing for evaluating TB disease are performed in a hospital setting. This category also covers work settings where high-hazard procedures are performed, e.g., medical examiners' offices. (Laboratories are covered in a later chart). However, there may be other work settings such as correctional facilities or long-term care facilities for the elderly that provide isolation or perform high-hazard procedures on individuals with suspected or confirmed infectious TB. In these cases, employers at these facilities would be required to comply with the provisions outlined in this chart.

What Would Be Required in Work Settings Where Individuals With Suspected or Confirmed Infectious TB Are Admitted or Provided Medical Services?
(c) Exposure Control
(c)(1) Exposure Determination
(c)(2)(i) Written Exposure Control Plan including:
(A) the exposure determination
(B) procedures for providing information to occupationally exposed employees about individuals with suspected or confirmed infectious TB or air that may reasonably be anticipated to contain aerosolized *M. tuberculosis*
(C) procedures for reporting exposure incidents
(c)(2)(iii):
(A) procedures for prompt identification of individuals with suspected or confirmed infectious TB
(B) procedures for isolating and managing the care of individuals with suspected or confirmed infectious TB (e.g., minimizing the time and number of employees entering an isolation room)
(C) a list of high-hazard procedures
(D) a schedule for inspection, maintenance, and performance monitoring of engineering controls
(c)(2)(iv) If the employer operates an onsite laboratory, the plan must include a determination as to whether the facility should operate at Biosafety Level 2 or 3 containment and document the need for controlled access, anterooms, sealed windows, directional airflow, measures to prevent the recirculation of lab exhaust air, filtration of exhaust air and thimble exhaust connections.
(c)(2)(vi) Document the number of confirmed cases of TB if claiming reduced responsibilities under paragraph (g)(3)(iii)(D)
(c)(2)(vii) The exposure control plan must be:
(A) accessible
(B) reviewed annually and updated whenever necessary
(C) available for copying by the Assistant Secretary and Director upon request
(d) Work Practices and Engineering Controls
All provisions of paragraph (d) are applicable
(e) Clinical and Research Laboratories
If the facility operates an onsite laboratory, the additional provisions under paragraph (e) must be followed (See Chart 6 for Clinical and Research Laboratories)
(f) Respiratory Protection
(f)(1)(i) Provide respirators to employees who:
(A) enter isolation rooms or areas in use for TB isolation
(B) are present during the performance of procedures or services for an individual with suspected or confirmed infectious TB who is not masked
(C) transport an unmasked individual with suspected or confirmed infectious TB within the facility
(D) repair, replace, or maintain air systems or equipment that may reasonably be anticipated to contain aerosolized *M. tuberculosis*
(E) work in an area where an unmasked individual with suspected or confirmed infectious TB has been segregated or otherwise confined
(f)(1)(iii) Provide respirators at no cost and assure that the employee uses the respirator in accordance with this standard
(f)(1)(iv) Assure that the employee dons the respirator before entering any of the work settings or performing any of the tasks identified in paragraph (f)(1)(i) (A) through (E) and uses it until leaving the work setting or the task has been completed
All remaining provisions of paragraph (f) are applicable, i.e., (f)(2)–(f)(8)
(g) Medical Surveillance
All provisions of paragraph (g) are applicable
(h) Communication of Hazards and Training

What Would Be Required in Work Settings Where Individuals With Suspected or Confirmed Infectious TB Are Admitted or Provided Medical Services?
(h)(1)(i) Label air systems that may reasonably be anticipated to contain aerosolized *M. tuberculosis* ''Contaminated Air—Respiratory Protection Required''
(h)(1)(ii) If the employer operates an onsite laboratory, label clinical and research laboratory wastes with the biohazard symbol
(h)(2)(i) Post signs at entrances to:
(A) isolation rooms or areas
(B) areas where procedures or services are being performed on an individual with suspected or confirmed infectious TB
(C) clinical and research laboratories where *M. tuberculosis* is present if the employer operates an onsite laboratory
(h)(2)(ii) Ventilate isolation rooms or areas vacated by individuals with suspected or confirmed infectious TB, in accordance with Appendix C, unless those individuals are medically determined to be noninfectious
(h)(2)(iii) Signs must be readily visible and have a stop sign with the legend ''No Admittance Without Wearing a Type N95 or More Protective Respirator''
(h)(2)(iv) Signs at the entrances to clinical or research laboratories (for employers who operate onsite laboratories) and autopsy suites where procedures are being performed that may generate aerosolized *M. tuberculosis*
(h)(3) Information and Training
All elements are applicable
(i) Recordkeeping
All recordkeeping is applicable

Chart 2: What Would Be Required in Work Settings Where Early Identification and Transfer Procedures Are Used for Individuals With Suspected or Confirmed Infectious TB ?

OSHA anticipates that the types of establishments falling under this category are likely to be long term care facilities for the elderly, correctional facilities, immigration detainment facilities, hospices, homeless shelters, substance abuse treatment centers, and hospitals that do not admit individuals with suspected or confirmed infectious TB. In these work settings, employers will use the signs and symptoms of active TB as well as any other available information (e.g., tuberculin skin test status) to identify individuals with suspected or confirmed infectious TB. These individuals will then be transferred to facilities with appropriate isolation capabilities. Therefore, facilities that transfer do not need to have engineering controls. Temporary engineering controls will only be necessary in limited situations where transfer cannot be accomplished within 5 hours.

What Would Be Required in Work Settings Where Early Identification and Transfer Procedures Are Used for Individuals With Suspected or Confirmed Infectious TB?
(c) Exposure Control
(c)(1) Exposure Determination
(c)(2)(i) Written Exposure Control Plan including:
(A) the exposure determination
(B) procedures for providing information to occupationally exposed employees about individuals with suspected or confirmed infectious TB or air that may reasonably be anticipated to contain aerosolized *M. tuberculosis*
(C) procedures for reporting exposure incidents
(c)(2)(ii) Employers who transfer individuals with suspected or confirmed infectious TB must include in the plan: procedures for prompt identification, masking or segregation, and transfer of such individuals
(c)(2)(vi) Document the number of confirmed cases of TB if claiming reduced responsibilities under paragraph (g)(3)(iii)(D)
(c)(2)(vii) The exposure control plan must be:
(A) accessible
(B) reviewed annually and updated whenever necessary
(C) available for copying by the Assistant Secretary and Director upon request
(d) Work Practices and Engineering Controls
(d)(1) Use work practices and engineering controls to eliminate or minimize employee exposure to *M. tuberculosis*
(d)(2) Implement the work practices in the Exposure Control Plan
(d)(3) Identify individuals with suspected or confirmed infectious TB and:
(i) mask or segregate the individual until transfer can be accomplished
(ii) place the individual in temporary isolation if transfer cannot be accomplished within 5 hours from the time of identification
(d)(5) Engineering controls (i.e., negative pressure, direct exhaust or HEPA filtration, etc.) shall be used when temporary isolation is used
(d)(6) Provide information about TB hazards to any contractor who provides temporary or contract employees who will incur occupational exposure
(f) Respiratory Protection
(f)(1)(i) Provide respirators to employees who:
(A) enter a temporary isolation room or area
(E) work in an area where an unmasked individual with suspected or confirmed infectious TB has been segregated or otherwise confined and is awaiting transfer
(f)(1)(iii) Provide respirators at no cost and assure that the employee uses the respirator in accordance with this standard
(f)(1)(iv) Assure that the employee dons the respirator before entering the work setting and uses it until leaving the work setting
All remaining provisions of paragraph (f) are applicable, i.e., (f)(2)–(f)(8)
(g) Medical Surveillance
All provisions of paragraph (g) are applicable
(h) Communication of Hazards and Training
(h)(1)(i) Label air systems that may reasonably be anticipated to contain aerosolized *M. tuberculosis* ''Contaminated Air—Respiratory Protection Required'' if temporary isolation is used
(h)(2)(i)(A) Post signs at entrances to temporary isolation rooms or areas
(h)(2)(ii) Ventilate temporary isolation rooms or areas vacated by individuals with suspected or confirmed infectious TB in accordance with Appendix C, unless those individuals are medically determined to be noninfectious
(h)(2)(iii) Signs used for temporary isolation must be readily visible and have a stop sign with the legend ''No Admittance Without Wearing a Type N95 or More Protective Respirator''

What Would Be Required in Work Settings Where Early Identification and Transfer Procedures Are Used for Individuals With Suspected or Confirmed Infectious TB?
(h)(3) Information and Training All elements are applicable (i) Recordkeeping All recordkeeping is applicable

Chart 3: What Would Be Required for Employers With Employees Who Provide Services to Individuals Isolated or Otherwise Confined Due to Having Suspected or Confirmed Infectious TB or Who Work in Areas Identified as Reasonably Anticipated to Contain Aerosolized M. tuberculosis?

OSHA anticipates that the type of employees falling under this category will be workers providing social work services, social welfare services, teaching, law enforcement or legal services to individuals who are in isolation or confined to their homes due to having suspected or confirmed infectious TB. Also included in this category are maintenance employees such as contract HVAC maintenance employees who work on air systems that have been identified as carrying air that may reasonably be anticipated to contain aerosolized *M. tuberculosis*. Employers in these situations will not need to perform early identification procedures since the identification of individuals with suspected or confirmed infectious TB has already been accomplished. Similarly, air systems will already be labeled as containing ''Contaminated Air''.

What Would Be Required for Employers with Employees Who Provide Services to Individuals Isolated or Otherwise Confined Due to Having Suspected or Confirmed Infectious TB or Who Work in Areas Identified as Reasonably Anticipated to Contain Aerosolized *M. tuberculosis*?
(c) Exposure Control (c)(1) Exposure Determination (c)(2)(i) Written Exposure Control Plan including: (A) the exposure determination (B) procedures for providing information to occupationally exposed employees about individuals with suspected or confirmed infectious TB or air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* (C) procedures for reporting exposure incidents (c)(2)(vii) The exposure control plan must be: (A) accessible (B) reviewed annually and updated whenever necessary (C) available for copying by the Assistant Secretary and Director upon request (d) Work Practices and Engineering Controls (d)(1) Use work practices to eliminate or minimize employee exposure to *M. tuberculosis* (d)(2) Implement the work practices in the Exposure Control Plan (d)(6) Provide information about TB hazards to any contractor who provides temporary or contract employees who will incur occupational exposure (f) Respiratory Protection (f)(1)(i) Provide respirators to employees who: (A) enter isolation rooms or areas (D) repair, replace or maintain air systems or equipment that may reasonably be anticipated to contain aerosolized *M. tuberculosis* (F) work in a residence where an individual with suspected or confirmed infectious TB is known to be present (f)(1)(iii) Provide respirators at no cost and assure that the employee uses the respirator in accordance with this standard (f)(1)(iv) Assure that the employee dons the respirator before entering the work setting and uses it until leaving the work setting All remaining provisions of paragraph (f) are applicable, i.e., (f)(2)—(f)(8) (g) Medical Surveillance All provisions of paragraph (g) are applicable (h) Communication of Hazards and Training (h)(3) Information and Training All elements are applicable (i) Recordkeeping All recordkeeping, except for engineering controls records, is applicable

Chart 4: What Would Be Required for Home Health Care and Home-Based Hospice Care?

In general, most of the provisions of the proposed standard would be applicable for employers providing home health care or home-based hospice care. However, OSHA realizes that home health care providers do not have control over the home environment and therefore, the standard would not require these employers to provide or maintain engineering controls in the homes of their clients. OSHA also realizes that some individuals with infectious TB may be sent home instead of being admitted to the hospital; OSHA would not expect employers to transfer such individuals out of their home. However, individuals with suspected or confirmed infectious TB need to be identified so that home health care providers can take appropriate precautions to protect themselves while in the home.

What Would Be Required for Home Health Care and Home-Based Hospice Care?
(c) Exposure Control (c)(1) Exposure Determination (c)(2)(i) Written Exposure Control Plan including:

What Would Be Required for Home Health Care and Home-Based Hospice Care?
(A) the exposure determination (B) procedures for providing information to occupationally exposed employees about individuals with suspected or confirmed infectious TB or air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* (C) procedures for reporting exposure incidents (c)(2)(v) Employers who provide home health care or home-based hospice care must include procedures for prompt ID of individuals with suspected or confirmed infectious TB, procedures for minimizing exposure to such individuals, a list of high-hazard procedures performed, if any, and procedures for delaying elective high-hazard procedures or surgery until the individual is noninfectious (c)(2)(vii) The exposure control plan must be: (A) accessible (B) reviewed annually and updated whenever necessary (C) available for copying by the Assistant Secretary and Director upon request (d) Work Practices and Engineering Controls (d)(1) Use work practices to eliminate or minimize employee exposure to *M. tuberculosis* (d)(2) Implement the work practices in the Exposure Control Plan (d)(3) Identify individuals with suspected of confirmed infectious TB (d)(6) Provide information about TB hazards to any contractor who provides temporary or contract employees who will incur occupational exposure (f) Respiratory Protection (f)(1)(i) Provide respirators to employees who: (F) work in a residence where an individual with suspected or confirmed infectious TB is known to be present (f)(1)(iii) Provide respirators at no cost and assure that the employee uses the respirator in accordance with this standard (f)(1)(iv) Assure that the employee dons the respirator before entering the work setting and uses it until leaving the work setting All remaining provisions of paragraph (f) are applicable, i.e., (f)(2)–(f)(8) (g) Medical Surveillance All provisions of paragraph (g) are applicable (h) Communication of Hazards and Training (h)(3) Information and Training All elements are applicable except those related to the use of engineering controls (i) Recordkeeping All recordkeeping, except for engineering controls records, is applicable

Chart 5: What Would Be Required for Emergency Medical Services?

Similar to Home Health Care or Home-Based Hospice Care, employers providing emergency medical services do not have control over many of the work settings in which they may provide services. Thus, OSHA would not require these employers to provide or maintain engineering controls. In addition, while these types of employers are likely to be transferring individuals with infectious TB, it is not their responsibility to initiate the transfer of an individual identified as having suspected or confirmed infectious TB to a facility with appropriate isolation capabilities. However, where it is feasible to do so, such individuals need to be identified so that emergency medical service employees can take precautions to protect themselves.

What Would Be Required for Emergency Medical Services?
(c) Exposure Control (c)(1) Exposure Determination (c)(2)(i) Written Exposure Control Plan including: (A) the exposure determination (B) procedures for providing information to occupationally exposed employees about individuals with suspected or confirmed infectious TB or air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* (C) procedures for reporting exposure incidents (c)(2)(iii): (A) Procedures for prompt identification of individuals with suspected or confirmed infectious TB (B)(4) Procedure or policy for using properly-fitted masks on individuals with suspected or confirmed infectious TB (C) A list of high-hazard procedures (c)(2)(vii) The exposure control plan must be: (A) accessible (B) reviewed annually and updated whenever necessary (C) available for copying by the Assistant Secretary and Director upon request (d) Work Practices and Engineering Controls (d)(1) Use work practices to eliminate or minimize employee exposure to *M. tuberculosis* (d)(2) Implement the work practices in the Exposure Control Plan (d)(3) Identify individuals with suspected or confirmed infectious TB (d)(6) Provide information about TB hazards to any contractor who provides temporary or contract employees who will incur occupational exposure (f) Respiratory Protection (f)(1)(i) Provide respirators to employees who: (A) enter an isolation room or area (B) are present during the performance of procedures or services for an individual with suspected or confirmed infectious TB who is not masked (C) transport an individual with suspected or confirmed infectious TB in an enclosed vehicle or who transport an unmasked individual with suspected or confirmed infectious TB within the facility (F) work in a residence where an individual with suspected or confirmed infectious TB is known to be present (f)(1)(iii) Provide respirators at no cost and assure that the employee uses the respirator in accordance with this standard (f)(1)(iv) Assure that the employee dons the respirator before entering the work setting and uses it until leaving the work setting

What Would Be Required for Emergency Medical Services?
All remaining provisions of paragraph (f) are applicable, i.e., (f)(2)–(f)(8)
(g) Medical Surveillance
All provisions of paragraph (g) are applicable
(h) Communication of Hazards and Training
(h)(3) Information and Training
All elements are applicable except those related to the use of engineering controls
(i) Recordkeeping
All recordkeeping, except for engineering controls records, is applicable

Chart 6: What Would Be Required for Clinical and Research Laboratories?

Employers in clinical and research laboratories that handle specimens that may contain *M. tuberculosis* or process or maintain the resulting cultures or perform activities that may result in the aerosolization of *M. tuberculosis* must follow most of the provisions of the proposed standard. In addition, a special paragraph has been added to address the unique hazards of the lab environment. Clinical and research labs are not responsible for developing or implementing procedures for the early ID of individuals with suspected or confirmed infectious TB or the transfer of those individuals.

What Would Be Required for Clinical and Research Laboratories?
(c) Exposure Control
(c)(1) Exposure Determination
(c)(2)(i) Written Exposure Control Plan including:
(A) the exposure determination
(B) procedures for providing information to occupationally exposed employees about individuals with suspected or confirmed infectious TB or air that may reasonably be anticipated to contain aerosolized *M. tuberculosis*
(C) procedures for reporting exposure incidents
(c)(2)(iv) Employers who operate a laboratory must include a determination as to whether the facility should operate a laboratory at Biosafety Level 2 or 3 containment and document the need for controlled access, anterooms, sealed windows, directional airflow, measures to prevent the recirculation of lab exhaust air, filtration of exhaust and thimble exhaust connections
(c)(2)(vii) The exposure control plan must be:
(A) accessible
(B) reviewed annually and updated whenever necessary
(C) available for copying by the Assistant Secretary and Director upon request
(d) Work Practices and Engineering Controls
(d)(1) Use work practices and engineering controls to eliminate or minimize employee exposure to *M. tuberculosis*
(d)(2) Implement the work practices in the Exposure Control Plan
(d)(6) Provide information about TB hazards to any contractor who provides temporary or contract employees who will incur occupational exposure
(e) Clinical and Research Laboratories
All provisions of paragraph (e) are applicable
(f) Respiratory Protection
(f)(1)(ii) For research laboratories, provide respirators to employees who are present when aerosols of *M. tuberculosis* cannot be safely contained
(f)(1)(iii) Provide respirators at no cost and assure that the employee uses the respirator in accordance with this standard
(f)(1)(iv) Assure that the employee dons the respirator before performing the tasks under (f)(1)(ii) and uses it until completing the tasks
All remaining provisions of paragraph (f) are applicable, i.e., (f)(2)–(f)(8)
(g) Medical Surveillance
All provisions of paragraph (g) are applicable
(h) Communication of Hazards and Training
(h)(1)(i) Labels:
(h)(1)(i) Label air systems that may reasonably be anticipated to contain aerosolized *M. tuberculosis* ''Contaminated Air—Respiratory Protection Required''
(h)(1)(ii) Label clinical and research laboratory wastes with the biohazard symbol
(h)(2) Signs:
(h)(2)(i)(C) Post signs at entrances to clinical and research laboratories where *M. tuberculosis* is present
(h)(2)(iv) Include on the sign the biohazard symbol, the name and telephone number of the laboratory director or other designated responsible person, the infectious agent designation *M. tuberculosis,* and special requirements for entering the laboratory
(h)(3) Information and Training
All elements are applicable
(i) Recordkeeping
All recordkeeping is applicable

Chart 7: What Would Be Required for Personnel Services?

This category covers employers who provide temporary employees to any of the other employers covered under the scope of the standard (e.g., temporary nurses hired to work at a hospital, temporary lab technicians working in a clinical laboratory). Employees in these situations are covered by the standard in the same manner as other employees who have occupational exposure to tuberculosis. A shared responsibility for worker protection exists between the personnel service employer and the client (or ''host'') employer. These matters may be specified as a matter of contract or employment agreement existing between the personnel service employer and the host employer. In this chart OSHA has assumed that a typical contract or employment agreement exists between the two employers with the personnel provider accepting responsibility for the general requirements and the host employer being responsible for site-specific measures. Therefore, the personnel service provider is shown complying with non-site specific provisions such as exposure determination, medical surveillance, and non-site specific employee training. The host employer would comply with more site-specific

provisions such as procedures for early ID, engineering controls and site-specific employee training. In addition, the chart assumes that the personnel service provider has accepted the responsibility for respiratory protection. OSHA requires that workers in these situations receive full protection under the standard.

What Would Be Required for Personnel Services?
(c) Exposure Control
(c)(1) Exposure Determination
(c)(2)(i) Written Exposure Control Plan including:
(A) the exposure determination
(B) procedures for providing information to occupationally exposed employees about individuals with suspected or confirmed infectious TB or air that may reasonably be anticipated to contain aerosolized *M. tuberculosis*
(C) procedures for reporting exposure incidents
(c)(2)(vii) The exposure control plan must be:
(A) accessible
(B) reviewed annually and updated whenever necessary
(C) available for copying by the Assistant Secretary and Director upon request
(d) Work Practices and Engineering Controls
(d)(1) Use work practices to eliminate or minimize employee exposure to *M. tuberculosis*
(d)(2) Implement the work practices in the Exposure Control Plan
(f) Respiratory Protection
All provisions of paragraph (f) are applicable
(g) Medical Surveillance
All provisions of paragraph (g) are applicable except those related to conducting site-specific follow-up investigations after an exposure incident or skin test conversion
(h) Communication of Hazards and Training
(h)(3) Information and Training
All elements are applicable except those training elements which are site-specific
(i) Recordkeeping
All recordkeeping, except for engineering control records, is applicable

OSHA's preliminary conclusion is that all employees who have occupational exposure to aerosolized *M. tuberculosis*, as a result of performing their duties, are at risk of infection. Under paragraph (a) the Agency has listed those facilities, work settings and services where it believes that significant occupational exposure is most likely to occur. OSHA requests comment and supporting data as to whether there are other work settings or services where significant occupational exposures can be reasonably anticipated.

Paragraph (b) Application

As discussed above, OSHA has preliminarily determined that there are elevated risks of TB infection associated with certain types of work settings and services. However, the Agency realizes that there may be employers covered under the scope of the standard who have work settings in counties where the risk of TB infection is low. Some geographical areas in the U.S. have not reported cases of TB to CDC and facilities in these areas have not encountered any individuals with confirmed infectious TB in their work settings within the recent past.

In consideration of the lessened likelihood of employee exposure in these work settings, OSHA is proposing that some employers be permitted to qualify for a more limited program. Paragraph (b), Application, states that an employer covered under paragraph (a), Scope, other than the operator of a laboratory, may choose to comply only with the provisions of Appendix A if the Exposure Control Plan demonstrates that his or her facility or work setting: (1) does not admit or provide medical services to individuals with suspected or confirmed infectious TB; (2) has not encountered a case of confirmed infectious TB in the past 12 months; and (3) is located in a county that, in the past 2 years, has had no cases of confirmed infectious TB reported in one year and fewer than 6 cases of confirmed infectious TB reported in the other year. Thus, in the past two year period, the number of reported TB cases must be 0 for at least one of the two years. (It may even be zero for both years). In the other year, the number of cases must be no greater than 5. For example, if in the first year of the preceding two-year period the number of reported cases was 0, but in the second year there were 4 reported cases of confirmed infectious TB in the county, an employer would still qualify for the limited program under paragraph (b), provided that none of the cases were encountered in his or her employees' work setting. However, for the employer in this scenario to continue to qualify for the limited program, the number of cases reported in the third year would have to return to zero. Similarly, employers would not qualify for the limited program if the number of cases of confirmed infectious TB reported in the county was greater than zero in both of the preceding two years or if 6 or more cases were reported in one of the preceding two years.

OSHA has taken this approach because the number of TB cases fluctuates widely and different locations and geographical areas may be affected at different times. For example, many counties report no cases in one year or even in two consecutive years, or report a few cases in one year but then have no cases in the following year. From 1992 to 1994 (Ex.7–262), 55.3 percent of the counties in the U.S., representing 12.9 percent of the population, reported no confirmed cases of TB in one year of the preceding two-year period and fewer than 6 cases in the other year. OSHA believes that the approach described above is appropriate given these fluctuations and that it reduces the burden on employers who rarely encounter TB cases by allowing them to qualify for the limited program. OSHA initially considered allowing employers to qualify for the limited program only if there had been no cases of confirmed infectious TB reported in the county in the preceding one-year period. This would have meant that an employer would be required to comply with the full program if even a single case was reported in the county in any year. OSHA requests comment on the approach taken in the proposed rule and the appropriateness of the ''zero-county'' trigger used in the standard.

Although OSHA believes that the risk of incurring TB is substantially reduced in facilities located in counties qualifying for the limited program, the risk of infection continues because all counties have residents who are infected and who may therefore develop active TB and transmit it. In addition, the mobility of the U.S. population means that it is easy to carry the disease from higher risk areas to lower risk areas. Thus, OSHA believes that certain TB exposure control provisions, i.e., those reflected in the limited program required by the standard, need to be in place in all work settings where cases of TB could be encountered.

Under the limited program, employers are responsible for (1) preparing a written exposure control plan with certain minimal elements, (2) providing a baseline skin test and medical history, (3) making medical management and follow-up available after an exposure incident, (4) providing medical removal protection if necessary, (5) providing information and training to employees with potential occupational exposure, and (6) complying with pertinent recordkeeping requirements. The specific paragraphs of the proposed standard that would apply in these situations are outlined in Appendix A.

OSHA believes that these provisions are the minimum requirements necessary for employee protection, even in work settings where no TB has recently been reported in the county and no individuals with confirmed infectious TB have been encountered within the work setting during the past 12 months. OSHA's reasoning is that, although no cases of confirmed infectious TB have been reported for the preceding two years, there is considerable fluctuation among counties from one year to the next, as explained above. In addition, as discussed in the preliminary risk assessment section of the preamble, there is a high prevalence of TB infection nationwide, approximately 6.5 percent. Infections may become active after a latency period of years. Therefore, the absence of a reported active case in the immediate past does not mean that active cases will not be manifested in the current or subsequent years. For these reasons, it is necessary for covered facilities to maintain, at a minimum, a TB program that incorporates the basic TB exposure control provisions that will protect employees from exposures.

A primary element of the limited program is a written exposure control plan. The exposure control plan includes an exposure determination to identify those employees who would incur occupational exposure if an individual with infectious TB were encountered in the work setting. The exposure control plan would also have to contain procedures and policies for the early identification and masking of individuals with suspected or confirmed infectious TB and procedures for transferring those individuals to other facilities. This would assure that if an individual with suspected or confirmed infectious TB were to enter the workplace, he or she would be promptly identified and transferred to a facility with AFB isolation capabilities. In addition, while awaiting transfer, these individuals could be masked to the extent that it is feasible (e.g., in the case of a non-combative individual) in order to prevent transmission. Similarly, the exposure control plan must include procedures for reporting exposure incidents should they occur. Employees need to know what steps to take if an exposure occurs so that appropriate follow-up can be initiated for the medical management of the exposed employee and investigation of the incident.

In order to qualify for the limited program pursuant to paragraph (b), the employer must include in his or her exposure control plan the number of TB cases reported in the county and the number of individuals with confirmed infectious TB who have been encountered within the work setting. An employer is required by the standard to check and document the number of confirmed infectious TB cases in the county once a year. Typically, county health departments collect this information for reporting purposes and report it both on a monthly and an annual basis. Obtaining the annual count from the county health department would meet the requirements of the proposed rule. County case counts must be recorded for the two most recent annual reporting periods, i.e., the two preceding years. This count must be reflected in the employer's Exposure Control Plan, as described below in paragraph (c), Exposure Control Plan, of this Summary and Explanation. The count of cases and the notation in the Plan can be kept in any media, e.g., paper or electronic.

In addition to an abbreviated exposure control plan, the limited program would include some of the basic elements of medical surveillance, i.e., baseline skin tests and medical histories for employees identified under the exposure determination and medical management and follow-up for those employees who have had an exposure incident. Baseline skin tests and histories will help to assure that true conversions are appropriately identified should an exposure incident occur. Medical management and follow-up provisions will assure that exposed employees receive the proper medical evaluation after an exposure incident and that the incident is properly investigated so that it will not occur again. Under this limited program, no periodic medical surveillance would be required.

Where necessary, the employer is also required to provide medical removal and protection (MRP) of benefits for those employees who develop active TB. OSHA anticipates that the need to provide MRP would be a rare event because little active TB has been reported in many of these counties. In addition, if employees are properly trained to identify suspected and confirmed infectious TB and to promptly transfer those individuals, few occupational exposures should occur, thus minimizing the likelihood that employees will become infected. Therefore, training is an important element of the limited program. Training is a key element in assuring that employees know how to identify individuals with suspected or confirmed infectious TB and the necessary steps to take if such an individual is encountered.

Certain minimal records must also be kept by the employer. Medical records for documenting baseline skin tests and any potential medical evaluations made as a result of an exposure incident, as well as records for training and records for OSHA illnesses and injuries, would have to be kept. Keeping records should not be burdensome for the employer since it is likely that only a minimal number of employees would be identified by the exposure determination as having potential occupational exposure (e.g., intake workers in admitting areas or emergency departments); only such employees need medical surveillance or training.

The elements of the limited program outlined under this paragraph closely track the recommendations of the CDC for facilities designated as having ''minimal risk'' under the CDC's TB Guidelines for Health Care Facilities (Ex. 4B). Under these guidelines, CDC considers facilities to have ''minimal risk'' if there is no TB in the community and no TB in the facility. CDC's recommendations for such facilities include a written TB control plan, procedures for early identification and prompt transfer of individuals with suspected or confirmed infectious TB, and employee training. CDC does not specifically recommend baseline skin testing. However, CDC's guidelines do say that baseline testing would be

advisable in these facilities so that, if an unexpected exposure does occur, conversions can be distinguished from positive skin test results caused by previous exposures. CDC also recommends that a risk assessment be conducted by such facilities each year. In the case of a ''minimal risk'' facility, as defined by CDC, this would essentially involve checking on the number of reported cases of TB in the community and within the facility, which is essentially what OSHA requires under the exposure control plan as documentation to qualify for the limited program available under paragraph (b).

Paragraph (c) Exposure Control

Employees incur risk each time they are exposed to aerosolized *M. tuberculosis*. A worker can become infected from a single exposure incident, and thus it is necessary to prevent exposure incidents whenever possible. The goal of this proposed standard is to reduce the significant risk of infection by minimizing or eliminating occupational exposure to aerosolized *M. tuberculosis*.

One purpose of paragraph (c), Exposure Control, is to identify the tasks and procedures where occupational exposure may occur and to identify those employees whose duties include these tasks and procedures. An additional purpose of the paragraph is to develop and document, in an exposure control plan, policies and procedures for eliminating or minimizing occupational exposure, e.g., developing procedures for identifying individuals with suspected or confirmed TB, for appropriately isolating and minimizing employee contact with those individuals, and for reporting exposure incidents.

Paragraph (c)(1) requires each employer who has an employee with occupational exposure to prepare an exposure determination that identifies those employees who have occupational exposure to aerosolized *M. tuberculosis*. As discussed under paragraph (j), Definitions, ''occupational exposure'' means ''reasonably anticipated contact that results from the performance of an employee's duties, with an individual with suspected or confirmed infectious TB or air that may contain aerosolized *M. tuberculosis*.'' Thus, the exposure determination needs to include, in addition to those employees who have direct contact with individuals with suspected or confirmed infectious TB and employees who perform procedures that may aerosolize *M. tuberculosis*, those employees who can reasonably be anticipated as part of their job duties to be exposed to air that may contain aerosolized *M. tuberculosis*.

For example, while an admissions clerk in a homeless shelter will not perform medical procedures on a client with suspected infectious tuberculosis, the clerk may reasonably be anticipated to encounter and share the same airspace with such an individual. Therefore, the admissions clerk would be included in the Exposure Control Plan and would be covered by this standard.

Exposure determination is a key provision of exposure control because the employer must know which tasks or procedures involve occupational exposure in order to determine what measures can be taken to eliminate or minimize exposure incidents. In addition, an exposure determination is necessary in order to ascertain which employees are to be provided with respiratory protection, medical surveillance, and training.

Each employer is required to consider the duties, tasks, and procedures of all employees in each job classification in each work area where occupational exposure occurs when making the exposure determination. OSHA believes that it is appropriate to allow the employer to identify and document job classifications where all or some employees have occupational exposure as a basis for the required exposure determination. By identifying the job classification, each employee included in the description will know that he or she is within the scope of the standard. Listing of every employee's name is not required, however, because that may be burdensome for employers who have many employees with occupational exposure.

The term ''job classification'' is used generically. During the development of the Bloodborne Pathogens standard, commenters used several terms (e.g., ''job category'', ''job responsibility'', ''job title'', ''position description'') to identify and document employees at risk in the exposure determination. OSHA sought to use a term that would encompass all of these terms. Therefore, as in the Bloodborne Pathogens standard, OSHA has chosen to use the term ''job classification'' because it has the broadest application to facilities of all sizes that use formal and less formal designations to classify employees. Thus, the standard would allow employers to use existing job titles, job descriptions, or other designations to identify those job classifications in which occupational exposure occurs. OSHA solicits comment on whether this term needs further defining in this paragraph or in paragraph (j), Definitions.

The standard does not require that every task and procedure that could result in occupational exposure be listed in the exposure control plan, but instead gives the employer a choice in how to document the exposure determination. Paragraph (c)(1)(i) states that the exposure determination shall contain:

(A) A list of the job classifications in which all employees have occupational exposure; and

(B) A list of the job classifications in which some employees have occupational exposure, and a list of all tasks and procedures (or groups of closely related tasks and procedures) that these employees perform and that involve occupational exposure.

This means that the employer may choose to extend ''blanket'' coverage to those job classifications where essentially all employees have occupational exposure [the paragraph (c)(1)(i)(A) option]. In this case, the employer would not have to list all tasks and procedures for those employees in the exposure control plan, since all of these employees would be covered by the standard. For example, if a hospital determines that all employees within the job classification ''respiratory therapist'' have duties or responsibilities that involve tasks and procedures where occupational exposure occurs, the job classification ''respiratory therapist'' can simply be listed in the exposure determination in accordance with paragraph (c)(1)(i)(A) and no subsequent listing of those tasks and procedures is required. Similarly, the job classification of ''homeless shelter admissions clerk'' in the previous example could be included under the ''blanket'' job classification list in paragraph (c)(1)(i)(A).

On the other hand, the employer may determine that job classifications exist in which only *some* employees have occupational exposure. The employer may determine that it is not necessary to include all employees in such job classifications under the standard since only a portion of them have occupational exposure. In these situations [paragraph (c)(1)(i)(B)], the employer must list the job classification as well as the tasks and procedures or groups of closely related tasks and procedures performed by employees within that job classification that result in occupational exposure. For example, within the job classification ''laboratory technician,'' there may be some employees who experience occupational exposure (e.g., laboratory technicians who perform microbiological procedures on *M. tuberculosis* cultures), while others would not be expected to

have such exposure (e.g., laboratory technicians who work in clinical chemistry). In such a case, the employer may not wish to extend coverage to all employees in the job classification ''laboratory technician''. Consequently, the job classification ''laboratory technician'' would be listed in the exposure determination along with the tasks and procedures in which occupational exposure occurs. This approach would inform employees within the job classification ''laboratory technician'' about those tasks that they perform that involve occupational exposure and that employees performing those tasks and procedures triggers their inclusion in the scope of the standard. However, it would not be necessary for the employer to list each procedure performed by a ''laboratory technician''. For example, performing sputum smears, culturing the bacteria in the sputum, and conducting drug-susceptibility testing on the culture all involve manipulation of specimens that could contain *M. tuberculosis*. Therefore, these tasks could be grouped under the designation ''manipulation of specimens that may contain *M. tuberculosis*.''

Although the standard permits the exposure determination to list job classifications, grouping job classifications according to location would not be sufficient to meet the requirement for identifying job classifications with occupational exposure. For example, identifying job classifications by using the ''Emergency Department'' would not fulfill this requirement because it does not identify the specific employee job classifications that have occupational exposure. An employer who has determined that employees in the ''Emergency Department'' warrant coverage under the standard would have to list the job classifications that involve occupational exposure and identify the tasks and procedures that result in occupational exposure. OSHA believes that merely grouping employees by location, e.g., designating all employees who work in the Emergency Department, may exclude employees who have occupational exposure since such a grouping could overlook employees who may occasionally enter the Emergency Department but are not routinely assigned there. OSHA seeks comment about the protectiveness of permitting exposure determinations to be made by location within a work setting in certain specific instances where the employer believes such a delineation is useful and will not misclassify employees and specifically requests examples of regulatory language that could achieve these objectives.

Paragraph (c)(1)(ii) requires that the exposure determination be made without regard to the use of respiratory protection. It has been OSHA's long-standing position that the determination of occupational exposure be made without regard to the use of personal protective equipment such as respirators. The reason for this is that several conditions must be met for respiratory protection to effectively lessen exposures. First, the employee must be trained to use the equipment properly. Second, respiratory protection must be used each time the task requiring such protection is performed. Third, respiratory protection must fit properly. If even one of these conditions is not fully met, protection cannot be assured. Therefore, all tasks that entail occupational exposure need to be included in the exposure determination, regardless of the use of respiratory protection. This approach is consistent with other OSHA standards (e.g., Bloodborne Pathogens, 29 CFR 1910.1030; Formaldehyde, 29 CFR 1910.1048; Cadmium, 29 CFR 1910.1027) and is essential to designing an appropriate exposure control program. Utilizing this approach assures that workers who perform tasks requiring respiratory protection will receive the training, medical surveillance, and other provisions of this standard that will enhance their safety should respiratory protection fail.

Paragraph (c)(2) requires that each employer covered under the scope of the standard establish a written exposure control plan. The exposure control plan is a key provision of the standard because it requires the employer to identify the employees who receive training, respiratory protection and medical surveillance and to develop a number of policies and procedures that will eliminate or minimize employees' exposure to sources of aerosolized *M. tuberculosis*. However, because not all employers' work settings are the same, not all employers' exposure control plans will need to contain the same elements. The goal of the exposure control plan is to address the type of exposure that occurs in a given work setting, as identified under the exposure determination, and then to develop procedures and policies to minimize or eliminate that exposure. Thus, the size and complexity of the exposure control plan will be relative to the types of exposure encountered in the employer's work setting. For example, social service employees who must provide services to individuals who are in AFB isolation are covered under the scope of the standard. The employer in this case would only have to include certain minimal elements in his or her exposure control plan. This employer would not have to include elements for identifying individuals with suspected or confirmed infectious TB since these individuals will already have been identified by someone else. Similarly, the exposure control plan of such employers would not have to include procedures for isolating or managing the care of individuals with infectious TB. On the other hand, hospitals that admit or provide medical services to individuals with suspected or confirmed infectious TB would be required to have a more extensive exposure control plan since the employer in this case would be responsible for identifying, isolating and possibly performing high-hazard procedures on individuals with suspected or confirmed infectious TB.

Under paragraph (c)(2)(i), the proposed standard requires that the exposure control plan be written. There are several reasons for having the plan in writing. First, because exposure control must be practiced by everyone—employee and employer—it is imperative that an employee be able to find out what provisions are in place in his or her workplace. In addition, the exposure determination gives an employee who may be unfamiliar with the job a ready reference for ascertaining which job classifications, tasks, and procedures entail occupational exposure. Second, the exposure control plan also serves as an on-site adjunct to the overall infection control plan for the work setting and reinforces the employer's training program. Employees will be trained about the various procedures developed by the employer to eliminate and minimize exposure. Having the procedures written and available at the work site will provide a ready reference for employees and will serve as an adjunct to their training. Third, having the plan in writing is also important for enforcement purposes. By reviewing the exposure control plan, an OSHA compliance officer will be able to become familiar with the employer's determination of tasks and procedures with occupational exposure, the job classifications whose duties include those identified tasks, and the policies and procedures the employer uses to minimize occupational exposure along with any revisions to the exposure control plan.

OSHA realizes that many workplaces covered under the scope of the proposed standard may already have comprehensive infection control plans

that may include many of the measures required by the proposed standard. It is not OSHA's intent for employers to duplicate current infection control plans solely for the purpose of complying with the standard. Therefore, the exposure control plan may be comprised of existing documents that are part of a larger infection control plan. However, all elements of the exposure control plan for TB required by the proposed standard must be included. In addition, the plan must be in some manner a cohesive entity by itself or a guidance document must exist that states the overall policy goals and directs the reader to the location of the separate documents that are being used to fulfill the requirements of the standard.

While there will be differences in the elements of employers' exposure control plans, each employer covered under the scope of the standard must have certain minimal elements in his or her plan. Paragraphs (c)(2)(i)(A) through (c)(2)(i)(C) contain the minimal elements that must be included in the exposure control plans of every employer covered under the scope of the standard. Paragraph (c)(2)(i)(A) requires that the exposure control plan must include the exposure determination required under paragraph (c)(1). As discussed above, the exposure determination is necessary to identify those employees who have occupational exposure so that the employer can determine which employees are to be given respiratory protection, medical surveillance and training.

Paragraph (c)(2)(i)(B) requires that the employer develop procedures for informing occupationally exposed employees about suspected or confirmed infectious TB cases and about air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* in order that the employees can take proper precautions against *M. tuberculosis* exposure. Once individuals with suspected or confirmed infectious tuberculosis have been identified, it is necessary to convey this information to employees who may be exposed so that they may take the steps necessary to eliminate or minimize their exposure. When patient confidentiality may be a concern, it is not necessary to use an individual's name to satisfy this provision. For example, lists do not need to be made of all patients in the hospital with active TB. Information may be conveyed to employees by simply labeling the isolation room with the warning sign required under paragraph (h)(2)(iii) while the room is in use for TB isolation. Labeling the room will inform the employees that the individual in the room is in respiratory isolation and the employee must stay out of the room or don the appropriate respiratory protection before entering. Another scenario in which such notification is necessary would be when such an individual must be transported to another facility in an ambulance. In this case, the employees who will be present in the ambulance would have to be notified so that they could utilize proper precautions during the transport.

Paragraph (c)(2)(i)(C) requires that the employer include in the exposure control plan procedures for reporting exposure incidents, including identification of the person to whom the incident is to be reported, and the procedures the employer will use for evaluating the circumstances surrounding exposure incidents as required by paragraph (g)(4)(iv). Under paragraph (j), Definitions, an *exposure incident* * * * is defined as

> * * * an event in which an employee has been exposed to an individual with confirmed infectious TB or to air containing aerosolized *M. tuberculosis* without the benefit of all applicable exposure control measures required by this section.

In the event that unprotected employees are exposed to aerosolized *M. tuberculosis*, it is necessary that this exposure incident be reported to the employer as soon as feasible in order to promptly initiate proper medical management and follow-up of the exposed employee. In addition, quick reporting of exposure incidents permits the employer to investigate the circumstances surrounding such incidents while pertinent conditions remain relatively unchanged and are fresh in the employee's memory.

Procedures need to be in place describing how the exposure incident is to be investigated. Having investigation procedures in place beforehand will help to assure that such investigations are able to be done promptly and in a consistent and thorough manner from case to case. This will assist the employer in complying with the requirement of paragraph (g)(4)(iv) that directs the employer to investigate and document the circumstances surrounding the exposure incident to determine if changes can be instituted that will prevent similar occurrences in the future.

Paragraph (c)(2)(ii) applies to employers who transfer individuals with suspected or confirmed infectious TB to a facility with AFB isolation capabilities. This would apply to employers who operate a facility from which an individual with suspected or confirmed infectious TB is transferred and would not apply to employers whose employees provide certain services such as social welfare services to individuals who have been isolated and in settings where home health care and home hospice care is provided.

The standard does not require any employer to transfer individuals with suspected or confirmed infectious TB. Transfer is an option that employers have that relieves the employer of many provisions of the standard, such as AFB isolation rooms. If an employer chooses to use the transfer option, the employer must include the procedure for implementing the transfer in the exposure control plan.

Paragraph (c)(2)(ii) requires employers who transfer individuals with suspected or confirmed infectious TB to develop exposure control plan procedures that address the following: (1) prompt identification of individuals with suspected or confirmed infectious TB; (2) masking or segregation of individuals with suspected or confirmed infectious TB; and (3) transfer of such individuals to a facility with AFB isolation capabilities.

One of the most important steps in preventing TB transmission is the early detection of individuals who may have infectious TB (Exs. 3–33, 3–34, 3–35, 4B). It is essential that individuals with suspected or confirmed infectious TB be identified as soon as possible so that employees who must have contact with them will be warned early and be able to use appropriate infection control practices to protect themselves from exposure. Obviously, the sooner this is done, the less occupational exposure there will be and the less likely that TB will be transmitted. In addition, early identification of individuals with suspected or confirmed infectious TB will allow for the timely transfer and initiation of effective treatment of those individuals for whom the diagnosis of TB is likely. By promptly administering effective treatment, these individuals can be rendered noninfectious, thus decreasing the time they are infectious and their potential for exposing employees and other people.

OSHA is proposing that employers develop a procedure for the prompt identification of individuals with suspected or confirmed infectious TB as part of the exposure control plan. In order to assure prompt identification, it is necessary for the employer to have procedures in place regarding how this identification will be made. CDC has recommended that identification procedures be based on the prevalence and characteristics of TB in the population served by the specific facility (Ex. 4B). For example,

individuals who come from communities with a high prevalence of TB and exhibit certain signs of TB may be more highly suspected as having infectious TB than individuals from communities with a low prevalence of TB. OSHA, therefore, expects that the procedures may be different depending upon the local conditions.

The procedure needs to contain the following:

Methodology—The employer must describe how he or she will make the determination that an individual should be considered as having suspected or confirmed infectious TB. There are several ways of doing this. The employer can use information provided by a physician or other health care provider in advance of an individual's admission to the employer's facility that the individual has been diagnosed with suspected or confirmed infectious TB. If this is not available the employer must determine whether an individual should be considered as having suspected infectious TB. OSHA defines suspected infectious TB as:

> * * * a potential disease state in which an individual is known, or with reasonable diligence should be known, by the employer to have one or more of the following conditions, unless the individual's condition has been medically determined to result from a cause other than TB: (1) to be infected with *M. Tuberculosis* and to have the signs or symptoms of TB; (2) to have a positive acid-fast bacilli (AFB) smear; or (3) to have a persistent cough lasting 3 or more weeks and two or more symptoms of TB, e.g., bloody sputum, night sweats, anorexia, weight loss and fever. An individual with suspected infectious TB has neither confirmed infectious TB nor has he or she been medically determined to be noninfectious.

Although the definition specifies the criteria the employer must incorporate in his or her plan, the employer will still need to exercise judgment in determining whether an individual meets one or more prongs of the definition. Of course, an employer, such as one who operates a facility in an area of particularly high TB prevalence, is free to use more stringent (i.e., additional) criteria for considering an individual to have suspected infectious TB in his or her particular work setting.

In situations where a medical diagnosis is not available either before or at the time of admission, an employer must collect the information he or she needs to make the determination. This can be accomplished in two ways. The employer can have an employee administer a medical history questionnaire to individuals seeking services from the facility. Another way to obtain information to make this determination is by having an employee observe the individual to ascertain his or her health status, looking for the signs, and asking about the symptoms included in OSHA's definition that may indicate infectious TB. Many employers will use both questionnaires and observation. The employee collecting the information will have to be trained on how to conduct the investigation effectively and with respect for the privacy of the individual.

Responsibilities—The employer must designate responsibilities for determining whether an individual should be considered as having suspected or confirmed infectious TB. However, all employees need to be given clear instructions regarding their roles in the prompt identification of suspected or confirmed infectious TB cases. For example, the health care workers who are the first points of contact in ambulatory care settings and emergency rooms in hospitals could be involved with the initial screening of patients. They may be given several questions to ask a patient, which would be used as information to begin the determination. The next actions would depend upon the responses, and the authority of the health care workers. Some employees, for example, would only report answers to questions or their observation of signs of infectious TB in the client population to someone more knowledgeable. Other employees would be making determinations. The hospital would probably have a different procedure that would be used before or at admission to the hospital for scheduled services. The same hospital might have still another procedure designating responsibility to other employees for identifying patients who develop TB while in the hospital. The Exposure Control Plan must designate those employees who make the determination as to whether an individual has suspected or confirmed infectious TB. An employer should consider such designation(s) carefully because, regardless of who determines that an individual has suspected infectious TB, it is the employer who is responsible for ensuring that the employee knows and uses the proper criteria.

The identification procedures will likely vary among establishments, depending upon the type of work done in the facility. For example, facilities that provide long-term care for the elderly will likely have a different procedure from hospitals that have an open admissions policy. OSHA also expects that the methods different employers use may vary depending on whether the employer is in an area of high or low TB prevalence. This approach is consistent with CDC recommendations.

Promptness—Prompt identification of an individual with suspected or confirmed infectious TB is important because it allows isolation before the disease is spread through the facility. CDC recommends that procedures be in place for prompt identification. However, OSHA expects that the determination will be made as soon as reasonably practical since an employer cannot always make such a determination immediately. For many situations, such as those occurring in a hospice, the employer will have information regarding an individual's health status prior to admitting the individual to the facility. The employer can use this information to determine whether the individual should be considered as having suspected or confirmed infectious TB. In a long-term health care facility, the employer needs to be continually aware of each resident's health status because it can change rapidly. Information regarding the signs or symptoms suspected infectious TB needs to be reported and processed as soon as possible.

Effectiveness—OSHA believes that an effective procedure, when implemented, will identify individuals as having suspected or confirmed infectious TB. OSHA believes that many employers affected by this proposed standard currently use effective procedures and find them to be practical. However, OSHA also recognizes that it will not be possible to ensure that the identification procedure will promptly detect all individuals with infectious TB each time. In homeless shelters, for example, the clients may withhold information requested in a questionnaire because they believe that such information may persuade the shelter to refuse to admit them. Therefore, homeless shelters may have to place greater reliance on observation of the residents for the cluster of signs and symptoms associated with infectious TB. Although this standard would require that homeless shelter workers and others be trained to look for signs in individuals, it is unlikely that all cases will be identified. However, if the employer finds that individuals with suspected and confirmed infectious TB are not being identified, the employer must investigate in order to determine what procedures need to be modified. During an inspection, an OSHA compliance officer will review the adequacy of the procedures, and although a citation would not be issued solely on the basis of failure to identify an individual with suspected infectious TB because no identification system is fool-proof,

failure to identify a number of individuals with undetected suspected or confirmed infectious TB would be good evidence that the procedures or their implementation need to be investigated and improved and could result in a citation.

The employer must also include in the exposure control plan procedures for transferring individuals with suspected or confirmed infectious TB to facilities with AFB isolation capabilities. The procedures must address how those transfers are to take place in order that the transfers may be conducted promptly and with minimal exposure to employees. Specifically, they will include where the cases are to be transferred, how the transfer will occur, and what precautions employees are to take while individuals with suspected or confirmed TB are awaiting transfer.

As the note to paragraph (c)(2)(ii) states, an employer's duties regarding transfer of an individual with suspected or confirmed infectious TB will vary with the type of facility the employer operates and the work performed by his or her employees. For example, the transfer responsibilities of hospitals, long-term care for the elderly, correctional facilities, and hospices may include contacting the receiving facility, providing transport, and taking other steps to ensure the individual can get to the receiving facility. These types of facilities often exercise custodial care over such individuals and, hence, have more responsibility for assuring completion of the transfer. Conversely, the responsibilities a homeless shelter or a facility that offers drug treatment for drug abuse, but that does not have custody over individuals, may only include providing information about the receiving facility, contacting the facility, and providing directions to the facility. An employer who provides home health care or home-based hospice care has no obligation to transfer an individual from his or her home to a receiving facility. Transferring an individual with suspected or confirmed infectious TB protects employees within the facility by making sure the source of occupational exposure is removed and, of course, benefits the individual in that he or she receives help in locating and getting to a receiving facility with the capability for appropriately managing their care.

Paragraph (c)(2)(iii) outlines the additional elements required of employers who have work settings where individuals with suspected or confirmed infectious TB are admitted or provided with medical services. Paragraph (c)(2)(iii)(A) requires that their exposure control plans include procedures for the prompt identification of individuals with suspected or confirmed infectious TB. As discussed above, the early identification of individuals with infectious TB will help to assure that employees who must have contact with those individuals will be warned early and be able to use appropriate infection control practices to protect themselves from exposure. In addition, for employers who have facilities where individuals with suspected or confirmed infectious TB are admitted and provided medical services, prompt identification is essential so that isolation precautions and effective treatment can be initiated as soon as possible, thereby reducing exposure to employees and other people.

Paragraph (c)(2)(iii)(B) requires that the employer develop procedures for isolating and managing the care of individuals with suspected or confirmed infectious TB. Having isolation procedures in place will help to assure that employees are aware of the steps to take in the event that individuals with suspected or confirmed infectious TB are identified. If employees know the proper procedures to follow, they will be better equipped to initiate isolation promptly, thereby reducing the likelihood that individuals with infectious TB will infect others. This provision is in accordance with the most recent CDC guidelines, which also recommend the procedures include:

> (1) The indications for isolation, (2) who is authorized to initiate and discontinue isolation, (3) isolation practices, (4) monitoring of isolation, (5) management of patients who will not comply with isolation practices, and (6) criteria for discontinuing isolation. (Ex. 4B)

While OSHA allows the employer to determine what criteria should be included in the procedures to isolate, the Agency believes that it is prudent for the employer also to consider the elements listed in the CDC guidelines.

Paragraph (c)(2)(iii)(B) also requires that the employer develop policies and procedures for managing the care of individuals with suspected or confirmed infectious TB once they have been placed in isolation. The exposure control plan must include procedures and polices addressing: (1) Minimization of the time an individual with suspected or confirmed infectious TB remains outside of an AFB isolation room or area, (2) minimization of employee exposure in AFB isolation rooms or areas, (3) delay of elective transport or relocation of individuals with infectious TB within the facility and, to the extent feasible, performance of services or procedures for such individuals in an AFB isolation room or area, (4) masking of individuals with infectious TB or use of portable containment engineering controls during transport outside of AFB isolation rooms and return of the individual to an AFB isolation room or area as soon as is practical after completion of the service or procedure, and (5) delay of elective high-hazard procedures and elective surgery until an individual with suspected or confirmed infectious TB is determined to be noninfectious.

It is important to minimize, to the extent feasible, exposure of employees to aerosolized *M. tuberculosis* even while maintaining a high quality of health care and other required services. Developing policies and procedures addressing the items listed above will help to assure that this overall goal is met. For example, there may be times when an individual with suspected or confirmed infectious TB must leave the isolation room or area (e.g., when certain equipment necessary for providing care to the patient cannot be brought into the room). On these occasions having policies in place that minimize the time those individuals must be outside the isolation room or area will help to reduce the likelihood that droplet nuclei are spread. For example, if a particular procedure must be performed outside of the isolation room, time could be minimized by taking the individual directly to the procedure area, performing the procedure upon arrival, and returning the individual to isolation immediately after completion of the procedure. In addition, if a procedure is to be performed outside of the isolation room, a time could be chosen when the procedure area is not being used by others.

The exposure control plan must also contain procedures for minimizing employee exposure in AFB isolation rooms or areas. For example, policies addressing minimizing both the number of employees and time that such employees spend in isolation rooms can reduce exposure. This can be accomplished in a variety of ways. For example, in order to minimize the number of employees entering an isolation room, certain tasks or procedures that might normally be done by several different employees could be done by one person. A nurse coming into the room to administer daily TB treatment could also bring in the patient's breakfast at the same time rather than have a hospital dietician deliver the meal. In addition, the

employer must address minimization of time that employees spend in an isolation room or area. For example, rather than conducting an entire discharge planning interview with an individual in person, the employee may be able to collect and convey a large part of the information over the phone with the individual. Personal contact could be limited to just the time needed to obtain items requiring direct interaction, such as the individual's signature.

Policies are to be included that address the masking of individuals with infectious TB during transport outside of AFB isolation rooms or areas. Masking of individuals may be accomplished, for example, through the use of surgical masks or valveless respirators. A barrier such as a surgical mask, when placed over the mouth of an individual who is coughing, will reduce the formation of droplet nuclei because the mask will collect and contain the droplets as they are discharged before they have time to evaporate and form droplet nuclei. A respirator that does not have an exhalation valve can also be used to capture droplets being discharged. An exhalation valve would permit droplets to pass through and discharge into the air, where they could evaporate and form droplet nuclei. However, while surgical masks prevent the formation of droplet nuclei, they do not prevent exposure to droplet nuclei. As the document ''Biosafety Precautions for Airborne Pathogens'' states:

> There is no reciprocity between the means of prevention of the actual formation of droplet nuclei (coughing into a tissue) and the means of prevention of exposure (barriers to breathing in the droplet nuclei). Once a droplet nucleus has been allowed to form, its small size can penetrate the fiber of a tissue or a surgical mask. Thus these products do not represent adequate physical barriers to the aerosol transmission of droplet nuclei. The appropriate barrier is a well fitted respirator that does not allow leakage of air around the edges and blocks passage of microorganisms in the filter media (fibers or pores) through which air is inspired. Although a simple surgical mask applied to a tuberculosis patient who must be transported outside the isolation room will prevent the dispersal of organisms as droplet nuclei, such a mask does not provide adequate protection to the individual who must breathe air containing droplet nuclei. (Ex. 7–134)

Since masking of an individual with suspected or confirmed infectious TB will reduce the number of droplet nuclei expelled into the air, the employer is required to develop policies addressing the masking of such individuals during transport outside of an AFB isolation room.

It is not OSHA's intent to dictate patient management practices, nor will it be the Compliance Officer's responsibility to determine the correctness of certain patient management policies. However, the Agency believes that the employer must consider the above situations and develop policies that address them, keeping in mind the goal of minimizing employee exposure. This provision is in accordance with CDC recommendations (Ex. 4B).

The exposure control plan must also contain policies for the delay of elective transport or relocation within the facility of individuals with suspected or confirmed infectious TB outside of an AFB isolation room or area. For example, delaying the transfer of an inmate with suspected or confirmed infectious TB from one prison to another, where possible, until the inmate has been determined to be noninfectious, will reduce not only the number of employees exposed, but will also minimize the exposure of other inmates, thereby decreasing the risk of transmission of disease.

Similarly, the exposure control plan is to include policies for the delay of elective high-hazard procedures until an individual with suspected or confirmed infectious TB has been determined to be noninfectious. Elective high-hazard procedures (e.g., pulmonary function testing) or elective surgery (e.g., noncritical dental procedures) might be easily delayed, without compromising care, until an individual with infectious TB has been determined to be noninfectious.

Paragraph (c)(2)(iii)(C) requires the employer to list all high-hazard procedures performed in the workplace. As discussed in paragraph (j), Definitions, high-hazard procedures are defined as ''* * * those procedures performed on an individual with suspected or confirmed infectious tuberculosis in which the potential for being exposed to *M. tuberculosis* is increased due to the reasonably anticipated generation of aerosolized *M. tuberculosis* * * *'' Under paragraph (d)(4) of Work Practice and Engineering Controls, the proposed standard requires that all employers assure that high-hazard procedures are conducted in an AFB isolation room or area. Thus, listing the high-hazard procedures will serve to identify those procedures that require special ventilation considerations (e.g., maintaining negative pressure and properly exhausting contaminated air). This will assist employees in determining which procedures must be performed using such engineering controls and, consequently, will help minimize employee exposure.

For employers who have work settings where TB cases are isolated, paragraph (c)(2)(iii)(D) requires the employer to develop a schedule for the inspection, maintenance, and performance monitoring of engineering controls. Engineering controls required by the proposed standard play an essential role in reducing employee exposures to *M. tuberculosis.* Thus, it is necessary that these controls be appropriately maintained, inspected and monitored in order to assure that they are functioning properly. Since engineering controls are mechanical systems, they are prone to occasional lapses in performance caused by occurrences such as clogged filters, slipping or broken drive belts, burned-out motors, obstructed ducts, and so forth. Since these situations cannot be predicted, it is necessary to regularly inspect engineering controls for proper functioning. Hence, a schedule must be developed for such activities. In addition, employees who are responsible for the maintenance will have a record that they can check to see when certain engineering controls need to be inspected, maintained or monitored. In general, OSHA has left the time frame for these activities up to the employer, except as required under paragraphs (d)(5)(ii) and (d)(5)(iii), since the employer is familiar with the characteristics of the workplace that could affect the performance of these controls (e.g., dusty conditions, high heat and humidity, seasonal variations).

For facilities with clinical or research laboratories, Paragraph (c)(2)(iv) requires that the exposure control plan contain a determination from the director of the laboratory as to whether the laboratory facility should operate at Biosafety Level 2 or 3 containment according to CDC/NIH recommendations. Under paragraph (e), Clinical and Research Laboratories, the proposed standard requires a number of provisions to eliminate or minimize exposure in clinical and research laboratory settings. These provisions are based on CDC/NIH recommendations (Ex. 7–72) for laboratory procedures performed under Biosafety Levels 2 and 3 for an infectious agent such as *M. tuberculosis*. However, as noted in the CDC/NIH recommendations, the selection of a biosafety level depends on a number of factors and it may be necessary to adapt the biosafety level based upon such factors. For example, the CDC/NIH recommendations state that:

Occasions will arise when the laboratory director should select a biosafety level higher than that recommended. For example, a higher biosafety level may be indicated by the unique nature of the proposed activity (e.g., the need for special containment for experimentally generated aerosols for inhalation studies) or by the proximity of the laboratory to areas of special concern (e.g., a diagnostic laboratory located near patient care areas). Similarly, a recommended biosafety level may be adapted to compensate for the absence of certain recommended safeguards. For example, in those situations where Biosafety Level 3 is recommended, acceptable safety may be achieved for routine or repetitive operations (e.g., diagnostic procedures involving the propagation of an agent for identification, typing and susceptibility testing) in laboratories where facilities satisfy Biosafety Level 2 recommendations, provided the recommended Standard Biological Practices, Special Practices, and Safety Equipment for Biosafety Level 3 are rigorously followed. (Ex. 7–72, pg. 70)

OSHA agrees that it is appropriate that such decisions be made by the laboratory director and would allow such adaptations to the CDC/NIH recommendations. However, regardless of adaptations, OSHA requires the laboratory director to determine and document the need for controlled access, anterooms, sealed windows, directional airflow, preventing recirculation of laboratory exhaust air, filtration of exhaust air before discharge outside, and thimble exhaust connections for biological safety cabinets. These determinations, along with any adaptations to the CDC/NIH biosafety level, must be made a part of the exposure control plan. The documentation will provide information to the laboratory employees of adaptations to and changes in recommended biosafety levels.

For employers who provide home health care or home-based hospice care, paragraph (c)(2)(v) specifies the elements that are to be included in the exposure control plan. In home health care and home-based hospice care situations, individuals are in their private homes receiving health care and other services and thus the employer has limited control over the work site in which he or she provides those services. In addition, employers providing such home-based care will not be transferring individuals identified as having suspected or confirmed infectious TB from their homes to facilities with isolation capabilities, nor will the employer be initiating isolation precautions in the home. In recognition of the uniqueness of home-based work settings, OSHA has limited the elements of the exposure control plan for an employer who provides home health care and home-based hospice care. The elements included under this paragraph are intended to address the type of activities that are likely to occur in the home health care work setting. Under this paragraph the employer must include procedures for prompt identification of individuals with suspected or confirmed infectious TB and for minimizing employee exposure to such individuals. As discussed above, in order for employees to take proper precautions in protecting themselves from exposure to TB, it is essential that there be procedures to identity potentially infectious individuals. In many cases the home health care employer may already know that the individual has been identified as having suspected or confirmed infectious TB and has been confined to their home. However, in other cases, an individual may be suffering from other immunocompromised conditions and may develop active TB. Because employees in home health care and home-based hospice care may be providing services to individuals at risk of developing active TB, it is necessary that there be procedures in place for identifying those individuals. In addition, the exposure control plan must include procedures for minimizing employee exposure. Such procedures might include minimizing the time spent in the home by combining tasks to limit the number of entries or by minimizing the number of employees who must enter the home along with the time they spend there. Paragraph (c)(2)(v) also requires that the exposure control plan include a list of high-hazard procedures, if any, performed in the workplace and procedures for delaying elective high-hazard procedures until the individual is noninfectious. Listing the high-hazard procedures will serve to identify those procedures that may require special considerations. In the home setting, this would not include the use of AFB isolation precautions. To the extent possible the employer should also include procedures for when these types of procedures can be delayed. This will decrease the exposure of employees to aerosolized *M. tuberculosis* that might be generated performing these procedures.

Paragraph (c)(2)(vi) stipulates that the employer must document the number of confirmed infectious tuberculosis cases encountered in the work setting in the past 12 months in the Exposure Control Plan whenever the employer is using this information to claim reduced responsibilities related to paragraph (b), Application, and paragraph (g)(3)(iii)(D), Medical Surveillance, of the standard. Under paragraph (b), employers are relieved from implementing certain provisions of the standard if they do not admit or provide medical services to individuals with suspected or confirmed infectious TB and they can demonstrate that, in the past 2 years, there have been no cases of confirmed infectious TB reported in the local county in one or both years and, if any cases have occurred in one of the past 2 years, fewer than 6 confirmed infectious cases were reported in that year. Furthermore, employers desiring to follow the limited program must demonstrate that no such cases have been encountered in his or her employees' work setting in the past 12 months. Under paragraph (g)(3)(iii)(D) of Medical Surveillance, employees with negative TB skin tests are to be provided with a TB skin test every 6 months if the employee works in an intake area where early identification procedures are performed in facilities where six or more individuals with confirmed infectious TB have been encountered in the past 12 months. However, if the employer can document that fewer than 6 individuals with confirmed infectious TB have been encountered in the facility, the employee in the intake area would only have to be provided with a TB skin test annually. The count of the number of confirmed infectious TB cases in the exposure control plan would serve to document that fewer than 6 individuals with confirmed infectious TB had been encountered in the past 12 months, thus relieving the employer of the burden of providing skin tests every 6 months for those affected employees.

Paragraph (c)(2)(vii)(A) requires that a copy of the exposure control plan be accessible to employees. The reason for this is to assure that an employee can get and consult the exposure control plan within a reasonable time, place and manner. Having access to the plan encourages employees to develop a complete understanding of the plan and its application, so that the program can be carried out by both employer and employees. Having the plan available also serves as an on-site adjunct to the overall infection control program and may reinforce the training programs.

For fixed work sites and primary workplace facilities, the plan must be maintained on-site at all times. For those situations where an employee(s) travels between work sites or where the employee's work is carried out at more than one geographical location, the plan may be maintained at the primary workplace facility. To ensure access, the plan should be in a central location

where an employee may see it whenever he or she wishes. However, in order to allow flexibility, OSHA is not specifying where the plan must be kept. The employer is permitted to determine where the plan is kept provided that the employee can access a copy of the plan at the workplace, within the workshift. For example, if the plan is maintained on a computer, access to the computer or hard copy must be available to the employee. Likewise, if the plan is comprised of several separate policy documents, copies of all documents must be accessible in addition to any general policy statement or guiding document that may exist.

Paragraph (c)(2)(vii)(B) requires that the exposure control plan be reviewed at least annually and updated whenever necessary to reflect new or modified tasks, procedures, or engineering controls that affect occupational exposure and to include new or revised employee positions with occupational exposure. An example of such a situation would be when an employer in a facility that had previously transferred individuals with suspected or confirmed infectious TB decided that such individuals would be admitted and provided medical services. The purpose of this requirement is to assure that all new tasks and procedures are evaluated in order to determine whether they could result in occupational exposure. New and revised job classifications must be added to the lists of job classifications and tasks and procedures identified in (c)(1)(i) of this section in order to assure full coverage of occupationally exposed employees. The updating must occur as soon as feasible and may not be postponed until the annual review.

Paragraph (c)(2)(vii)(C) requires that the exposure control plan be made available to the Assistant Secretary and the Director upon request for examination and copying. The purpose of this requirement is to allow the OSHA representative to review an employer's plan, including the exposure determination of employees at risk for occupational exposure. Although the Assistant Secretary or the Director could request the plan at any time, it will usually be requested by an OSHA compliance safety and health officer (CSHO) during the course of a workplace inspection. The CSHO needs to examine the plan in order to see what procedures and program planning for the control of occupational exposures have been instituted and whether they meet the requirements of the standard.

Paragraph (d) Work Practices and Engineering Controls

It is generally acknowledged that protection of the employee is most effectively attained by elimination or minimization of the hazard at its source, which engineering controls and work practices are both designed to do. Industrial hygiene principles also teach that control methods that depend upon the vagaries of human behavior are inherently less reliable than well-maintained mechanical methods. For these reasons, OSHA has preferred engineering and work practice controls and has required, under paragraph (d)(1), that they be used to eliminate or minimize employee exposure to *M. tuberculosis.* Nevertheless, OSHA recognizes that situations may exist in which neither of these control methods is feasible and that, in these circumstances, employee protection must be achieved through the use of personal protective equipment, primarily respirators. In other situations, personal protective equipment may have to be utilized in conjunction with engineering controls and/or work practices to obtain a further reduction in employee exposure.

Engineering controls serve to reduce employee exposure in the workplace by either removing the hazard or isolating the worker from exposure. These controls include process or equipment redesign, process or equipment enclosure (e.g., biosafety cabinets), and employee isolation. In general, engineering controls act on the source of the hazard and eliminate or reduce employee exposure without reliance on the employee to take self-protective action.

In comparison, work practice controls reduce the likelihood of exposure through alteration of the manner in which a task is performed (e.g., closing the door of an AFB isolation room immediately upon entering or exiting). Although work practice controls also act on the source of the hazard, the protection they provide is based upon employer and employee behavior rather than installation of a physical device. In many instances these two control methodologies work in tandem, because it is often necessary to employ work practice controls to assure effective operation of engineering controls. Under the provisions of the preceding paragraph, Exposure Control Plan, the employer is required to develop a number of work practices relative to controlling occupational exposure to TB. In paragraph (d)(2), these work practices are required to be implemented in the work setting.

In developing the methods of compliance section for this proposal, OSHA carefully considered the work environments that have the potential for producing occupational exposures. Since the source of the hazard is frequently a living person, typical methods of reducing or eliminating the hazard at the source may not always be feasible. For example, in an industrial operation a process may be entirely enclosed and operated or monitored by an employee at a remote location, a situation that would rarely, if ever, occur in the work settings covered by this standard. The Agency believes, therefore, that prevention of exposures to *M. tuberculosis* will often require use of a combination of control methods to achieve adequate protection of employees. Paragraph (d)(1) requires work practices and engineering controls to be used to eliminate or minimize employee exposures.

Not all facilities will have the capabilities to admit or provide medical services to individuals with suspected or confirmed infectious tuberculosis. Consequently, these facilities will have to transfer such individuals to another facility where isolation rooms or areas are available. Paragraph (d)(3) requires that individuals with suspected or confirmed infectious TB must be identified and, except in settings where home health care or home-based hospice care is provided, shall be: (i) masked or segregated in such a manner that contact with employees who are not wearing respiratory protection is eliminated or minimized until transfer or placement in an AFB isolation room or area can be accomplished; and (ii) placed in an AFB isolation room or area or transferred to a facility with AFB isolation rooms or areas within 5 hours from the time of identification, or temporarily placed in AFB isolation within 5 hours until placement or transfer can be accomplished.

Masking or segregation of individuals with suspected or confirmed infectious TB while those individuals are awaiting placement in isolation or transfer to another facility is done to assure that employee exposure is minimized to the extent feasible. This provision, drawn from CDC recommendations (Ex. 4B), is aimed at minimizing the exposure of employees in areas where individuals are first identified as having suspected or confirmed infectious TB. Although CDC recommends masking such individuals, OSHA presents a choice of masking or segregation because the Agency believes that this practice is directly involved with the medical management of such individuals. It is OSHA's mission to protect employees

from occupational exposure to tuberculosis and it is not the Agency's intent to dictate medical practice relative to individuals with suspected or confirmed infectious TB. Therefore, where the employer has chosen not to mask individuals with suspected or confirmed infectious TB when they are not in isolation rooms or areas or when such individuals cannot be masked (e.g., because they are combative), the employer must segregate these individuals in a manner such that contact with employees who are not wearing respiratory protection is eliminated or minimized. Segregation could be accomplished, for example, by having the individual wait in an area out of the main traffic of a waiting room or intake area or in a vacant examination room that is not needed for patient/client consultations. The time that a facility can permit an individual to await placement or transfer is limited to 5 hours. After that the individual must be placed in isolation.

The primary purposes of AFB isolation rooms or areas are to (1) isolate patients who are likely to have infectious TB from unprotected employees, (2) prevent escape of droplet nuclei from the room, thus preventing entry of *M. tuberculosis* into the corridor and other areas of the facility where unprotected employees may be exposed, and (3) provide an environment that will promote reduction of the concentration of droplet nuclei through various engineering controls (Ex. 4B). All of these will reduce employee exposure. Indeed, placement of individuals with suspected or confirmed infectious TB in an AFB isolation room is the most effective way to prevent or lessen transmission.

OSHA has proposed that individuals with suspected or confirmed infectious TB be isolated or transferred within 5 hours from the time of being identified as a suspected or confirmed case. The Agency realizes that the time it will take to isolate or transfer an individual once he or she is identified as having suspected or confirmed infectious TB may vary and that circumstances may arise that cause delays in initiating isolation (e.g., all isolation rooms may be occupied by other patients). However, OSHA is also concerned about the amount of time an individual, who has been identified as having suspected or confirmed infectious TB, should be permitted to stay in non-isolation areas. Individuals who must wait for extended periods of time before placement in AFB isolation or transfer may present a risk of exposure to employees working in these areas even though these individuals may be masked. A study by Moran et. al. shows that emergency departments that made a presumptive diagnosis of TB were able to initiate isolation in an average of 5 hours from the time of patient registration (Ex. 7–251). Patient registration usually precedes identification. The standard requires that procedures be in place for prompt identification of individuals with suspected or confirmed infectious TB. In view of this requirement and the fact that the study was based on time elapsed from patient registration to isolation, which included the time the patient waited to be medically observed, the Agency has preliminarily concluded that five hours from the time of being identified is a reasonable cutoff point for transfer or placement in isolation.

The Agency's concern regarding permitting identified individuals to wait for extended periods, even though they are masked, before they are transferred or isolated is not unfounded. The American Thoracic Society, in its document Control Of Tuberculosis In The United States, states:

> * * *Patients unable to cooperate in covering coughs and sneezes can wear ordinary surgical masks for *short periods,* for example, while being transported within institutions. For *longer periods,* masks on patients are stigmatizing, uncomfortable, and probably ineffective. (Ex. 5–80) (emphasis added)

Consequently, a cutoff point of 5 hours has been proposed as the maximum amount of time individuals who have been identified with suspected or confirmed infectious TB may await transfer or placement into AFB isolation. As discussed under the Exposure Control Plan, paragraph (c), employers are required to have procedures in place for isolating or transferring individuals identified with suspected or confirmed infectious TB so that AFB isolation can be executed expeditiously. Five hours would appear to be a reasonable amount of time to carry out these procedures. OSHA believes that longer periods of time are likely to pose too great a risk of exposure to employees in the vicinity. The longer an individual with suspected or confirmed infectious TB remains outside of AFB isolation, the greater the risk of transmission.

It should be noted that the 5-hour cutoff is the amount of time allotted *per facility* to accomplish AFB isolation or transfer of these individuals. More specifically, if an individual spent 4 hours awaiting transfer at an identifying facility, the receiving facility would still be allowed 5 hours to accomplish isolation, not just the one hour remaining since initial identification of the individual. The intent of the proposed facility-based 5-hour period is to allow the receiving facility adequate time to accomplish isolation and to recognize that the receiving facility should not be held responsible for circumstances beyond the facility's control (e.g., the time the individual waited before arrival at the receiving facility).

If placement or transfer cannot be completed within five hours, it must be done as soon as possible thereafter. In addition, the employer must assure in such a case that his or her facility has AFB isolation rooms or areas for the isolation of the individual until placement or transfer can be accomplished. More specifically, it is not necessary to construct a dedicated AFB isolation room or area to isolate such individuals while awaiting transfer or placement within the facility. The definition of ''AFB isolation room or area'' states that this may be a room, area, booth, tent, or other enclosure that is maintained at negative pressure to adjacent areas in order to control the spread of aerosolized *M. tuberculosis.* For example, such isolation might be achieved by placing a portable stand-alone HEPA filtration unit (vented to the outside) in an unused examination room. Another method is the use of a rigid enclosure on casters with a ventilation unit to achieve negative pressure, a window kit to safely exhaust the enclosure's air to the outside, and a digital pressure monitor to assure maintenance of negative pressure within the enclosure. As is the case with any AFB isolation room or area, the means used to isolate an individual awaiting placement or transfer must achieve negative pressure and have its air safely discharged to the outside. OSHA seeks comment regarding the 5-hour limit on placement or transfer and measures that can be used for AFB isolation in those situations when transfer or placement cannot be accomplished within that time.

Paragraph (d)(4) stipulates that high-hazard procedures must be conducted in AFB isolation rooms or areas. High-hazard procedures as defined in paragraph (b), Definitions, are procedures performed on an individual with suspected or confirmed infectious TB in which the probability of *M. tuberculosis* being expelled into the air is increased. These procedures include, but are not limited to, endotracheal intubation and suctioning, diagnostic sputum induction, aerosol treatments (including pentamidine therapy), pulmonary function testing, and bronchoscopy. These procedures also include autopsy, clinical, surgical, and laboratory procedures that may

aerosolize *M. tuberculosis*. In view of the increased probability of droplet nuclei generation associated with these procedures, all high-hazard procedures are required to be performed in rooms, areas, or booths that meet AFB isolation criteria (e.g., negative pressure) in order to contain the droplet nuclei and eliminate or minimize employee exposure. Other procedures that may generate aerosols (e.g., irrigation of tuberculous abscesses, homogenizing or lyophilizing infectious tissue), are also covered by this provision. (See paragraph (e) of this proposal for requirements for microbiological practices and containment equipment in laboratories.)

Paragraph (d)(5) requires that engineering controls be used in facilities that admit or provide medical services or AFB isolation to individuals with suspected or confirmed infectious TB except in settings where home health care or home-based hospice care is being provided. For example, engineering controls must be used in isolation rooms or areas, areas where high hazard procedures are performed, and autopsy rooms where *M. tuberculosis* may be aerosolized. This provision specifically excepts settings where home health care or home-based hospice care is being provided. In such situations, the employer is not in control of the employee's work setting because the setting is the private home of the individual being provided with care. In view of this, an employer providing home health care or home-based hospice care would not be required to implement engineering controls in the individual's home.

In conjunction with this provision, paragraph (d)(5)(i) requires that negative pressure be maintained in AFB isolation rooms or areas. The purpose of this provision is to prevent the escape of aerosolized *M. tuberculosis* from a room and into the corridors and other areas of the facility where unprotected employees may be exposed. In order for air to flow from one area to another, there must be a difference in the pressure between the two areas. Air will flow from the higher pressure to the lower pressure area. The lower pressure area is at ''negative pressure'' relative to the higher pressure area. The level of negative pressure achieved will depend on the physical configuration of the area, including the air flow path and flow openings. A pressure differential of 0.001 inch of water and an inward air velocity of 100 feet per minute (fpm) are minimum acceptable levels. The pressure difference necessary to achieve and maintain negative pressure in a room is very small and may be difficult to measure accurately. Negative pressure can be achieved by balancing the room supply and exhaust flows to set the exhaust flow to a value of 10% [but no less than 50 cubic feet per minute (cfm)] greater than the supply (Ex. 4B).

As stated above, the negative pressure principle plays an important role in controlling the spread of *M. tuberculosis* to other areas of the facility where unprotected workers may be exposed. In isolation rooms and areas, and in areas where high hazard procedures (including autopsies) are performed, engineering controls creating negative pressure will prevent the escape of droplet nuclei from the room, thus preventing dispersion of *M. tuberculosis* into the corridor and other areas of the facility where unprotected employees may be working.

In addition, negative pressure fulfills the secondary purpose of general ventilation by reducing the concentration of contaminants in the air. General ventilation maintains air quality by two processes, dilution and removal of airborne contaminants. Dilution reduces the concentration of contaminants in a room by supplying air that does not contain those contaminants. The supply air mixes with and then displaces some of the contaminated room air, which is subsequently removed from the room by the exhaust system. This process reduces the concentration of droplet nuclei in the room air and the risk of TB transmission.

OSHA is not proposing to allow the use of ultraviolet germicidal irradiation (UVGI) in place of ventilation for controlling aerosolized *M. tuberculosis*. Although the germicidal properties of certain wavelengths of ultraviolet light (UV–C) are generally recognized, the Agency has not included UVGI as a primary engineering control in the proposed standard. With regard to the use of UVGI, CDC states:

> Because the clinical effectiveness of UV systems varies, and because of the risk for transmission of *M. tuberculosis* if a system malfunctions or is maintained improperly, UVGI is not recommended for the following specific applications: 1. Duct systems using UVGI are not recommended as a substitute for HEPA filters if air from isolation rooms must be recirculated to other areas of a facility. 2. UVGI alone is not recommended as a substitute for HEPA filtration or local exhaust of air to the outside from booths, tents, or hoods used for cough-inducing procedures. 3. UVGI is not a substitute for negative pressure. (Ex. 4B)

The CDC goes on to discuss a number of factors that affect the effectiveness of UVGI and UV lamps in killing airborne tubercle bacilli. These factors include the intensity of UVGI, the duration of irradiation of the organism, the relative humidity of the environment, the age of the UV lamp, and the amount of dust on the lamp's surface (Ex. 4B). In light of this information, the Agency does not believe that UVGI can reliably and uniformly control airborne tubercle bacilli. Consequently, UVGI is not acceptable as a primary engineering control. However, some employers may choose to use UVGI as a supplement to ventilation or HEPA filtration. In recognition of this, OSHA has included information regarding UVGI safety and health concerns in Appendix D of this section.

Paragraph (d)(5)(ii) requires that in those areas where negative pressure is required (i.e., AFB isolation rooms or areas), maintenance of negative pressure must be qualitatively demonstrated (e.g., by smoke trails) daily while in use for tuberculosis isolation. In Supplement 3 of its 1994 guidelines, CDC states:

> TB isolation rooms should be checked daily for negative pressure while being used for TB isolation. (Ex. 4B)

The principle and advantages of negative pressure have been discussed above. Proper maintenance of negative pressure will prevent the contaminated air from escaping from the room or area and exposing unprotected employees. One means of qualitatively demonstrating negative pressure is through the use of smoke trail testing (see Appendix G of this section). Other methods include flutter strips or continuous monitoring devices. With regard to the safety and effectiveness of these methods, the CDC states:

> The concern over the use of smoke tubes is unfounded. Controlled tests by NIOSH have shown that the quantity of smoke that is released is so minute that it is not measurable in the air. The location of the patient and the length of time the patient is exposed dilute the smoke to several orders of magnitude below an 8-hour exposure limit. It is not practical and often not effective to use flutter strips or continuous monitoring devices as alternatives to indicate directional air movement. The air flow (due usually to the small clearance area under the door) is insufficient to move the flutter strip. Likewise, low negative pressure, which will satisfactorily provide adequate directional air flow into the isolation room, may not be readable on continuous monitoring devices. Devices must be capable of reading 0.001 inch of water, the established minimum, to be effective. (Ex. 4B)

In light of this information, employers should be aware that when choosing a method other than smoke trails to demonstrate maintenance of negative pressure, the method chosen should be

reviewed carefully in order to assure that the intended test can be effectively conducted.

Paragraph (d)(5)(iii) stipulates that engineering controls must be maintained, and inspected and performance monitored for filter loading and leakage every six months, whenever filters are changed, and more often if necessary to maintain effectiveness. The primary intent of this provision is to assure that engineering controls are maintained in such a manner that they continue to function effectively. As discussed previously, a number of factors can affect the functioning of engineering controls, such as frozen bearings, broken belts, and burned out motors. It is the employer's responsibility to maintain engineering controls in proper working condition. That is, if a belt breaks on a fan motor, it is not appropriate to delay repairs until the six-month inspection. This provision does, however, stipulate a maximum time period of six months between inspections and performance monitoring of engineering controls and HEPA filters in air systems carrying air that may reasonably be anticipated to contain aerosolized *M. tuberculosis.* The employer's maintenance schedule may specify more frequent inspection, maintenance, and performance monitoring based upon conditions found in that particular work site. For example, the employer, being more familiar with his or her own work setting, may have knowledge that the work environment is very dusty, thus necessitating a more frequent period for changing the filters. When filters are changed, performance monitoring must be conducted to assure that the filter has been correctly installed and is functioning properly. In view of the importance of these systems in reducing the concentration of droplet nuclei and thereby the risk of TB transmission, OSHA believes that six months is the longest period that these systems should be allowed to operate without inspection and performance monitoring. This maximum six-month period of time between consecutive inspections and performance monitoring of HEPA filters is supported by CDC (Ex. 4B).

Paragraph (d)(5)(iv) requires that air from AFB isolation rooms or areas must be exhausted directly outside, away from intake vents and employees. If the air from these areas cannot be exhausted in such a manner or must be recirculated, it must pass through HEPA filters before discharge or recirculation.

In order for the air to be safely discharged, exhaust ducts must not be located near areas that may be populated (e.g., sidewalks or windows that may be opened). In addition, ventilation system exhaust discharges must be designed to prevent re-entry of exhaust air. Wind blowing over a building creates a highly turbulent recirculation zone, which can cause re-entry of the exhaust into the building. Exhaust flow needs to be discharged above the zone. When exhaust air cannot be safely discharged, it must pass through HEPA filters to remove droplet nuclei, thereby precluding re-entry of potentially contaminated air or exposure of individuals who may have to pass through the exhaust airstream. The employer should be aware that exhausting of this air may also fall under federal, state and local regulations concerning environmental discharges.

This provision also states that if a portion of this air is recirculated, it must pass through a properly designed, installed, and maintained HEPA filter before discharge back into general facility ventilation. HEPA filters clean air through the physical removal of particulates from the airstream. These filters have a minimum removal efficiency of 99.97% for particles ≥ 0.3 microns in diameter. Droplet nuclei of *M. tuberculosis* range in size from 1 micron to 5 microns in diameter. Therefore, HEPA filtration can be expected to remove most droplet nuclei from the air. It should be noted that whenever feasible, exhaust air from the AFB isolation rooms or areas must be exhausted to the outside. In its 1994 guidelines, CDC states:

> Air from TB isolation rooms and treatment rooms used to treat patients who have confirmed or suspected infectious TB should be exhausted to the outside in accordance with applicable Federal, state, and local regulations. The air should not be recirculated into the general ventilation. In some instances, recirculation of air into the general ventilation system from such rooms is unavoidable (i.e., in existing facilities in which the ventilation system or facility configuration makes venting the exhaust to the outside impossible). In such cases, HEPA filters should be installed on the exhaust duct leading from the room to the general ventilation system to remove infectious organisms and particulates the size of droplet nuclei from the air before it is returned to the general ventilation system (Section II.F; Suppl. 3). Air from TB isolation rooms and treatment rooms in new or renovated facilities should not be recirculated into the general ventilation system. (Ex. 4B)

The Agency agrees with CDC that exhaust air should be vented to the outside. However, OSHA recognizes that there may be instances where outside discharge may not be feasible and has, therefore, permitted recirculation with HEPA filtration of the recirculated air, in such instances.

Paragraph (d)(5)(v) states that ducts carrying air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* must be maintained under negative pressure for their entire length before in-duct HEPA filtration or until the ducts exit the building for discharge. Ducts maintained under negative pressure will contain exhaust air within the system. Air will not escape to the outside as it would under positive pressure even if there are leaks in the ducts. The purpose of this provision is to prevent escape of air that may contain aerosolized *M. tuberculosis* into areas where occupational exposure is not anticipated and unprotected employees may be exposed.

Paragraph (d)(5)(vi) requires that, while in use for TB isolation, doors and windows of AFB isolation rooms or areas must be kept closed except when doors are opened for the purpose of entering or exiting and when windows are part of the ventilation system being used to achieve negative pressure. For example, the window may be serving as the exit for the exhaust from an in-room HEPA filtration unit. As stated above, AFB isolation rooms and areas are to be maintained under negative pressure while in use for TB isolation. Negative pressure in a room can be altered by small changes in the ventilation system operation, or by the opening and closing of the isolation room doors or windows. In order to assure that the ventilation system functions as intended, it is essential that, once an operating configuration has been established, doors and windows be opened only when necessary.

Paragraph (d)(5)(vii) stipulates that when an AFB isolation room or area is vacated by an individual with suspected or confirmed infectious TB, the room or area must be ventilated for an appropriate period of time, according to current CDC recommendations for a removal efficiency of 99.9%, before permitting employees to enter without respiratory protection (see Appendix C of this section). The time required for removing airborne particles from an enclosed space depends on several factors. These include the number of air changes per hour (which is determined, in part, by the number of cubic feet of air in the room or booth), the rate at which air is entering the room or booth at the intake source versus the rate at which it is being exhausted, the location of the ventilation inlet and outlet, and the physical configuration of the room or booth. The times needed to achieve a given removal efficiency (i.e., 90%, 99%, and 99.9%) presented in

Appendix C of this section assume perfect air mixing within a space. However, perfect mixing of air normally does not occur because a number of factors, such as room configuration, may influence the movement of air. Because perfect air mixing is not likely to occur, the necessary time required for a specific removal efficiency, as presented in Appendix C of this section, may be underestimated. In order to compensate for this shortcoming, OSHA has proposed that the most conservative (i.e., protective) removal efficiency, i.e., 99.9%, be used to determine the appropriate amount of time an AFB isolation room or area must be ventilated before permitting employees to enter without respiratory protection. Using this conservative approach will help to assure that an appropriate time has passed before unprotected employees enter the area, even in situations where perfect air mixing has not occurred. Ventilation of the room would not be necessary if the room was previously occupied by an individual with suspected infectious tuberculosis and that individual was medically determined to be noninfectious, since there would be no droplet nuclei present.

Paragraph (d)(6) requires that the employer must inform any outside contractor who provides temporary or contract employees who may incur occupational exposure of the hazard, so that the contractor can institute precautions to protect his or her employees. OSHA is concerned that the contractor be aware of the existence of TB hazards so that appropriate actions can be undertaken to prevent the contractor's employees from being unwittingly exposed. By conveying such information to the contractor, accountability for these employees is established. If the contractor is aware of the hazards, then it is the responsibility of the contractor to institute procedures to protect his or her employees from occupational exposure to *M. tuberculosis*.

Paragraph (e) Clinical and Research Laboratories

This paragraph addresses requirements that must be met by clinical and research laboratories engaged in the culture, production, concentration, experimentation, and manipulation of *M. tuberculosis*. These requirements apply in addition to the other requirements of the standard.

The risks associated with direct and routine work with pathogens have long been recognized:

> Microbiology laboratories are special, often unique, work environments that may pose special infectious disease risks to persons in or near them. Personnel have contracted infections in the laboratory throughout the history of microbiology. (Ex. 7–72)

Clinical and research laboratories working with *M. tuberculosis* are no exception, and the risks associated with work in such facilities warrant additional protective measures.

Prior to 1984, no single code of practice, standards, guidelines or other publication providing detailed descriptions of techniques or equipment for laboratory activities involving pathogens was available. In that year, the CDC and the National Institutes of Health (NIH) published guidelines entitled ''Biosafety in Microbiological and Biomedical Laboratories''. These biosafety guidelines were based on combinations of standard and special practices, equipment, and facilities recommended for use when working with various infectious agents in laboratory settings. The most current revision of these guidelines is dated 1993. (Ex. 7–72)

The biosafety guidelines are not limited to *M. tuberculosis*, which is the subject of this standard. They are applicable to work with any infectious agent. The basic format for the biosafety guidelines categorizes infectious agents and laboratory activities into four classes or levels denoted as Biosafety Levels 1 through 4. These biosafety levels (BSL) are comprised of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed and the hazard posed. The Guidelines indicate the BSL to be used when working with various infectious agents and infected animals.

There is a risk to employees working with materials containing *M. tuberculosis*. When the concentration of this bacterium is increased as the result of growing it in cell culture or through artificial concentration, then the risk of transmission to employees increases if the bacteria are not contained. Therefore, the proposed standard requires the employer to implement a number of provisions specifically related to these laboratory work settings.

The requirements in paragraph (e), including those regarding biosafety cabinets, are derived primarily from the CDC/NIH recommendations found in ''Biosafety in Microbiological and Biomedical Laboratories'' (Ex. 7–72). Only those provisions that relate to the health and safety of employees are required by the standard. The provisions in paragraph (e) are a minimal program, and OSHA anticipates that employers affected by this paragraph will continue to follow any other appropriate portions of the above recommendations in addition to the requirements of this standard. In addition, the employer is responsible for following this entire standard (e.g. training employees, medical surveillance).

Paragraph (e) applies to two types of facilities that OSHA has designated as ''clinical laboratories'' and ''research laboratories.'' For the purpose of this standard a clinical laboratory is a laboratory or area of a facility that conducts routine and repetitive operations for the diagnosis of TB, such as preparing acid-fast smears and culturing sputa or other clinical specimens for identification, typing or susceptibility testing. A research laboratory is a laboratory that propagates and manipulates cultures of *M. tuberculosis* in large volumes or high concentrations that exceed those used for the identification and typing activities common to clinical laboratories.

The proposed standard requires, in paragraphs (e)(2)(i)(A) through (D), that both clinical and research laboratories follow several standard microbiological practices. All procedures are to be performed in a manner that minimizes the creation of aerosols. In view of the mode of transmission of *M. tuberculosis*, that is, through inhalation of airborne organisms, this provision is extremely important in eliminating or minimizing employee exposure. It is the responsibility of the employer to evaluate laboratory tasks and institute the measures necessary to minimize the creation of aerosols.

OSHA also proposes to adopt the good laboratory and infection control practice of prohibiting pipetting or suctioning by mouth. The use of cotton plugs or other barriers does little to reduce the hazards of mouth pipetting. Even a technician who is skilled in mouth pipetting may inadvertently suck fluids containing *M. tuberculosis* into the mouth. In addition to producing *M. tuberculosis*-containing aerosols when the fluid is expelled, these fluids may also contain bloodborne pathogens that would have contacted the employee's mucous membranes (i.e., the mouth) as well as any blisters, cuts, or other lesions in the mouth or on the lips.

Work surfaces and laboratory equipment must be decontaminated at the end of each shift and after any spill of viable material. This is recognized as good laboratory practice in minimizing the spread of contamination.

Finally, the proposed standard requires that all cultures, stocks, and other wastes contaminated with *M. tuberculosis* be decontaminated before

disposal by a decontamination method, such as autoclaving, known to effectively destroy *M. tuberculosis*. Materials to be decontaminated outside of the immediate laboratory are to be placed in a durable leakproof container, closed to prevent leakage for transport from the laboratory, and labeled or color coded in accordance with paragraph (h)(1)(ii) of this section. Decontamination before disposal helps assure that other employees are not inadvertently exposed to the bacterium.

Although the proposed standard requires proper containerization of laboratory wastes, it includes no such requirement for wastes originating from the provision of care or services to individuals with suspected or confirmed infectious TB (e.g., facial tissues that the individual has used). The reason for this is that items, such as facial tissues, capture and contain the liquids generated by the individual. Once captured, the liquid is not readily aerosolized. In their guidelines, the CDC states:

> Disposable items contaminated with respiratory secretions are not associated with transmission of *M. tuberculosis*. (Ex. 4B)

In the laboratory, however, the liquids containing *M. tuberculosis* are generally not captured or contained on an item but exist as an individual specimen or culture. Also, in some instances, the bacilli have been concentrated. The possibility, therefore, for formation of droplet nuclei from these wastes is increased. Consequently, it is necessary to properly containerize and label laboratory wastes to assist in preventing droplet nuclei formation and possible infection. Proper containerization and labeling of wastes to be decontaminated outside a laboratory not only help prevent employee exposure but also warn employees who come in contact with this waste of the hazard within the container.

Paragraphs (e)(2)(ii)(A) through (E) describe special practices to be followed in clinical and research laboratories, such as limiting access to the laboratory to authorized personnel, preparing and maintaining a biosafety manual, properly containerizing materials contaminated with *M. tuberculosis*, immediately containerizing and cleaning up all spills potentially contaminated with *M. tuberculosis*, and posting a sign with the universal biohazard symbol on access doors when materials containing or animals infected with *M. tuberculosis* are present. Limiting access to these laboratories assures that unauthorized individuals are not placed at risk, and that they do not distract or otherwise interfere with the activity of the authorized employees. This provision works in concert with the requirement for signs in paragraph (h)(2)(iv) and ensures that only employees who meet the special requirements set forth by the laboratory director, which will include training, personal protective equipment, and other requirements, could enter the area.

The requirement for a biosafety manual helps assure that any additional procedures are developed to address situations that are unique to a particular facility and to provide appropriate protection to exposed employees. The manual must be reviewed as necessary and at least annually. The manual must also be updated as necessary to reflect changes in the work setting. The phrase ''as necessary'' has been used to indicate that updating of the manual to reflect work setting changes is to be done as soon as possible and is not to be postponed until the annual review. Employees are required to read the biosafety manual's sections on potential hazards and practices and procedures.

The requirement that contaminated material removed from the work area be placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping is to assure that there are no accidental spills or other contamination that may place other employees at risk.

Paragraph (e)(2)(ii)(D) requires that spills be cleaned up immediately by employees trained and equipped to work with potentially concentrated *M. tuberculosis*. Because *M. tuberculosis* can become aerosolized during cleanup procedures, the task cannot be done by someone who is not skilled and properly equipped. In addition, exposure incidents must be reported so that the post-exposure management and follow-up required by paragraph (g) can be initiated and the circumstances surrounding the exposure incidents can be investigated.

Paragraph (e)(2)(ii)(E) requires that, when materials or animals infected with *M. tuberculosis* are present in the laboratory, a hazard warning sign, in accordance with paragraph (h)(2)(iv) of Communication of Hazards and Training, incorporating the universal biohazard symbol, shall be posted on all laboratory and animal room access doors. Because *M. tuberculosis* is present in the materials listed above, it is necessary to warn individuals who may enter this area of the hazards that are present so that they can take proper precautions to guard themselves against exposure.

The requirements of paragraph (e)(2)(iii)(A) stipulate that whenever activities with the potential for generating aerosols of *M. tuberculosis* are conducted, and whenever high concentrations or volumes of *M. tuberculosis* are used, a certified Class 2 biological safety cabinet must be used. Such materials may be centrifuged in the open laboratory, i.e., outside of a biosafety cabinet, if sealed rotor heads or centrifuge safety cups are used. These requirements protect employees from exposure during the performance of procedures by assuring that aerosolized *M. tuberculosis* will be contained and kept away from the worker's breathing zone.

Paragraph (e)(2)(iii)(B) requires that biological safety cabinets shall be certified when they are installed, annually thereafter, whenever they are moved, and whenever filters are changed. Biological safety cabinets must be certified to ensure that they will provide the proper protection. The National Sanitation Foundation (NSF) Standard 49 describes design, construction, and performance criteria for biosafety cabinets. (Ex. 7–135) Moreover, this NSF standard is subject to periodic review by the NSF in order to keep the requirements consistent with new technology. OSHA has incorporated the current NSF Standard 49 performance criteria into the OSHA standard. For example, Standard 49 states:

> * * * that each cabinet be tested and performance evaluated on site, assuring that all physical containment criteria are met at the time of installation, prior to use, and periodically thereafter. (Ex. 7–135)

NSF Standard 49 also calls for recertification of cabinets at least annually, when HEPA filters are changed, and after maintenance repairs or relocation of a cabinet. Therefore, OSHA believes that the requirements in the proposed standard are appropriate and that cabinets that are certified by the manufacturer as Class 2 or 3 will provide adequate protection to employees.

Paragraph (e)(2)(iv) requires that a method for decontamination of wastes contaminated with *M. tuberculosis* (e.g., autoclave, chemical disinfection, incinerator, or other approved decontamination system known to effectively destroy *M. tuberculosis*) must be available within or as near as feasible to the work area. The availability of such methods of decontamination is required for inactivating or destroying *M. tuberculosis* in or on a variety of media, including culture fluids, plastic ware, and equipment. These materials must be decontaminated to prevent potential aerosolization of *M.*

tuberculosis and inadvertent exposure of employees outside of the laboratory.

Research laboratories working with *M. tuberculosis* are held to several additional requirements. Paragraph (e)(3)(i)(A) requires that research facilities keep laboratory doors closed when working with *M. tuberculosis*. Paragraph (e)(3)(i)(B) requires that access to the work area be limited to persons who comply with specified entry and exit requirements. These provisions are adopted from the CDC/NIH recommendations for ''Biosafety in Microbiological and Biomedical Laboratories'' (Ex. 7–72). In addition, paragraph (e)(3)(i)(C) requires that respiratory protection shall be worn in research laboratories when aerosols cannot be safely contained (e.g., when aerosols are generated outside a biological safety cabinet). As stated previously, research laboratories are working with larger volumes and higher concentrations of *M. tuberculosis* than clinical laboratories. As such, the risk to employees from aerosolized bacilli is increased, necessitating that these employees be protected whenever lapses in containment occur. An example of when aerosols would be generated would be when a flask containing *M. tuberculosis* is dropped and broken outside of the biosafety cabinet. Another example would be centrifugation of *M. tuberculosis*-containing cultures in an open centrifuge without aerosol-proof centrifuge safety containers, or utilizing such containers but then opening them outside of the biosafety cabinet (Ex. 7–134).

Paragraph (e)(3)(ii) requires employers to ensure that employees manipulating cultures and clinical or environmental materials that may generate *M. tuberculosis*-containing aerosols, challenging animals with *M. tuberculosis* aerosols, harvesting tissues or fluids from infected animals, or performing necropsies on infected animals use the appropriate containment equipment and/or devices when performing these activities. Such equipment and devices include Class 2 or 3 biosafety cabinets, or appropriate combinations of personal protective equipment and physical containment devices (such as respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals). This requirement, like the others in this paragraph, is intended to ensure that employees are protected during the performance of these potentially high-hazard procedures.

Research laboratories are also held to additional requirements with regard to facility construction. Paragraph (e)(3)(iii)(A) requires that the laboratory be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of self-closing doors is the requirement for entry into the work area from access corridors or other contiguous areas. This type of entrance reduces the likelihood of untrained employees accidentally entering the work area, since such entry necessitates deliberate action on the part of the individual.

Paragraph (e)(3)(iii)(B) requires that windows in the laboratory be closed and sealed. This helps assure containment of any aerosols and helps maintain proper operation of biosafety cabinets through minimization of cross drafts.

Paragraph (e)(3)(iii)(C) requires that a ducted exhaust air ventilation system shall be provided which creates directional airflow that draws air from clean areas into the laboratory toward contaminated areas. The proper direction of the airflow shall be verified (i.e., into the work area) by the employer at least every six months. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The requirement that research laboratories have verified directional airflow into the work area is to assure that air is drawn into the laboratory toward contaminated areas to assist in maintaining containment of aerosols within the laboratory.

Paragraph (e)(3)(iii)(D) requires that the HEPA-filtered exhaust from Class 2 or 3 biosafety cabinets is to be discharged to the outside of the building or through the building exhaust system. If it is discharged through the building exhaust system, it must be connected to this system in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system. This is required to assure that biosafety cabinets and the building exhaust system continue to function as intended.

Paragraph (e)(3)(iii)(E) requires that continuous flow centrifuges or other equipment that may produce aerosols must be contained in devices that exhaust air through a HEPA filter before discharge into the laboratory. This assures that any aerosols which may contain *M. tuberculosis* are effectively filtered from the exhaust air before discharge into the laboratory, thereby protecting employees against inadvertent exposure.

All of the requirements discussed above were derived directly from the CDC/NIH's ''Biosafety in Microbiological and Biomedical Laboratories.'' OSHA requests comment on the applicability and OSHA's application of CDC/NIH's guidelines for their use in laboratories which handle *M. tuberculosis*.

Paragraph (f) Respiratory Protection

Respirators serve as supplemental protection to reduce employee exposures when engineering and work practice controls are not sufficient to provide adequate protection against airborne contaminants.

At the opening of the public hearings for the revision of OSHA's General Industry Respiratory Standard, 29 CFR 1910.134, the Agency stated that all aspects of respirator use for protection against tuberculosis would be addressed in the rulemaking for Occupational Exposure to Tuberculosis. Consequently, the respiratory protection portion of this proposal contains all of the respiratory protection provisions that have been preliminarily determined to be applicable to respirator use for TB. In the past, OSHA standards have referred to the Respirator Standard (29 CFR 1910.134) for the general requirements for respirator use (e.g., written respiratory protection program; respirator maintenance) and have included only the respirator provisions specific to the hazard addressed by the standard. OSHA's approach in this proposal, however, is to include provisions relative to all aspects of respirator use for tuberculosis. This will provide interested parties with the opportunity to review and comment on these aspects. To assure consistency across OSHA respiratory protection standards, however, OSHA is considering including in the final TB rule cross-referencing to the general requirements of the Respiratory Protection Standard (29 CFR 1910.134) and retaining in the final TB rule only those provisions specific to respirator use for TB. OSHA seeks comment on this intended approach in the final standard for TB.

Paragraph (f)(1)(i) states that each employer must provide a respirator to each employee who: (A) enters an AFB isolation room or area in use for TB isolation; (B) is present during performance of procedures or services for an individual with suspected or confirmed infectious TB who is not masked; (C) transports an individual with suspected or confirmed infectious TB in an enclosed vehicle or who transports an individual with suspected or confirmed infectious TB within the facility whenever that individual is not masked; (D) repairs, replaces, or maintains air systems or equipment that may reasonably be anticipated to contain aerosolized *M. tuberculosis*; (E)

is working in an area where an unmasked individual with suspected or confirmed infectious TB has been segregated or otherwise confined (e.g., while awaiting transfer), and (F) is working in a residence where an individual with suspected or confirmed infectious TB is known to be present. In addition, paragraph (f)(1)(ii) requires that each employer who operates a research laboratory provide a respirator to each employee who is present when aerosols of *M. tuberculosis* cannot be safely contained.

In discussing the use of respiratory protection in their guidelines, CDC states:

> Personal respiratory protection should be used by (a) persons entering rooms where patients with known or suspected infectious TB are being isolated, (b) persons present during cough-inducing or aerosol-generating procedures performed on such patients, and (c) persons in other settings where administrative and engineering controls are not likely to protect them from inhaling infectious airborne droplet nuclei. These other settings include transporting patients who may have infectious TB in emergency transport vehicles and providing urgent surgical or dental care to patients who may have infectious TB before a determination has been made that the patient is noninfectious. (Ex. 4B)

The guidelines also state that respiratory protection should be worn by personnel who are performing maintenance and testing procedures on HEPA filtration systems (Ex. 4B). Furthermore, the CDC/NIH document ''Biosafety in Microbiological and Biomedical Laboratories'' recommends that respiratory protection be worn whenever aerosols of organisms such as *M. tuberculosis* cannot be safely contained (Ex. 7–72). Consequently, employees who may need to wear respirators could include not only health care providers but also employees such as housekeepers, dietary personnel, laboratory technicians, employees in intake areas, maintenance personnel, social workers, and so forth. It is the employer's responsibility to determine which occupationally exposed employees would be covered under this provision and, therefore, would need to wear a respirator.

With regard to utilization of respiratory protection when entering an AFB isolation room or area, the reader is referred to the definition of ''AFB isolation room or area'' in paragraph (j), Definitions. This definition clarifies that the requirement refers not only to situations such as entering a patient room occupied by an individual with suspected or confirmed infectious TB but also refers to entering any area where high-hazard procedures are being performed and entering an autopsy room where *M. tuberculosis* may be aerosolized.

Paragraph (f)(1)(i)(B) requires respirator use when an employee is present during performance of procedures or services for an unmasked individual with suspected or confirmed infectious TB. This provision is intended to cover those situations in which a procedure or service is performed outside of an AFB isolation room or area. For example, a facility may not have a portable X-ray and may, therefore, perform this procedure in a standard X-ray room. If the individual is not masked in such a situation, all employees present (i.e., the X-ray technician and any other employees in the room) must utilize respiratory protection.

As stated previously under discussion of Scope, employees rendering emergency medical services may spend time in very close proximity to individuals with suspected or confirmed infectious TB within an enclosed vehicle. Even though the individual may be masked, droplet nuclei that escape capture in the mask are contained within the vehicle, thereby increasing the likelihood that employees will breathe droplet nuclei generated when the patient coughs or speaks. In addition, under paragraph (f)(1)(i)(D), employees who repair, replace, on maintain air systems or equipment that may reasonably be anticipated to contain aerosolized *M. tuberculosis* are at risk of occupational exposure as a result of exposure to air that could contain aerosolized bacilli. Therefore, respirator use would be required in this situation.

As discussed under Scope, aerosolized *M. tuberculosis* is a recognized hazard to laboratory personnel. When aerosols of *M. tuberculosis* cannot be safely contained, such as during a spill, the employer is required to provide a respirator to each employee who is present during this time. This is consistent with CDC/NIH recommendations regarding respirator use in research laboratories (Ex. 7–72).

Unlike some other airborne contaminants, the quantity of *M. tuberculosis* that, when inhaled, will result in infection (i.e., infectious dose) has not been determined conclusively. The number of droplet nuclei expelled into a room by an infectious individual or aerosol-producing procedure and the concentration of droplet nuclei in a room or area are unknown. Consequently, there is no basis to judge the effectiveness of other control measures present even though they may be operating as intended. OSHA therefore agrees with the CDC that, in the above situations, other controls that may be in place cannot be assumed to adequately protect employees against exposure to airborne TB droplet nuclei and therefore that the use of respiratory protection is necessary.

While OSHA agrees with and has adopted most of the CDC's recommendations regarding when respiratory protection is necessary, the Agency has extended respirator use to two additional situations. More specifically, when an individual with suspected or confirmed infectious TB is not masked and is transported within a facility, the employee transporting the individual must wear a respirator. While CDC recommends masking individuals with suspected or confirmed infectious TB prior to transporting them, there may be special circumstances in which the individual may not be masked (e.g., individual is combative and will not wear a mask). The employee transporting the individual would most likely spend an extended period of time in close proximity to the individual, either walking beside or behind (e.g., pushing a wheelchair) the individual. The employee would, therefore, be walking directly through the airspace into which the individual would be expelling droplet nuclei, receiving exposure each time the individual coughed, resulting in multiple relatively concentrated exposures. In view of this, the latter portion of paragraph (f)(1)(i)(C) addresses the Agency's belief that it is necessary and justified that respiratory protection be worn by the employee to protect against occupational exposure if the individual is not masked.

The second situation, under paragraph (f)(1)(i)(E), requires respirator use by an employee when working in an area where an unmasked individual with suspected or confirmed infectious TB has been segregated or otherwise confined, for example while awaiting transfer. As discussed above, it is assumed that such individuals would normally be masked. Here again, however, there may be circumstances that preclude the individual from being masked (e.g., the individual is combative). Therefore, employees who must work in the area where these unmasked individuals are located, whether working directly with the individual or performing other duties, must wear a respirator to protect against possible tuberculosis infection.

Paragraph (f)(1)(i)(F) requires that a respirator be worn by an employee who is working in a residence where an individual with suspected or confirmed

infectious TB is known to be present. In this situation, whether the individual is masked or unmasked does not trigger respirator use since the individual has been releasing droplet nuclei into the residence airspace. The CDC refers to this type of situation in its discussion of the provision of home health care and states:

> Health care workers who provide medical services in the homes of patients who have suspected or confirmed infectious TB should instruct such patients to cover their mouths and noses with a tissue when coughing or sneezing. Until such patients are no longer infectious, HCWs should wear respiratory protection when entering these patients' homes. (Ex. 4B)

In addition to home health care and home-based hospice care workers, other employees, such as social workers who are entering these residences, would come under this provision. It is the Agency's intent that a respirator be used by an employee in these situations for the time that the employee is in the residence and that respirator use continue until the individual is noninfectious.

The proposed standard, in paragraphs (f)(1)(iii) and (f)(1)(iv), places several general responsibilities upon the employer regarding respiratory protection. Paragraph (f)(1)(iii) states that where respirators are required by the standard, the employer shall provide them at no cost to the employee and assure that they are used in accordance with the requirements of the standard. Paragraph (f)(1)(iv) stipulates further that the employer must assure that the employee dons a respirator before entering the work settings or performing the tasks set forth in paragraphs (f)(1)i and (f)(1)(ii) above and uses it until leaving the work setting or completing the task, regardless of other control measures in place.

It has been OSHA's long-standing policy to hold the employer responsible for controlling exposure to hazards in his or her workplace and to fulfill this responsibility at no cost to the employee. Therefore, the financial burden for purchasing and providing personal protective equipment, including respirators, rests upon the employer just as it does for all other control measures (e.g., engineering controls). OSHA believes that in order to assure that employees are adequately protected, the employer has the responsibility not only to provide respiratory protection, but also to assure that it is utilized when necessary. Furthermore, respiratory protection must be donned prior to entering the above work settings or performing the tasks, for the period of time that the employee remains in these work settings, and must not be removed until the employee leaves the work setting or completes the tasks. In this way, the employee is protected for the entire period of occupational exposure.

It is not OSHA's intent that each employee be monitored constantly for compliance; however, the Agency does believe that the employer has the power to assure that employees follow specific rules. For example, most employers have requirements that they require employees to follow, such as reporting to work on time, working a minimum number of hours per day, notifying the employer when the individual is unable to report for work, and taking certain precautions to prevent nosocomial infections. Following these requirements is not left to the employee's discretion, and employers generally have some process to ensure conformance with these procedures. Therefore, the Agency believes that the employer has not only the responsibility, but also the ability, to assure that respiratory protection is used in accordance with the requirements of this section.

Paragraph (f)(2)(i) requires that each employer who has any employee whose occupational exposure is based on entering any of the work settings or performing any of the tasks described in paragraph (f)(1) must establish and implement a written respiratory protection program that assures that respirators are properly selected, fitted, used, and maintained. The program must include the following elements: (A) Procedures for selecting respirators for use in the work setting; (B) a determination of each employee's ability to wear a respirator, as required under paragraph (g)(3)(ii), Medical Surveillance, for each employee required to wear a respirator; (C) procedures for the proper use of respirators; (D) fit testing procedures for tight-fitting respirators; (E) procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, or otherwise maintaining respirators; (F) training of employees to assure the proper use and maintenance of the respirators as required under paragraph (h), Communication of Hazards and Training; and (G) procedures for periodically evaluating the effectiveness of the program. Written standard operating procedures are essential to an effective respiratory protection program. Developing and writing down standard operating procedures require employers to think through how all of the requirements pertaining to respirators will be met in their workplace. In addition, this provision assures that the employer establishes standardized procedures for selecting, using, and maintaining respirators in the workplace. OSHA's long-standing position has been that a systematic respiratory protection program is necessary to provide for consistency in protection. Guidance that has been developed by an outside party (e.g., a respirator manufacturer) on the general use of a particular respirator would not address the site-specific aspects of the employer's work setting and would not be an appropriate substitute for a respiratory protection program.

Paragraph (f)(2)(ii) requires the employer to designate a person qualified by appropriate training or experience to be responsible for the administration of the respiratory protection program and for conducting the required periodic evaluations of its effectiveness. To assure that the integrity of the respiratory protection program is maintained through the continuous oversight of one responsible individual, OSHA is proposing that a qualified person be designated as responsible for the administration of the program. That individual can work with a committee or assign responsibility for portions of the program to other personnel, but the overall responsibility for the operation of the program remains with the designated person. This approach ensures coordination of all facets of the program. The level of training or experience necessary for a designated person has been left performance oriented since this will vary with the complexity of the respirator program. However, the person chosen would need to have sufficient knowledge of respiratory protection and the workplace to properly supervise the program.

Employers are required, in paragraph (f)(2)(iii), to review and update the written program as necessary to reflect current workplace conditions and respirator use. Reviewing and updating will assure that the program addresses current conditions. The reason OSHA has not set a schedule for reviewing the program is because conditions may change frequently in some work settings while remaining relatively stable in others. Thus, the employer determines the frequency of the review. However, when an employer is aware of changes in the workplace or respirator use which could necessitate changes in the written program, it is not appropriate to delay revising the written program. OSHA's use of the phrase ''as necessary'' in the requirement is intended to assure that such changes are incorporated into the written program expeditiously. As the workplace situation or respirator use

changes, the program is to be revised. In addition, paragraph (f)(2)(iv) requires that employers, upon request, make the written respiratory protection program available to affected employees, their designated representatives, the Assistant Secretary, and the Director. This provision also requires that a copy of the program be submitted to the Assistant Secretary and/or the Director, if requested.

Paragraph (f)(3) sets out the respirator characteristics that must be satisfied in order to provide employees with a respirator that will protect them against aerosolized *M. tuberculosis.* These criteria are presented in performance-oriented language to provide flexibility in choice of respirators and have been drawn from CDC recommendations (Ex. 4B). CDC has based these criteria on currently available information relative to respirators that includes:

* * * (a) data on the effectiveness of respiratory protection against noninfectious hazardous material in workplaces other than health-care settings and on an interpretation of how these data can be applied to respiratory protection against *M. tuberculosis*; (b) data on the efficiency of respirator filters in filtering biological aerosols; (c) data on face-seal leakage; and (d) data on the characteristics of respirators that were used in conjunction with administrative and engineering controls in outbreak settings where transmission to HCWs and patients was terminated (Ex. 4B).

The CDC Guidelines go on to state:

Available data suggest that infectious droplet nuclei range in size from 1 [micron] to 5 [microns]; therefore, respirators used in health-care settings should be able to efficiently filter the smallest particle in this range. Fifty liters per minute is a reasonable estimate of the highest airflow rate an HCW is likely to achieve during breathing, even while performing strenuous work activities (Ex. 4B).

In their 1994 TB guidelines, the CDC states:

Respiratory protective devices used in health-care settings for protection against *M. tuberculosis* should meet the following standard performance criteria:

1. The ability to filter particles 1 um in size in the unloaded state with a filter efficiency of ≤ 95% (i.e., filter leakage of ≤ 5%), given flow rates of up to 50 L per minute.
2. The ability to be qualitatively or quantitatively fit tested in a reliable way to obtain a face-seal leakage of ≤ 10%.
3. The ability to fit different facial sizes and characteristics of HCWs [health care workers], which can usually be met by making the respirators available in at least three sizes.
4. The ability to be checked for facepiece fit, in accordance with standards established by the Occupational Safety and Health Administration (OSHA) and good industrial hygiene practice, by HCWs each time they put on their respirators. (Ex. 4B)

The various respirator provisions that OSHA is proposing rely heavily on the CDC's aforementioned respirator performance criteria. The second, third, and fourth CDC criteria are addressed by paragraphs (f)(3)(i) (A) and (B) and paragraph (f)(5)(ii). Paragraph (f)(3)(i) requires the employer to select and provide properly fitted negative pressure or more protective respirators. Negative pressure respirators must be capable of being: (A) Qualitatively or quantitatively fit tested in a reliable way to verify a face-seal leakage of no more than 10%; and (B) fit checked by the employee each time the respirator is donned. Paragraph (f)(5)(ii) requires that employers assure that each employee who must wear a tight-fitting respirator is fit tested and passes the fit test. All of these provisions deal with the ability of the respirator to achieve a good face seal with a particular employee.

Good face fit is critical in assuring proper performance of respiratory protection. When an employee inhales through a respirator that does not fit properly, contaminated workplace air can enter the respirator through gaps and leaks in the seal between the face and the facepiece. OSHA is requiring the employer to provide each employee who must wear a respirator with one that fits. To do so, the employer will have to consider the facial sizes and characteristics in his or her workplace. It is not necessary for the employer to have respirators of different sizes of characteristics unless the employees need them. In other words, an employer may need only one or two styles and sizes. However, in workplaces where employees have different facial sizes and characteristics, obtaining proper respirator fit for each employee may require the fit testing of different mask sizes, possibly from several manufacturers. Proper respirator fit reduces inhalation leakage through the face-to-facepiece seal to a minimum.

Once a respirator has been selected based on its ability to achieve an adequate face-to-facepiece seal, the employee must be able to check that the respirator is properly seated and sealed to his or her face each time it is donned. The respirator, therefore, must be able to be fit checked by the employee. This is a procedure in which the employee covers the filter surface of the respirator and inhales (negative fit check) and exhales (positive fit check). If the respirator has an exhalation valve, this valve must be covered during the positive fit check. A respirator that is properly sealed will firmly adhere to the wearer's face upon inhalation due to the negative pressure created inside the mask. Upon exhalation, the mask should lift slightly off of the wearer's face to allow air to escape around the face seal. Employers should be aware that a problem could exist with fit checking some disposable negative pressure respirators. That is, it is difficult to cover the entire filter surface, thereby hindering the employee's ability to perform a proper fit check. At least one respirator manufacturer has developed a ''fit-check cup'' that covers the filter surface of their disposable respirator, thereby permitting the user to more easily perform a fit check. Reusable elastomeric facepiece respirators utilize filter cartridges that can be covered for performing a fit check.

CDC's first criteria, regarding filter efficiency, is addressed under paragraph (f)(3)(ii) of the standard. This provision requires the employer to select a respirator that will function effectively in the conditions of the work setting. In addition to meeting the criteria in paragraph (f)(3)(i) above, the respirator shall be, at a minimum, either a High Efficiency Particulate Air (HEPA) respirator selected from among those jointly approved as acceptable by the Mine Safety and Health Administration (MSHA) and by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR part 11, or an N95 respirator certified by NIOSH under the provisions of 42 CFR part 84.

NIOSH and MSHA are the government agencies charged with testing and certifying respiratory protective devices. It has always been OSHA's policy that respiratory protection must be certified by these agencies before being deemed acceptable. Until recently, HEPA respirators were the only NIOSH certified negative pressure respirators that met the CDC's filter efficiency criteria. However, on July 10, 1995, NIOSH's original respirator certification procedures for air-purifying particulate respirators, 30 CFR part 11, were replaced by revised procedures, 42 CFR part 84 (Ex. 7–261). Under the new procedures, all nonpowered air-purifying particulate respirators are challenged with a 0.3 micron particle (the most penetrating size) at a flow rate of 85 liters per minute. At the conclusion of the test, those respirators that pass are placed into one of nine classes of filters (three levels of filter efficiency, with three categories of resistance to filter efficiency degradation). The three levels of filter efficiency are 99.97%, 99%, and 95%. The three categories of resistance to filter efficiency degradation are labeled N (not resistant to oil), R (resistant to